

*Mirvetuximab-Soravtansin (ELAHERE®)*

AbbVie Deutschland GmbH & Co. KG

### **Anhang 4-G zu Modul 4 A**

*Monotherapie zur Behandlung von erwachsenen Patientinnen mit Folatrezeptor-alpha (FR $\alpha$ )-positivem, platinresistentem, high-grade serösem epitheliale Ovarial-, Tuben- oder primärem Peritonealkarzinom, die zuvor ein bis drei systemische Behandlungslinien erhalten haben*

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# 1. Mortalität und Morbidität

## 1.1 Zeit bis zum Tod

### Zeit bis zum Tod: Subgruppenanalyse

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum Tod</b>			
<b>Alter</b>			
< 65 Jahre	N	160	155
	Ereignisse, n (%)	96 (60 %)	104 (67 %)
	50. Perzentil/Median [95 %-KI] (Monate)	16,00 [13,273; 18,595]	13,77 [11,203; 16,690]
	HR [95 %-KI] p-Wert	0,72 [0,540; 0,949] 0,0203	
≥ 65 Jahre	N	149	105
	Ereignisse, n (%)	82 (55 %)	71 (68 %)
	50. Perzentil/Median [95 %-KI] (Monate)	19,06 [14,094; 20,238]	12,39 [9,396; 15,901]
	HR [95 %-KI] p-Wert	0,62 [0,449; 0,862] 0,0047	
<b>Region</b>			
USA	N	90	64
	Ereignisse, n (%)	56 (62 %)	44 (69 %)
	50. Perzentil/Median [95 %-KI] (Monate)	15,41 [12,583; 19,778]	12,75 [10,875; 16,000]
	HR [95 %-KI] p-Wert	0,73 [0,487; 1,092] 0,1278	
Rest der Welt	N	219	196
	Ereignisse, n (%)	122 (56 %)	131 (67 %)
	50. Perzentil/Median [95 %-KI] (Monate)	17,51 [14,686; 19,943]	13,34 [10,940; 16,197]
	HR [95 %-KI] p-Wert	0,65 [0,510; 0,842] 0,0010	
<b>Stadium bei der Diagnose</b>			
I-III	N	200	181
	Ereignisse, n (%)	105 (52 %)	119 (66 %)
	50. Perzentil/Median [95 %-KI] (Monate)	19,42 [15,113; 22,899]	13,34 [11,203; 16,197]

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum Tod</b>			
	HR [95 %-KI] p-Wert	0,62 [0,478; 0,815] 0,0005	
IV	N	103	74
	Ereignisse, n (%)	70 (68 %)	53 (72 %)
	50. Perzentil/Median [95 %-KI] (Monate)	14,46 [12,090; 16,066]	12,71 [9,626; 15,441]
	HR [95 %-KI] p-Wert	0,76 [0,526; 1,103] 0,1514	
<b>BRCA Status</b>			
Positiv	N	40	39
	Ereignisse, n (%)	24 (60 %)	30 (77 %)
	50. Perzentil/Median [95 %-KI] (Monate)	18,60 [14,456; 20,501]	10,28 [7,392; 12,747]
	HR [95 %-KI] p-Wert	0,45 [0,250; 0,818] 0,0075	
Negativ/Unbekannt	N	269	221
	Ereignisse, n (%)	154 (57 %)	145 (66 %)
	50. Perzentil/Median [95 %-KI] (Monate)	16,07 [13,569; 19,088]	13,77 [12,090; 16,361]
	HR [95 %-KI] p-Wert	0,73 [0,576; 0,912] 0,0063	
<b>Baseline ECOG PS</b>			
0	N	177	141
	Ereignisse, n (%)	93 (53 %)	88 (62 %)
	50. Perzentil/Median [95 %-KI] (Monate)	19,32 [16,066; 24,279]	16,00 [13,142; 18,924]
	HR [95 %-KI] p-Wert	0,71 [0,524; 0,949] 0,0216	
1	N	131	114
	Ereignisse, n (%)	85 (65 %)	83 (73 %)
	50. Perzentil/Median [95 %-KI] (Monate)	14,09 [11,105; 16,427]	8,77 [7,294; 13,010]
	HR [95 %-KI] p-Wert	0,65 [0,475; 0,887] 0,0068	
<b>Anzahl vorheriger Therapielinien</b>			
1 oder 2	N	175	143



MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum Tod</b>			
	Ereignisse, n (%)	104 (59 %)	93 (65 %)
	50. Perzentil/Median [95 %-KI] (Monate)	16,43 [14,456; 19,351]	13,86 [11,828; 16,723]
	HR [95 %-KI] p-Wert	0,72 [0,538; 0,953] 0,0227	
3	N	134	117
	Ereignisse, n (%)	74 (55 %)	82 (70 %)
	50. Perzentil/Median [95 %-KI] (Monate)	17,31 [12,583; 19,943]	12,39 [9,363; 14,752]
	HR [95 %-KI] p-Wert	0,64 [0,465; 0,880] 0,0060	
<b>Vorherige Verabreichung von Bevacizumab</b>			
Ja	N	179	161
	Ereignisse, n (%)	112 (63 %)	113 (70 %)
	50. Perzentil/Median [95 %-KI] (Monate)	14,46 [12,517; 16,460]	11,01 [9,265; 13,339]
	HR [95 %-KI] p-Wert	0,69 [0,526; 0,896] 0,0057	
Nein	N	130	99
	Ereignisse, n (%)	66 (51 %)	62 (63 %)
	50. Perzentil/Median [95 %-KI] (Monate)	19,88 [17,314; 25,922]	16,20 [13,306; 17,971]
	HR [95 %-KI] p-Wert	0,64 [0,450; 0,916] 0,0149	
<b>Letztes Platin-freies Intervall</b>			
≤ 3 Monate	N	120	114
	Ereignisse, n (%)	66 (55 %)	83 (73 %)
	50. Perzentil/Median [95 %-KI] (Monate)	16,85 [13,273; 19,778]	10,45 [7,786; 13,766]
	HR [95 %-KI] p-Wert	0,55 [0,396; 0,766] 0,0004	
> 3 Monate	N	189	146
	Ereignisse, n (%)	112 (59 %)	92 (63 %)
	50. Perzentil/Median [95 %-KI] (Monate)	16,10 [13,569; 20,107]	15,47 [12,813; 18,103]
	HR [95 %-KI] p-Wert	0,80 [0,604; 1,059] 0,1202	

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum Tod</b>			
<b>IC-Chemotherapie vor der Randomisierung zugewiesen</b>			
Pegyliertes liposomales Doxorubicin	N	122	96
	Ereignisse, n (%)	67 (55 %)	63 (66 %)
	50. Perzentil/Median [95 %-KI] (Monate)	19,09 [14,094; 24,575]	14,55 [10,908; 16,854]
	HR [95 %-KI] p-Wert	0,64 [0,446; 0,909] 0,0134	
Paclitaxel	N	122	105
	Ereignisse, n (%)	70 (57 %)	70 (67 %)
	50. Perzentil/Median [95 %-KI] (Monate)	16,07 [12,813; 18,595]	13,34 [10,940; 16,690]
	HR [95 %-KI] p-Wert	0,69 [0,489; 0,970] 0,0331	
Topotecan	N	65	59
	Ereignisse, n (%)	41 (63 %)	42 (71 %)
	50. Perzentil/Median [95 %-KI] (Monate)	15,41 [10,283; 22,899]	9,63 [5,224; 16,460]
	HR [95 %-KI] p-Wert	0,72 [0,470; 1,118] 0,1459	
<b>Daten aus Studie</b>			
MIRASOL	N	227	226
	Ereignisse, n (%)	127 (56 %)	150 (66 %)
	50. Perzentil/Median [95 %-KI] (Monate)	16,46 [14,357; 19,877]	13,34 [11,368; 15,441]
	HR [95 %-KI] p-Wert	0,67 [0,531; 0,854] 0,0011	
FORWARD 1	N	82	34
	Ereignisse, n (%)	51 (62 %)	25 (74 %)
	50. Perzentil/Median [95 %-KI] (Monate)	16,43 [12,419; 20,501]	11,40 [6,111; 18,103]
	HR [95 %-KI] p-Wert	0,68 [0,424; 1,106] 0,1302	
<i>Analysepopulation: ITT/relevante Biomarker-Population</i> <i>Datenschritt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i> <i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i> <i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i>			

MIRASOL + FORWARD 1	Behandlungsarm	
	MIRV	Chemotherapie
<b>Zeit bis zum Tod</b>		
<p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>		

## 1.2 Zeit bis zur Progression oder Tod (gemäß Prüfarzt)

### Zeit bis zur Progression oder Tod (gemäß Prüfarzt): Subgruppenanalyse

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zur Progression oder Tod (gemäß Prüfarzt)</b>			
<b>Alter</b>			
< 65 Jahre	N	160	155
	Ereignisse, n (%)	134 (84 %)	117 (75 %)
	50. Perzentil/Median [95 %-KI] (Monate)	5,39 [4,172; 5,782]	4,21 [2,825; 4,665]
	HR [95 %-KI] p-Wert	0,67 [0,523; 0,866] 0,0023	
≥ 65 Jahre	N	149	105
	Ereignisse, n (%)	129 (87 %)	84 (80 %)
	50. Perzentil/Median [95 %-KI] (Monate)	5,68 [4,370; 6,998]	3,06 [2,530; 5,290]
	HR [95 %-KI] p-Wert	0,63 [0,472; 0,836] 0,0017	
<b>Region</b>			
USA	N	90	64
	Ereignisse, n (%)	76 (84 %)	42 (66 %)
	50. Perzentil/Median [95 %-KI] (Monate)	4,17 [3,088; 5,651]	3,91 [2,825; 5,651]
	HR [95 %-KI] p-Wert	0,91 [0,620; 1,342] 0,6417	
Rest der Welt	N	219	196
	Ereignisse, n (%)	187 (85 %)	159 (81 %)
	50. Perzentil/Median [95 %-KI] (Monate)	5,72 [5,454; 6,932]	4,04 [2,825; 4,501]
	HR [95 %-KI] p-Wert	0,57 [0,459; 0,711] < 0,0001	
<b>Stadium bei der Diagnose</b>			
I-III	N	200	181
	Ereignisse, n (%)	170 (85 %)	136 (75 %)
	50. Perzentil/Median [95 %-KI] (Monate)	5,72 [5,454; 6,998]	4,27 [2,825; 5,520]

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zur Progression oder Tod (gemäß Prüfarzt)</b>			
	HR [95 %-KI] p-Wert	0,62 [0,489; 0,781] 0,0001	
IV	N	103	74
	Ereignisse, n (%)	87 (84 %)	62 (84 %)
	50. Perzentil/Median [95 %-KI] (Monate)	4,34 [3,055; 5,749]	2,99 [1,643; 4,304]
	HR [95 %-KI] p-Wert	0,65 [0,461; 0,904] 0,0119	
<b>BRCA Status</b>			
Positiv	N	40	39
	Ereignisse, n (%)	31 (78 %)	32 (82 %)
	50. Perzentil/Median [95 %-KI] (Monate)	7,10 [4,567; 10,645]	2,53 [1,577; 4,107]
	HR [95 %-KI] p-Wert	0,33 [0,185; 0,580] 0,0001	
Negativ/Unbekannt	N	269	221
	Ereignisse, n (%)	232 (86 %)	169 (76 %)
	50. Perzentil/Median [95 %-KI] (Monate)	5,52 [4,271; 5,749]	4,24 [2,924; 4,994]
	HR [95 %-KI] p-Wert	0,71 [0,584; 0,875] 0,0012	
<b>Baseline ECOG PS</b>			
0	N	177	141
	Ereignisse, n (%)	156 (88 %)	115 (82 %)
	50. Perzentil/Median [95 %-KI] (Monate)	5,75 [5,454; 6,998]	4,34 [2,957; 5,585]
	HR [95 %-KI] p-Wert	0,62 [0,486; 0,799] 0,0002	
1	N	131	114
	Ereignisse, n (%)	107 (82 %)	83 (73 %)
	50. Perzentil/Median [95 %-KI] (Monate)	4,30 [3,910; 5,684]	2,99 [2,300; 4,205]
	HR [95 %-KI] p-Wert	0,69 [0,517; 0,932] 0,0159	
<b>Anzahl vorheriger Therapielinien</b>			
1 oder 2	N	175	143

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zur Progression oder Tod (gemäß Prüfarzt)</b>			
	Ereignisse, n (%)	154 (88 %)	112 (78 %)
	50. Perzentil/Median [95 %-KI] (Monate)	5,75 [5,454; 6,965]	4,27 [2,891; 5,520]
	HR [95 %-KI] p-Wert	0,62 [0,477; 0,794] 0,0002	
3	N	134	117
	Ereignisse, n (%)	109 (81 %)	89 (76 %)
	50. Perzentil/Median [95 %-KI] (Monate)	4,34 [3,318; 5,717]	3,12 [2,595; 4,337]
	HR [95 %-KI] p-Wert	0,69 [0,519; 0,917] 0,0112	
<b>Vorherige Verabreichung von Bevacizumab</b>			
Ja	N	179	161
	Ereignisse, n (%)	157 (88 %)	128 (80 %)
	50. Perzentil/Median [95 %-KI] (Monate)	4,34 [4,041; 5,651]	2,99 [2,398; 4,238]
	HR [95 %-KI] p-Wert	0,62 [0,490; 0,794] 0,0001	
Nein	N	130	99
	Ereignisse, n (%)	106 (82 %)	73 (74 %)
	50. Perzentil/Median [95 %-KI] (Monate)	6,60 [5,618; 8,148]	5,29 [3,088; 6,078]
	HR [95 %-KI] p-Wert	0,66 [0,489; 0,902] 0,0098	
<b>Letztes Platin-freies Intervall</b>			
≤ 3 Monate	N	120	114
	Ereignisse, n (%)	101 (84 %)	86 (75 %)
	50. Perzentil/Median [95 %-KI] (Monate)	4,30 [3,088; 5,520]	2,89 [2,300; 4,238]
	HR [95 %-KI] p-Wert	0,74 [0,550; 0,990] 0,0438	
> 3 Monate	N	189	146
	Ereignisse, n (%)	162 (86 %)	115 (79 %)
	50. Perzentil/Median [95 %-KI] (Monate)	5,78 [5,552; 6,998]	4,34 [3,023; 5,520]
	HR [95 %-KI] p-Wert	0,59 [0,458; 0,757] < 0,0001	

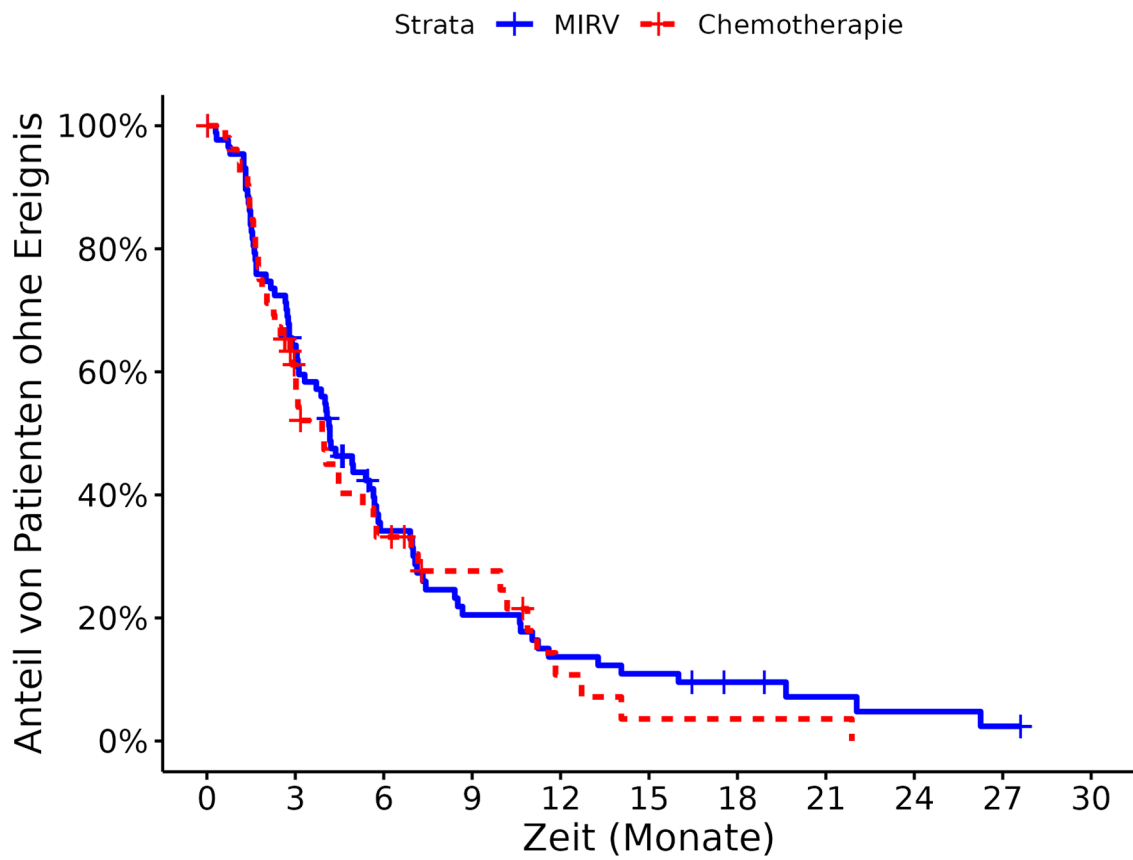
MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zur Progression oder Tod (gemäß Prüfarzt)</b>			
<b>IC-Chemotherapie vor der Randomisierung zugewiesen</b>			
Pegyliertes liposomales Doxorubicin	N	122	96
	Ereignisse, n (%)	102 (84 %)	76 (79 %)
	50. Perzentil/Median [95 %-KI] (Monate)	6,97 [5,618; 8,312]	2,83 [1,643; 4,534]
	HR [95 %-KI] p-Wert	0,53 [0,390; 0,723] 0,0001	
Paclitaxel	N	122	105
	Ereignisse, n (%)	106 (87 %)	80 (76 %)
	50. Perzentil/Median [95 %-KI] (Monate)	5,45 [4,107; 5,881]	4,47 [4,041; 5,585]
	HR [95 %-KI] p-Wert	0,73 [0,542; 0,988] 0,0429	
Topotecan	N	65	59
	Ereignisse, n (%)	55 (85 %)	45 (76 %)
	50. Perzentil/Median [95 %-KI] (Monate)	4,14 [2,891; 5,585]	3,02 [1,873; 4,271]
	HR [95 %-KI] p-Wert	0,76 [0,511; 1,143] 0,1934	
<b>Daten aus Studie</b>			
MIRASOL	N	227	226
	Ereignisse, n (%)	197 (87 %)	171 (76 %)
	50. Perzentil/Median [95 %-KI] (Monate)	5,62 [4,337; 5,947]	3,98 [2,858; 4,468]
	HR [95 %-KI] p-Wert	0,65 [0,527; 0,800] 0,0001	
FORWARD 1	N	82	34
	Ereignisse, n (%)	66 (80 %)	30 (88 %)
	50. Perzentil/Median [95 %-KI] (Monate)	5,62 [4,172; 7,129]	3,71 [1,708; 5,585]
	HR [95 %-KI] p-Wert	0,63 [0,408; 0,979] 0,0462	
<i>Analysepopulation: ITT/relevante Biomarker-Population</i> <i>Datenschritt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i> <i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i> <i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i>			

MIRASOL + FORWARD 1	Behandlungsarm	
	MIRV	Chemotherapie
<b>Zeit bis zur Progression oder Tod (gemäß Prüfarzt)</b>		
<p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>		



1.2.1 Zeit bis zur Progression oder Tod (gemäß Prüfarzt) Kaplan-Meier-Plot  
in Subgruppe Region: USA

Kaplan Meier Plot 233.1.3.02.02 02000 A03EM



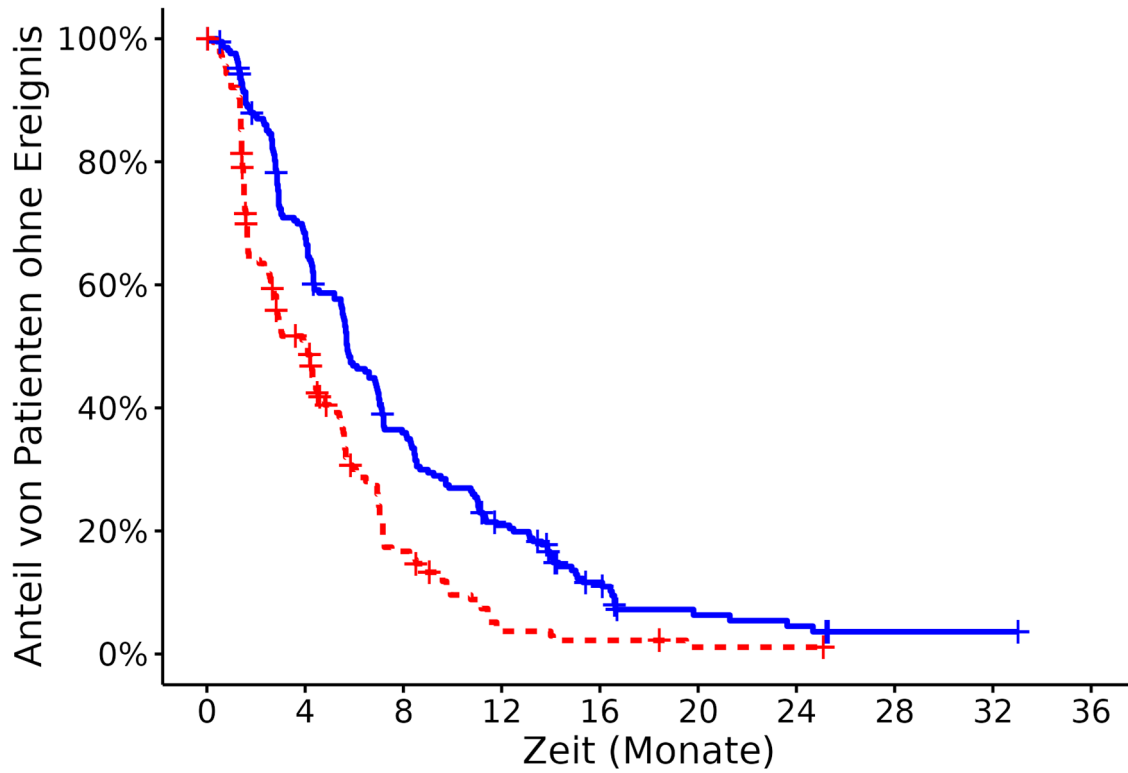
**Patienten unter Risiko**

MIRV	90	54	25	15	10	8	5	3	2	1	0
Chemotherapie	64	27	14	9	3	1	1	1	0	0	0

1.2.2 Zeit bis zur Progression oder Tod (gemäß Prüfarzt) Kaplan-Meier-Plot in Subgruppe Region: Rest der Welt

Kaplan Meier Plot 233.1.3.02.02 02000 A04EM

Strata + MIRV + Chemotherapie

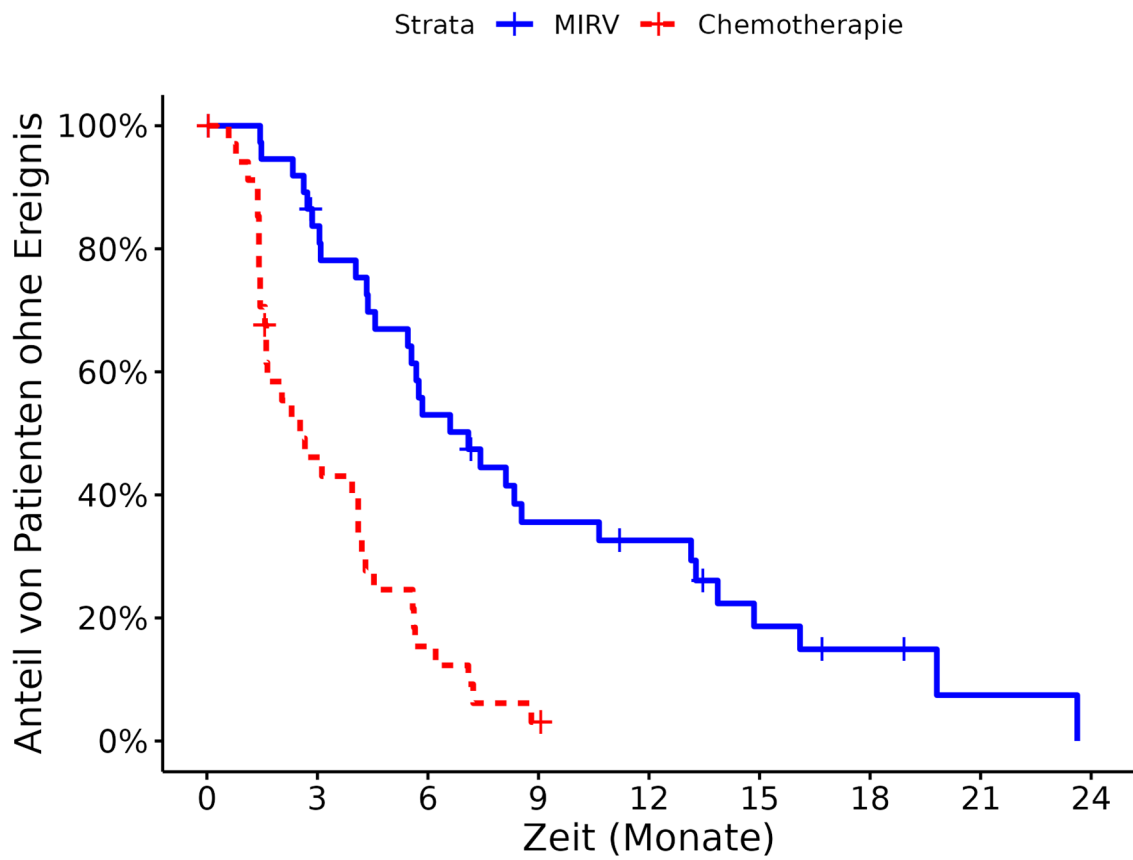


**Patienten unter Risiko**

MIRV	219	140	72	40	17	7	5	1	1	0
Chemotherapie	196	83	25	5	3	1	1	0	0	0

1.2.3 Zeit bis zur Progression oder Tod (gemäß Prüfarzt) Kaplan-Meier-Plot in Subgruppe BRCA Status: Positiv

Kaplan Meier Plot 233.1.3.02.02 04000 A07EM



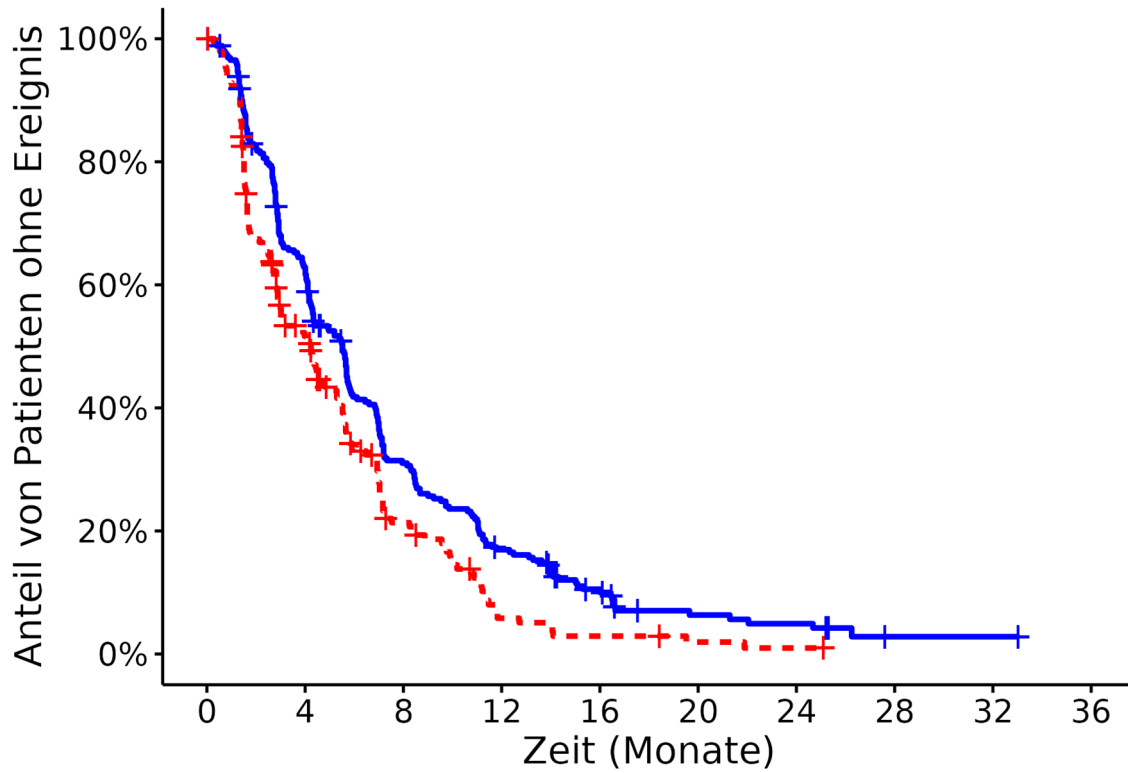
**Patienten unter Risiko**

MIRV	40	30	19	12	10	5	3	1	0
Chemotherapie	39	15	5	1	0	0	0	0	0

1.2.4 Zeit bis zur Progression oder Tod (gemäß Prüfarzt) Kaplan-Meier-Plot in Subgruppe BRCA Status: Negativ/Unbekannt

Kaplan Meier Plot 233.1.3.02.02 04000 A08EM

Strata + MIRV + Chemotherapie



**Patienten unter Risiko**

MIRV	269	159	75	40	20	9	7	1	1	0
Chemotherapie	221	90	32	8	4	2	1	0	0	0

### 1.3 Gesundheitszustand (EQ-5D-VAS)

#### Gesundheitszustand (EQ-5D-VAS): Subgruppenanalyse

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
<b>Gesundheitszustand (EQ-5D-VAS)</b>			
<b>Alter: &lt; 65 Jahre</b>			
Baseline			
n/N (%)	128/155 (83)	110/140 (79)	-
MW (SD)	68,03 (19,775)	64,60 (19,749)	
Absolute Werte zum Studienende			
n/N (%)	9/98 (9)	5/75 (7)	-
MW (SD)	69,89 (21,169)	55,20 (19,563)	
Effekt über Studiendauer			
n	128	110	LS MD 7,38 [3,672; 11,080] 0,0001
LS MW (SE)	2,06 (1,232)	-5,32 (1,410)	
95 %-KI	[-0,372; 4,486]	[-8,097; -2,541]	Hedges' g 0,51 [0,254; 0,772]
Veränderung zu Woche 3/4			
n/N (%)	90/153 (59)	76/134 (57)	LS MD 5,00 [0,951; 9,055]
MW (SD)	3,26 (15,449)	-0,03 (17,467)	
LS MW (SE)	2,55 (1,357)	-2,46 (1,539)	
95 %-KI	[-0,124; 5,215]	[-5,484; 0,570]	
Veränderung zu Woche 8/9			
n/N (%)	110/152 (72)	82/127 (65)	LS MD 6,04 [2,263; 9,823]
MW (SD)	1,23 (18,530)	-3,24 (20,550)	
LS MW (SE)	2,33 (1,269)	-3,71 (1,430)	
95 %-KI	[-0,167; 4,830]	[-6,527; -0,895]	
Veränderung zu Woche 12			
n/N (%)	70/148 (47)	50/122 (41)	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	5,91 (19,734)	-4,52 (20,852)	LS MD 6,77 [3,072; 10,469]
LS MW (SE)	2,18 (1,237)	-4,59 (1,402)	
95 %-KI	[-0,257; 4,620]	[-7,350; -1,828]	
Veränderung zu Woche 15/16			
n/N (%)	79/144 (55)	40/116 (34)	LS MD 7,50 [3,785; 11,212]
MW (SD)	1,71 (19,529)	-5,47 (20,897)	
LS MW (SE)	2,03 (1,234)	-5,47 (1,416)	
95 %-KI	[-0,400; 4,464]	[-8,255; -2,678]	
Veränderung zu Woche 20/21			
n/N (%)	55/137 (40)	35/110 (32)	LS MD 8,54 [4,640; 12,437]
MW (SD)	2,07 (20,851)	2,43 (16,191)	
LS MW (SE)	1,82 (1,277)	-6,72 (1,506)	
95 %-KI	[-0,697; 4,332]	[-9,685; -3,757]	
Veränderung zu Woche 24			
n/N (%)	41/133 (31)	23/105 (22)	LS MD 9,27 [5,136; 13,397]
MW (SD)	5,49 (22,336)	1,43 (15,605)	
LS MW (SE)	1,67 (1,337)	-7,60 (1,612)	
95 %-KI	[-0,965; 4,300]	[-10,769; -4,428]	
Veränderung zu Woche 36			
n/N (%)	58/117 (50)	36/91 (40)	LS MD 11,76 [6,379; 17,146]
MW (SD)	2,71 (21,366)	-10,58 (18,469)	
LS MW (SE)	1,15 (1,691)	-10,61 (2,155)	
95 %-KI	[-2,168; 4,476]	[-14,840; -6,377]	
Veränderung zu Woche 48			
n/N (%)	9/98 (9)	4/75 (5)	LS MD 14,26 [7,223; 21,293]
MW (SD)	4,44 (18,084)	-17,50 (12,583)	
LS MW (SE)	0,64 (2,179)	-13,62 (2,846)	
95 %-KI	[-3,636; 4,917]	[-19,204; -8,032]	
<b>Alter: ≥ 65 Jahre</b>			

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Baseline			
n/N (%)	109/142 (77)	74/99 (75)	-
MW (SD)	65,39 (20,348)	67,77 (19,443)	
Absolute Werte zum Studienende			
n/N (%)	12/92 (13)	4/51 (8)	-
MW (SD)	72,08 (17,881)	78,00 (18,956)	
Effekt über Studiendauer			
n	109	74	LS MD 4,95 [0,683; 9,220] 0,0232
LS MW (SE)	1,07 (1,314)	-3,89 (1,700)	
95 %-KI	[-1,529; 3,661]	[-7,239; -0,533]	Hedges' g 0,35 [0,052; 0,647]
Veränderung zu Woche 3/4			
n/N (%)	84/138 (61)	52/96 (54)	LS MD 4,47 [-0,205; 9,137]
MW (SD)	1,87 (15,606)	-3,38 (19,200)	
LS MW (SE)	1,15 (1,456)	-3,31 (1,856)	
95 %-KI	[-1,712; 4,022]	[-6,965; 0,343]	
Veränderung zu Woche 8/9			
n/N (%)	89/132 (67)	60/90 (67)	LS MD 4,67 [0,324; 9,025]
MW (SD)	0,20 (18,233)	-2,23 (21,793)	
LS MW (SE)	1,12 (1,357)	-3,56 (1,722)	
95 %-KI	[-1,559; 3,793]	[-6,952; -0,163]	
Veränderung zu Woche 12			
n/N (%)	67/127 (53)	34/88 (39)	LS MD 4,82 [0,565; 9,076]
MW (SD)	3,75 (22,376)	-6,85 (18,802)	
LS MW (SE)	1,09 (1,321)	-3,73 (1,687)	
95 %-KI	[-1,517; 3,697]	[-7,057; -0,403]	
Veränderung zu Woche 15/16			
n/N (%)	60/123 (49)	25/85 (29)	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	1,18 (20,652)	-5,32 (24,162)	LS MD 4,97 [0,690; 9,242]
LS MW (SE)	1,06 (1,315)	-3,90 (1,704)	
95 %-KI	[-1,533; 3,660]	[-7,263; -0,542]	
Veränderung zu Woche 20/21			
n/N (%)	47/120 (39)	24/78 (31)	LS MD 5,17 [0,675; 9,674]
MW (SD)	7,40 (22,729)	1,75 (20,581)	
LS MW (SE)	1,03 (1,360)	-4,15 (1,815)	
95 %-KI	[-1,658; 3,709]	[-7,725; -0,573]	
Veränderung zu Woche 24			
n/N (%)	46/115 (40)	20/72 (28)	LS MD 5,32 [0,543; 10,098]
MW (SD)	0,22 (24,688)	-6,80 (20,104)	
LS MW (SE)	1,00 (1,426)	-4,32 (1,946)	
95 %-KI	[-1,811; 3,809]	[-8,151; -0,492]	
Veränderung zu Woche 36			
n/N (%)	56/100 (56)	23/61 (38)	LS MD 5,82 [-0,448; 12,090]
MW (SD)	1,91 (19,162)	-5,39 (19,600)	
LS MW (SE)	0,91 (1,811)	-4,91 (2,611)	
95 %-KI	[-2,651; 4,467]	[-10,042; 0,216]	
Veränderung zu Woche 48			
n/N (%)	10/92 (11)	4/51 (8)	LS MD 6,32 [-1,900; 14,543]
MW (SD)	7,70 (28,151)	0,75 (7,890)	
LS MW (SE)	0,82 (2,341)	-5,50 (3,456)	
95 %-KI	[-3,781; 5,414]	[-12,290; 1,281]	
<b>Region: USA</b>			
Baseline			
n/N (%)	65/86 (76)	38/56 (68)	-
MW (SD)	72,29 (20,859)	71,32 (16,369)	
Absolute Werte zum Studienende			
n/N (%)	4/53 (8)	4/29 (14)	-



MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	81,50 (10,909)	78,00 (18,956)	
Effekt über Studiendauer			
n	65	38	LS MD 8,16 [2,587; 13,735] 0,0045  Hedges' g 0,60 [0,189; 1,006]
LS MW (SE)	3,15 (1,644)	-5,01 (2,281)	
95 %-KI	[-0,110; 6,419]	[-9,530; -0,483]	
Veränderung zu Woche 3/4			
n/N (%)	48/84 (57)	23/54 (43)	LS MD 8,22 [2,212; 14,238]
MW (SD)	2,40 (14,205)	-6,87 (20,130)	
LS MW (SE)	2,40 (1,783)	-5,83 (2,469)	
95 %-KI	[-1,133; 5,924]	[-10,711; -0,948]	
Veränderung zu Woche 8/9			
n/N (%)	57/79 (72)	33/50 (66)	LS MD 8,20 [2,516; 13,878]
MW (SD)	4,88 (19,598)	-5,09 (21,113)	
LS MW (SE)	2,73 (1,682)	-5,47 (2,327)	
95 %-KI	[-0,607; 6,064]	[-10,079; -0,858]	
Veränderung zu Woche 12			
n/N (%)	40/76 (53)	18/48 (38)	LS MD 8,18 [2,601; 13,753]
MW (SD)	4,78 (17,156)	-11,22 (16,879)	
LS MW (SE)	2,96 (1,648)	-5,22 (2,282)	
95 %-KI	[-0,310; 6,233]	[-9,741; -0,691]	
Veränderung zu Woche 15/16			
n/N (%)	34/72 (47)	12/46 (26)	LS MD 8,16 [2,574; 13,741]
MW (SD)	6,50 (16,366)	-2,58 (20,589)	
LS MW (SE)	3,19 (1,646)	-4,96 (2,285)	
95 %-KI	[-0,074; 6,464]	[-9,494; -0,432]	
Veränderung zu Woche 20/21			
n/N (%)	23/70 (33)	11/42 (26)	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	3,30 (9,407)	-3,64 (12,019)	LS MD 8,13 [2,345; 13,913]
LS MW (SE)	3,53 (1,701)	-4,60 (2,371)	
95 %-KI	[0,155; 6,901]	[-9,297; 0,094]	
Veränderung zu Woche 24			
n/N (%)	17/69 (25)	8/40 (20)	LS MD 8,11 [2,061; 14,159]
MW (SD)	10,12 (18,761)	-5,62 (25,343)	
LS MW (SE)	3,76 (1,776)	-4,35 (2,484)	
95 %-KI	[0,245; 7,277]	[-9,262; 0,564]	
Veränderung zu Woche 36			
n/N (%)	32/58 (55)	12/35 (34)	LS MD 8,04 [0,486; 15,599]
MW (SD)	4,88 (18,414)	-5,83 (14,850)	
LS MW (SE)	4,56 (2,209)	-3,48 (3,119)	
95 %-KI	[0,208; 8,912]	[-9,627; 2,662]	
Veränderung zu Woche 48			
n/N (%)	4/53 (8)	4/29 (14)	LS MD 7,97 [-1,661; 17,611]
MW (SD)	15,00 (19,270)	-1,75 (12,606)	
LS MW (SE)	5,36 (2,809)	-2,62 (3,986)	
95 %-KI	[-0,165; 10,884]	[-10,456; 5,225]	
<b>Region: Rest der Welt</b>			
Baseline			
n/N (%)	172/211 (82)	146/183 (80)	-
MW (SD)	64,75 (19,386)	64,46 (20,209)	
Absolute Werte zum Studienende			
n/N (%)	17/137 (12)	5/97 (5)	-
MW (SD)	68,71 (19,748)	55,20 (19,563)	
Effekt über Studiendauer			
n	172	146	LS MD 5,32 [2,183; 8,451] 0,0009 Hedges' g
LS MW (SE)	0,90 (1,036)	-4,41 (1,198)	
95 %-KI	[-1,136; 2,943]	[-6,771; -2,056]	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
			0,38 [0,156; 0,601]
Veränderung zu Woche 3/4			
n/N (%)	126/207 (61)	105/176 (60)	LS MD 3,18 [-0,277; 6,642]
MW (SD)	2,66 (16,014)	-0,19 (17,616)	
LS MW (SE)	1,52 (1,157)	-1,66 (1,315)	
95 %-KI	[-0,756; 3,792]	[-4,249; 0,920]	
Veränderung zu Woche 8/9			
n/N (%)	142/205 (69)	109/167 (65)	LS MD 4,11 [0,904; 7,306]
MW (SD)	-0,88 (17,640)	-2,13 (21,032)	
LS MW (SE)	1,25 (1,073)	-2,85 (1,211)	
95 %-KI	[-0,859; 3,363]	[-5,236; -0,471]	
Veränderung zu Woche 12			
n/N (%)	97/199 (49)	66/162 (41)	LS MD 4,75 [1,627; 7,876]
MW (SD)	4,89 (22,499)	-3,89 (20,561)	
LS MW (SE)	1,07 (1,042)	-3,69 (1,186)	
95 %-KI	[-0,986; 3,118]	[-6,019; -1,353]	
Veränderung zu Woche 15/16			
n/N (%)	105/195 (54)	53/155 (34)	LS MD 5,40 [2,257; 8,539]
MW (SD)	-0,14 (20,789)	-6,06 (22,473)	
LS MW (SE)	0,88 (1,037)	-4,52 (1,203)	
95 %-KI	[-1,161; 2,921]	[-6,884; -2,152]	
Veränderung zu Woche 20/21			
n/N (%)	79/187 (42)	48/146 (33)	LS MD 6,32 [2,998; 9,644]
MW (SD)	4,89 (24,277)	3,48 (18,886)	
LS MW (SE)	0,61 (1,073)	-5,71 (1,296)	
95 %-KI	[-1,497; 2,726]	[-8,254; -3,160]	
Veränderung zu Woche 24			
n/N (%)	70/179 (39)	35/137 (26)	
MW (SD)	0,90 (24,433)	-1,66 (16,417)	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	0,43 (1,127)	-6,54 (1,402)	LS MD 6,97 [3,420; 10,515]
95 %-KI	[-1,789; 2,645]	[-9,293; -3,786]	
Veränderung zu Woche 36			
n/N (%)	82/159 (52)	47/117 (40)	LS MD 9,18 [4,451; 13,915]
MW (SD)	1,32 (20,915)	-9,26 (19,908)	
LS MW (SE)	-0,21 (1,445)	-9,39 (1,926)	
95 %-KI	[-3,046; 2,626]	[-13,173; -5,613]	
Veränderung zu Woche 48			
n/N (%)	15/137 (11)	4/97 (4)	LS MD 11,40 [5,137; 17,661]
MW (SD)	3,80 (24,332)	-15,00 (12,910)	
LS MW (SE)	-0,85 (1,880)	-12,25 (2,578)	
95 %-KI	[-4,537; 2,842]	[-17,304; -7,189]	
<b>Stadium bei der Diagnose: I-III</b>			
Baseline			
n/N (%)	155/194 (80)	134/168 (80)	-
MW (SD)	67,50 (19,765)	65,96 (19,837)	
Absolute Werte zum Studienende			
n/N (%)	13/127 (10)	7/89 (8)	-
MW (SD)	66,15 (21,019)	66,86 (21,950)	
Effekt über Studiendauer			
n	155	134	LS MD 5,99 [2,584; 9,406] 0,0006
LS MW (SE)	0,71 (1,136)	-5,29 (1,301)	
95 %-KI	[-1,529; 2,945]	[-7,847; -2,726]	Hedges' g 0,41 [0,177; 0,644]
Veränderung zu Woche 3/4			
n/N (%)	114/190 (60)	97/162 (60)	LS MD 4,31 [0,591; 8,027]
MW (SD)	2,17 (15,648)	-2,04 (18,660)	
LS MW (SE)	1,22 (1,252)	-3,09 (1,410)	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-1,242; 3,681]	[-5,862; -0,317]	
Veränderung zu Woche 8/9			
n/N (%)	130/186 (70)	103/152 (68)	LS MD 5,03 [1,553; 8,515]
MW (SD)	-0,70 (18,173)	-3,24 (20,683)	
LS MW (SE)	1,00 (1,172)	-4,03 (1,318)	
95 %-KI	[-1,306; 3,305]	[-6,628; -1,441]	
Veränderung zu Woche 12			
n/N (%)	92/180 (51)	59/149 (40)	LS MD 5,54 [2,133; 8,949]
MW (SD)	4,00 (19,691)	-5,90 (21,198)	
LS MW (SE)	0,85 (1,142)	-4,70 (1,294)	
95 %-KI	[-1,403; 3,094]	[-7,241; -2,150]	
Veränderung zu Woche 15/16			
n/N (%)	97/176 (55)	45/144 (31)	LS MD 6,05 [2,632; 9,464]
MW (SD)	-0,30 (18,663)	-5,00 (21,627)	
LS MW (SE)	0,69 (1,137)	-5,36 (1,304)	
95 %-KI	[-1,546; 2,930]	[-7,923; -2,790]	
Veränderung zu Woche 20/21			
n/N (%)	75/168 (45)	41/135 (30)	LS MD 6,77 [3,205; 10,341]
MW (SD)	3,84 (22,280)	2,46 (19,781)	
LS MW (SE)	0,47 (1,171)	-6,30 (1,378)	
95 %-KI	[-1,833; 2,777]	[-9,010; -3,592]	
Veränderung zu Woche 24			
n/N (%)	60/165 (36)	32/127 (25)	LS MD 7,28 [3,517; 11,043]
MW (SD)	0,55 (23,869)	-0,75 (18,810)	
LS MW (SE)	0,32 (1,223)	-6,96 (1,465)	
95 %-KI	[-2,087; 2,724]	[-9,842; -4,082]	
Veränderung zu Woche 36			
n/N (%)	78/144 (54)	46/107 (43)	
MW (SD)	1,87 (21,052)	-10,17 (19,724)	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-0,21 (1,531)	-9,23 (1,923)	LS MD 9,02 [4,184; 13,854]
95 %-KI	[-3,216; 2,797]	[-13,004; -5,453]	
Veränderung zu Woche 48			
n/N (%)	12/127 (9)	7/89 (8)	LS MD 10,76 [4,489; 17,027]
MW (SD)	2,42 (24,916)	-9,57 (14,421)	
LS MW (SE)	-0,74 (1,963)	-11,50 (2,516)	
95 %-KI	[-4,588; 3,115]	[-16,431; -6,559]	
<b>Stadium bei der Diagnose: IV</b>			
Baseline			
n/N (%)	77/97 (79)	48/68 (71)	-
MW (SD)	66,69 (20,378)	65,52 (19,532)	
Absolute Werte zum Studienende			
n/N (%)	8/60 (13)	2/36 (6)	-
MW (SD)	79,25 (11,805)	60,00 (28,284)	
Effekt über Studiendauer			
n	77	48	LS MD 7,11 [2,212; 12,016] 0,0048
LS MW (SE)	3,48 (1,463)	-3,64 (1,972)	
95 %-KI	[0,576; 6,375]	[-7,540; 0,264]	Hedges' g 0,54 [0,170; 0,904]
Veränderung zu Woche 3/4			
n/N (%)	55/95 (58)	29/65 (45)	LS MD 6,72 [1,305; 12,138]
MW (SD)	2,51 (15,037)	1,28 (16,442)	
LS MW (SE)	3,40 (1,622)	-3,32 (2,190)	
95 %-KI	[0,200; 6,604]	[-7,639; 0,999]	
Veränderung zu Woche 8/9			
n/N (%)	64/92 (70)	37/62 (60)	LS MD 6,89 [1,914; 11,874]
MW (SD)	3,66 (18,721)	-2,14 (22,581)	
LS MW (SE)	3,43 (1,508)	-3,46 (1,991)	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[0,451; 6,418]	[-7,395; 0,476]	
Veränderung zu Woche 12			
n/N (%)	40/89 (45)	24/58 (41)	LS MD 7,01 [2,148; 11,881]
MW (SD)	6,45 (22,208)	-4,75 (17,349)	
LS MW (SE)	3,46 (1,468)	-3,56 (1,946)	
95 %-KI	[0,548; 6,365]	[-7,408; 0,293]	
Veränderung zu Woche 15/16			
n/N (%)	40/85 (47)	18/54 (33)	LS MD 7,13 [2,210; 12,060]
MW (SD)	4,60 (22,387)	-5,22 (21,457)	
LS MW (SE)	3,48 (1,465)	-3,66 (1,985)	
95 %-KI	[0,576; 6,383]	[-7,583; 0,272]	
Veränderung zu Woche 20/21			
n/N (%)	25/83 (30)	17/50 (34)	LS MD 7,31 [2,016; 12,598]
MW (SD)	5,12 (20,791)	0,76 (13,358)	
LS MW (SE)	3,51 (1,525)	-3,80 (2,179)	
95 %-KI	[0,494; 6,529]	[-8,096; 0,505]	
Veränderung zu Woche 24			
n/N (%)	26/78 (33)	10/48 (21)	LS MD 7,43 [1,711; 13,144]
MW (SD)	5,65 (21,103)	-6,30 (16,228)	
LS MW (SE)	3,53 (1,607)	-3,89 (2,391)	
95 %-KI	[0,359; 6,710]	[-8,606; 0,819]	
Veränderung zu Woche 36			
n/N (%)	35/69 (51)	12/44 (27)	LS MD 7,84 [-0,021; 15,702]
MW (SD)	2,91 (18,704)	-1,33 (14,649)	
LS MW (SE)	3,61 (2,073)	-4,23 (3,403)	
95 %-KI	[-0,467; 7,691]	[-10,920; 2,463]	
Veränderung zu Woche 48			
n/N (%)	7/60 (12)	1/36 (3)	
MW (SD)	12,57 (20,468)	0,00 (NA)	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	3,69 (2,701)	-4,56 (4,624)	LS MD 8,25 [-2,293; 18,800]
95 %-KI	[-1,620; 8,998]	[-13,654; 4,525]	
<b>BRCA Status: Positiv</b>			
Baseline			
n/N (%)	33/38 (87)	25/37 (68)	-
MW (SD)	64,94 (23,381)	54,52 (21,693)	
Absolute Werte zum Studienende			
n/N (%)	4/29 (14)	0/15 (0)	-
MW (SD)	80,50 (18,376)	NA (NA)	
Effekt über Studiendauer			
n	33	25	LS MD 11,01 [2,929; 19,084] 0,0084  Hedges' g 0,75 [0,208; 1,284]
LS MW (SE)	7,83 (2,351)	-3,18 (3,170)	
95 %-KI	[3,104; 12,556]	[-9,512; 3,159]	
Veränderung zu Woche 3/4			
n/N (%)	23/38 (61)	18/37 (49)	LS MD 1,15 [-7,483; 9,787]
MW (SD)	4,39 (18,944)	8,17 (20,601)	
LS MW (SE)	5,39 (2,596)	4,24 (3,364)	
95 %-KI	[0,214; 10,564]	[-2,456; 10,930]	
Veränderung zu Woche 8/9			
n/N (%)	30/37 (81)	22/32 (69)	LS MD 5,54 [-2,548; 13,619]
MW (SD)	4,30 (16,002)	6,59 (17,059)	
LS MW (SE)	6,47 (2,432)	0,94 (3,111)	
95 %-KI	[1,603; 11,347]	[-5,283; 7,161]	
Veränderung zu Woche 12			
n/N (%)	23/36 (64)	11/32 (34)	LS MD 8,60 [0,620; 16,588]
MW (SD)	4,83 (19,731)	1,55 (21,965)	
LS MW (SE)	7,23 (2,369)	-1,37 (3,091)	



MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[2,478; 11,992]	[-7,558; 4,819]	
Veränderung zu Woche 15/16			
n/N (%)	21/36 (58)	7/30 (23)	LS MD 11,67 [3,543; 19,803]
MW (SD)	6,95 (21,671)	1,29 (27,986)	
LS MW (SE)	7,99 (2,352)	-3,68 (3,205)	
95 %-KI	[3,268; 12,721]	[-10,081; 2,725]	
Veränderung zu Woche 20/21			
n/N (%)	17/35 (49)	5/26 (19)	LS MD 16,06 [7,316; 24,797]
MW (SD)	12,82 (24,247)	15,60 (23,223)	
LS MW (SE)	9,08 (2,409)	-6,98 (3,572)	
95 %-KI	[4,248; 13,912]	[-14,074; 0,121]	
Veränderung zu Woche 24			
n/N (%)	15/35 (43)	4/25 (16)	LS MD 19,12 [9,713; 28,536]
MW (SD)	9,47 (18,939)	-3,50 (28,641)	
LS MW (SE)	9,84 (2,503)	-9,28 (3,941)	
95 %-KI	[4,834; 14,846]	[-17,089; -1,481]	
Veränderung zu Woche 36			
n/N (%)	16/31 (52)	6/21 (29)	LS MD 29,65 [16,912; 42,380]
MW (SD)	3,81 (26,192)	-5,00 (33,082)	
LS MW (SE)	12,45 (3,091)	-17,20 (5,604)	
95 %-KI	[6,325; 18,566]	[-28,251; -6,150]	
Veränderung zu Woche 48			
n/N (%)	4/29 (14)	0/15 (0)	LS MD 40,17 [23,279; 57,053]
MW (SD)	19,00 (32,197)	NA (NA)	
LS MW (SE)	15,05 (3,933)	-25,12 (7,562)	
95 %-KI	[7,292; 22,809]	[-40,022; -10,210]	
<b>BRCA Status: Negativ/Unbekannt</b>			
Baseline			
n/N (%)	204/259 (79)	159/202 (79)	-

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	67,12 (19,496)	67,66 (18,747)	
Absolute Werte zum Studienende			
n/N (%)	17/161 (11)	9/111 (8)	-
MW (SD)	68,94 (18,843)	65,33 (21,691)	
Effekt über Studiendauer			
n	204	159	LS MD 5,89 [2,909; 8,880] 0,0001  Hedges' g 0,41 [0,204; 0,624]
LS MW (SE)	0,59 (0,973)	-5,30 (1,158)	
95 %-KI	[-1,321; 2,506]	[-7,578; -3,025]	
Veränderung zu Woche 3/4			
n/N (%)	151/253 (60)	110/193 (57)	LS MD 5,12 [1,850; 8,394]
MW (SD)	2,31 (14,957)	-2,95 (17,374)	
LS MW (SE)	1,34 (1,073)	-3,78 (1,267)	
95 %-KI	[-0,766; 3,449]	[-6,268; -1,292]	
Veränderung zu Woche 8/9			
n/N (%)	169/247 (68)	120/185 (65)	LS MD 5,46 [2,406; 8,506]
MW (SD)	0,14 (18,719)	-4,54 (21,272)	
LS MW (SE)	1,02 (1,001)	-4,44 (1,177)	
95 %-KI	[-0,951; 2,987]	[-6,752; -2,124]	
Veränderung zu Woche 12			
n/N (%)	114/239 (48)	73/178 (41)	LS MD 5,69 [2,708; 8,671]
MW (SD)	4,86 (21,350)	-6,52 (19,591)	
LS MW (SE)	0,79 (0,976)	-4,90 (1,152)	
95 %-KI	[-1,129; 2,712]	[-7,164; -2,632]	
Veränderung zu Woche 15/16			
n/N (%)	118/231 (51)	58/171 (34)	LS MD 5,92 [2,932; 8,914]
MW (SD)	0,51 (19,565)	-6,22 (21,353)	
LS MW (SE)	0,56 (0,974)	-5,36 (1,161)	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-1,351; 2,480]	[-7,641; -3,076]	
Veränderung zu Woche 20/21			
n/N (%)	85/222 (38)	54/162 (33)	LS MD 6,26 [3,121; 9,393]
MW (SD)	2,87 (21,030)	0,91 (17,110)	
LS MW (SE)	0,24 (1,009)	-6,02 (1,229)	
95 %-KI	[-1,743; 2,225]	[-8,431; -3,601]	
Veränderung zu Woche 24			
n/N (%)	72/213 (34)	39/152 (26)	LS MD 6,49 [3,170; 9,812]
MW (SD)	1,29 (24,361)	-2,28 (17,241)	
LS MW (SE)	0,01 (1,059)	-6,48 (1,311)	
95 %-KI	[-2,066; 2,095]	[-9,052; -3,901]	
Veränderung zu Woche 36			
n/N (%)	98/186 (53)	53/131 (40)	LS MD 7,29 [2,970; 11,616]
MW (SD)	2,07 (19,239)	-8,96 (17,104)	
LS MW (SE)	-0,76 (1,345)	-8,06 (1,739)	
95 %-KI	[-3,403; 1,878]	[-11,468; -4,642]	
Veränderung zu Woche 48			
n/N (%)	15/161 (9)	8/111 (7)	LS MD 8,09 [2,447; 13,742]
MW (SD)	2,73 (20,447)	-8,38 (13,773)	
LS MW (SE)	-1,54 (1,738)	-9,63 (2,291)	
95 %-KI	[-4,949; 1,870]	[-14,127; -5,140]	
<b>Baseline ECOG PS: 0</b>			
Baseline			
n/N (%)	144/174 (83)	112/133 (84)	-
MW (SD)	71,41 (18,271)	68,23 (17,393)	
Absolute Werte zum Studienende			
n/N (%)	13/121 (11)	5/84 (6)	-
MW (SD)	70,38 (17,323)	59,00 (24,341)	
Effekt über Studiendauer			

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n	144	112	LS MD 5,42 [1,954; 8,887] 0,0023  Hedges' g 0,39 [0,142; 0,640]
LS MW (SE)	-0,21 (1,123)	-5,63 (1,347)	
95 %-KI	[-2,425; 2,001]	[-8,284; -2,981]	
Veränderung zu Woche 3/4			
n/N (%)	109/173 (63)	77/130 (59)	LS MD 4,50 [0,665; 8,333]
MW (SD)	1,75 (13,532)	-2,34 (18,751)	
LS MW (SE)	0,58 (1,244)	-3,92 (1,493)	
95 %-KI	[-1,867; 3,026]	[-6,854; -0,984]	
Veränderung zu Woche 8/9			
n/N (%)	123/171 (72)	86/127 (68)	LS MD 4,89 [1,332; 8,454]
MW (SD)	-1,04 (18,133)	-3,62 (20,665)	
LS MW (SE)	0,24 (1,159)	-4,65 (1,380)	
95 %-KI	[-2,041; 2,524]	[-7,367; -1,936]	
Veränderung zu Woche 12			
n/N (%)	82/166 (49)	58/126 (46)	LS MD 5,17 [1,698; 8,639]
MW (SD)	3,22 (19,312)	-6,81 (19,646)	
LS MW (SE)	0,00 (1,129)	-5,16 (1,344)	
95 %-KI	[-2,219; 2,228]	[-7,811; -2,517]	
Veränderung zu Woche 15/16			
n/N (%)	86/163 (53)	41/121 (34)	LS MD 5,44 [1,974; 8,914]
MW (SD)	-1,08 (17,644)	-6,41 (21,213)	
LS MW (SE)	-0,23 (1,124)	-5,68 (1,349)	
95 %-KI	[-2,446; 1,982]	[-8,332; -3,021]	
Veränderung zu Woche 20/21			
n/N (%)	67/160 (42)	38/117 (32)	LS MD 5,84 [2,213; 9,463]
MW (SD)	0,84 (19,338)	-1,92 (15,773)	
LS MW (SE)	-0,57 (1,162)	-6,41 (1,422)	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-2,858; 1,718]	[-9,206; -3,611]	
Veränderung zu Woche 24			
n/N (%)	50/153 (33)	26/112 (23)	LS MD 6,11 [2,282; 9,946]
MW (SD)	-0,82 (20,684)	-2,27 (19,384)	
LS MW (SE)	-0,81 (1,218)	-6,92 (1,514)	
95 %-KI	[-3,203; 1,589]	[-9,899; -3,943]	
Veränderung zu Woche 36			
n/N (%)	74/136 (54)	44/100 (44)	LS MD 7,06 [2,075; 12,045]
MW (SD)	-1,04 (17,474)	-7,93 (17,243)	
LS MW (SE)	-1,62 (1,545)	-8,68 (2,011)	
95 %-KI	[-4,652; 1,416]	[-12,626; -4,731]	
Veränderung zu Woche 48			
n/N (%)	11/121 (9)	5/84 (6)	LS MD 8,01 [1,480; 14,531]
MW (SD)	5,27 (15,679)	-9,00 (15,166)	
LS MW (SE)	-2,43 (1,997)	-10,44 (2,657)	
95 %-KI	[-6,349; 1,489]	[-15,650; -5,222]	
<b>Baseline ECOG PS: 1</b>			
Baseline			
n/N (%)	93/123 (76)	71/103 (69)	-
MW (SD)	59,71 (20,673)	62,87 (21,753)	
Absolute Werte zum Studienende			
n/N (%)	8/69 (12)	4/41 (10)	-
MW (SD)	72,38 (22,379)	73,25 (17,727)	
Effekt über Studiendauer			
n	93	71	LS MD 7,81 [3,131; 12,486] 0,0012
LS MW (SE)	4,29 (1,483)	-3,52 (1,820)	
95 %-KI	[1,360; 7,224]	[-7,109; 0,076]	Hedges' g 0,53 [0,212; 0,841]

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	65/118 (55)	50/98 (51)	LS MD 4,77 [-0,263; 9,795]
MW (SD)	3,98 (18,355)	-0,32 (17,383)	
LS MW (SE)	3,82 (1,628)	-0,95 (1,940)	
95 %-KI	[0,608; 7,027]	[-4,771; 2,874]	
Veränderung zu Woche 8/9			
n/N (%)	76/113 (67)	55/88 (62)	LS MD 6,12 [1,406; 10,836]
MW (SD)	3,70 (18,463)	-1,69 (21,854)	
LS MW (SE)	4,03 (1,525)	-2,09 (1,813)	
95 %-KI	[1,018; 7,039]	[-5,668; 1,484]	
Veränderung zu Woche 12			
n/N (%)	55/109 (50)	25/83 (30)	LS MD 7,07 [2,426; 11,713]
MW (SD)	7,29 (23,302)	-4,32 (18,816)	
LS MW (SE)	4,18 (1,489)	-2,89 (1,793)	
95 %-KI	[1,235; 7,119]	[-6,432; 0,647]	
Veränderung zu Woche 15/16			
n/N (%)	53/104 (51)	24/79 (30)	LS MD 8,02 [3,316; 12,719]
MW (SD)	5,64 (22,777)	-3,71 (23,711)	
LS MW (SE)	4,32 (1,485)	-3,69 (1,835)	
95 %-KI	[1,389; 7,261]	[-7,313; -0,073]	
Veränderung zu Woche 20/21			
n/N (%)	35/97 (36)	20/70 (29)	LS MD 9,37 [4,375; 14,370]
MW (SD)	11,60 (24,624)	7,25 (17,035)	
LS MW (SE)	4,54 (1,538)	-4,84 (1,990)	
95 %-KI	[1,500; 7,572]	[-8,758; -0,915]	
Veränderung zu Woche 24			
n/N (%)	37/95 (39)	16/64 (25)	LS MD 10,32 [4,986; 15,656]
MW (SD)	7,46 (26,649)	-3,88 (16,161)	
LS MW (SE)	4,68 (1,611)	-5,64 (2,155)	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[1,507; 7,861]	[-9,879; -1,395]	
Veränderung zu Woche 36			
n/N (%)	40/81 (49)	15/51 (29)	LS MD 13,57 [6,518; 20,628]
MW (SD)	8,53 (23,516)	-10,40 (23,778)	
LS MW (SE)	5,19 (2,033)	-8,38 (2,941)	
95 %-KI	[1,194; 9,188]	[-14,161; -2,603]	
Veränderung zu Woche 48			
n/N (%)	8/69 (12)	3/41 (7)	LS MD 16,82 [7,574; 26,076]
MW (SD)	7,38 (32,337)	-7,33 (14,189)	
LS MW (SE)	5,70 (2,613)	-11,13 (3,904)	
95 %-KI	[0,565; 10,833]	[-18,794; -3,458]	
<b>Anzahl vorheriger Therapielinien: 1 oder 2</b>			
Baseline			
n/N (%)	142/171 (83)	102/131 (78)	-
MW (SD)	66,21 (20,901)	66,61 (19,938)	
Absolute Werte zum Studienende			
n/N (%)	15/116 (13)	4/76 (5)	-
MW (SD)	66,07 (19,440)	64,25 (26,311)	
Effekt über Studiendauer			
n	142	102	LS MD 4,75 [1,226; 8,282] 0,0085  Hedges' g 0,35 [0,093; 0,605]
LS MW (SE)	2,00 (1,102)	-2,76 (1,404)	
95 %-KI	[-0,177; 4,167]	[-5,524; 0,006]	
Veränderung zu Woche 3/4			
n/N (%)	104/167 (62)	72/127 (57)	LS MD 2,75 [-1,158; 6,661]
MW (SD)	2,17 (16,195)	0,06 (18,265)	
LS MW (SE)	2,42 (1,236)	-0,33 (1,552)	
95 %-KI	[-0,007; 4,853]	[-3,381; 2,724]	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	123/165 (75)	82/120 (68)	LS MD 3,60 [-0,007; 7,211]
MW (SD)	0,85 (18,634)	-0,61 (21,594)	
LS MW (SE)	2,24 (1,145)	-1,36 (1,425)	
95 %-KI	[-0,014; 4,497]	[-4,166; 1,444]	
Veränderung zu Woche 12			
n/N (%)	82/161 (51)	51/116 (44)	LS MD 4,20 [0,681; 7,715]
MW (SD)	5,37 (19,937)	-4,18 (20,655)	
LS MW (SE)	2,11 (1,111)	-2,08 (1,391)	
95 %-KI	[-0,075; 4,303]	[-4,824; 0,655]	
Veränderung zu Woche 15/16			
n/N (%)	86/158 (54)	37/112 (33)	LS MD 4,79 [1,261; 8,326]
MW (SD)	2,03 (18,951)	-4,14 (23,209)	
LS MW (SE)	1,99 (1,102)	-2,81 (1,407)	
95 %-KI	[-0,186; 4,159]	[-5,577; -0,037]	
Veränderung zu Woche 20/21			
n/N (%)	72/155 (46)	35/106 (33)	LS MD 5,64 [1,909; 9,380]
MW (SD)	3,68 (19,677)	2,91 (17,751)	
LS MW (SE)	1,80 (1,137)	-3,84 (1,512)	
95 %-KI	[-0,434; 4,044]	[-6,814; -0,866]	
Veränderung zu Woche 24			
n/N (%)	63/149 (42)	27/101 (27)	LS MD 6,24 [2,251; 10,229]
MW (SD)	3,30 (24,078)	0,74 (17,797)	
LS MW (SE)	1,68 (1,191)	-4,56 (1,634)	
95 %-KI	[-0,666; 4,021]	[-7,774; -1,351]	
Veränderung zu Woche 36			
n/N (%)	75/131 (57)	33/90 (37)	LS MD 8,28 [2,946; 13,618]
MW (SD)	2,21 (19,786)	-5,85 (19,447)	
LS MW (SE)	1,24 (1,517)	-7,04 (2,247)	



MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-1,739; 4,221]	[-11,451; -2,631]	
Veränderung zu Woche 48			
n/N (%)	14/116 (12)	3/76 (4)	LS MD 10,32 [3,246; 17,402]
MW (SD)	0,93 (17,696)	-10,67 (19,009)	
LS MW (SE)	0,80 (1,971)	-9,52 (3,011)	
95 %-KI	[-3,064; 4,673]	[-15,430; -3,609]	
<b>Anzahl vorheriger Therapielinien: 3</b>			
Baseline			
n/N (%)	95/126 (75)	82/108 (76)	-
MW (SD)	67,73 (18,756)	64,96 (19,335)	
Absolute Werte zum Studienende			
n/N (%)	6/74 (8)	5/50 (10)	-
MW (SD)	83,83 (9,827)	66,20 (20,487)	
Effekt über Studiendauer			
n	95	82	LS MD 8,52 [4,029; 13,013] 0,0002  Hedges' g 0,57 [0,264; 0,867]
LS MW (SE)	0,97 (1,514)	-7,55 (1,690)	
95 %-KI	[-2,022; 3,957]	[-10,888; -4,219]	
Veränderung zu Woche 3/4			
n/N (%)	70/124 (56)	56/103 (54)	LS MD 7,31 [2,464; 12,149]
MW (SD)	3,20 (14,487)	-3,25 (18,091)	
LS MW (SE)	1,05 (1,643)	-6,25 (1,818)	
95 %-KI	[-2,185; 4,291]	[-9,836; -2,672]	
Veränderung zu Woche 8/9			
n/N (%)	76/119 (64)	60/97 (62)	LS MD 7,85 [3,289; 12,415]
MW (SD)	0,63 (18,027)	-5,83 (19,977)	
LS MW (SE)	1,01 (1,546)	-6,84 (1,710)	
95 %-KI	[-2,036; 4,064]	[-10,211; -3,464]	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	55/114 (48)	33/94 (35)	LS MD 8,23 [3,750; 12,719]
MW (SD)	4,09 (22,700)	-7,45 (18,985)	
LS MW (SE)	0,99 (1,515)	-7,25 (1,683)	
95 %-KI	[-2,004; 3,979]	[-10,568; -3,926]	
Veränderung zu Woche 15/16			
n/N (%)	53/109 (49)	28/89 (31)	LS MD 8,62 [4,109; 13,124]
MW (SD)	0,58 (21,627)	-7,11 (20,646)	
LS MW (SE)	0,96 (1,518)	-7,66 (1,697)	
95 %-KI	[-2,036; 3,958]	[-11,005; -4,307]	
Veränderung zu Woche 20/21			
n/N (%)	30/102 (29)	24/82 (29)	LS MD 9,16 [4,449; 13,876]
MW (SD)	6,57 (26,454)	1,04 (18,532)	
LS MW (SE)	0,92 (1,579)	-8,24 (1,789)	
95 %-KI	[-2,192; 4,037]	[-11,766; -4,715]	
Veränderung zu Woche 24			
n/N (%)	24/99 (24)	16/76 (21)	LS MD 9,55 [4,578; 14,513]
MW (SD)	1,12 (22,804)	-7,69 (17,914)	
LS MW (SE)	0,90 (1,658)	-8,65 (1,896)	
95 %-KI	[-2,371; 4,163]	[-12,383; -4,915]	
Veränderung zu Woche 36			
n/N (%)	39/86 (45)	26/62 (42)	LS MD 10,86 [4,514; 17,197]
MW (SD)	2,51 (21,313)	-12,00 (18,018)	
LS MW (SE)	0,80 (2,098)	-10,05 (2,457)	
95 %-KI	[-3,320; 4,928]	[-14,879; -5,224]	
Veränderung zu Woche 48			
n/N (%)	5/74 (7)	5/50 (10)	LS MD 12,17 [3,992; 20,341]
MW (SD)	20,80 (32,683)	-7,00 (12,042)	
LS MW (SE)	0,71 (2,694)	-11,45 (3,187)	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-4,578; 6,004]	[-17,713; -5,195]	
<b>Vorherige Verabreichung von Bevacizumab: Ja</b>			
Baseline			
n/N (%)	134/173 (77)	110/149 (74)	-
MW (SD)	67,76 (17,939)	64,53 (20,172)	
Absolute Werte zum Studienende			
n/N (%)	8/102 (8)	4/68 (6)	-
MW (SD)	64,25 (20,755)	76,75 (18,500)	
Effekt über Studiendauer			
n	134	110	LS MD 6,54 [2,882; 10,197] 0,0005  Hedges' g 0,46 [0,202; 0,713]
LS MW (SE)	0,09 (1,186)	-6,45 (1,417)	
95 %-KI	[-2,250; 2,424]	[-9,244; -3,662]	
Veränderung zu Woche 3/4			
n/N (%)	93/168 (55)	79/142 (56)	LS MD 4,19 [0,185; 8,200]
MW (SD)	1,22 (13,826)	-2,42 (18,548)	
LS MW (SE)	0,34 (1,319)	-3,85 (1,540)	
95 %-KI	[-2,254; 2,935]	[-6,880; -0,823]	
Veränderung zu Woche 8/9			
n/N (%)	110/167 (66)	79/133 (59)	LS MD 5,25 [1,542; 8,961]
MW (SD)	-1,34 (16,024)	-2,99 (22,591)	
LS MW (SE)	0,23 (1,223)	-5,03 (1,419)	
95 %-KI	[-2,183; 2,635]	[-7,819; -2,232]	
Veränderung zu Woche 12			
n/N (%)	72/159 (45)	44/126 (35)	LS MD 5,99 [2,358; 9,629]
MW (SD)	3,33 (21,522)	-6,18 (19,270)	
LS MW (SE)	0,15 (1,190)	-5,85 (1,398)	
95 %-KI	[-2,200; 2,491]	[-8,600; -3,095]	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	78/153 (51)	36/121 (30)	LS MD 6,73 [3,054; 10,416]
MW (SD)	-0,14 (17,283)	-6,56 (22,160)	
LS MW (SE)	0,07 (1,188)	-6,67 (1,432)	
95 %-KI	[-2,276; 2,407]	[-9,488; -3,851]	
Veränderung zu Woche 20/21			
n/N (%)	56/145 (39)	32/112 (29)	LS MD 7,79 [3,852; 11,737]
MW (SD)	2,38 (21,644)	1,78 (18,187)	
LS MW (SE)	-0,05 (1,239)	-7,84 (1,568)	
95 %-KI	[-2,489; 2,390]	[-10,927; -4,760]	
Veränderung zu Woche 24			
n/N (%)	43/138 (31)	21/104 (20)	LS MD 8,54 [4,292; 12,780]
MW (SD)	2,02 (20,283)	-1,90 (13,678)	
LS MW (SE)	-0,13 (1,308)	-8,67 (1,713)	
95 %-KI	[-2,704; 2,444]	[-12,032; -5,299]	
Veränderung zu Woche 36			
n/N (%)	61/119 (51)	27/86 (31)	LS MD 11,08 [5,318; 16,840]
MW (SD)	0,16 (17,040)	-14,15 (17,920)	
LS MW (SE)	-0,41 (1,698)	-11,48 (2,399)	
95 %-KI	[-3,739; 2,929]	[-16,193; -6,774]	
Veränderung zu Woche 48			
n/N (%)	8/102 (8)	3/68 (4)	LS MD 13,62 [5,953; 21,290]
MW (SD)	-4,88 (17,083)	-2,33 (15,373)	
LS MW (SE)	-0,68 (2,221)	-14,30 (3,228)	
95 %-KI	[-5,040; 3,679]	[-20,637; -7,967]	
<b>Vorherige Verabreichung von Bevacizumab: Nein</b>			
Baseline			
n/N (%)	103/124 (83)	74/90 (82)	-
MW (SD)	65,59 (22,517)	67,88 (18,764)	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	13/88 (15)	5/58 (9)	-
MW (SD)	75,38 (17,071)	56,20 (21,206)	
Effekt über Studiendauer			
n	103	74	LS MD 6,07 [1,806; 10,340] 0,0055  Hedges' g 0,43 [0,129; 0,734]
LS MW (SE)	3,53 (1,357)	-2,54 (1,668)	
95 %-KI	[0,853; 6,212]	[-5,832; 0,751]	
Veränderung zu Woche 3/4			
n/N (%)	81/123 (66)	49/88 (56)	LS MD 5,13 [0,456; 9,807]
MW (SD)	4,16 (17,168)	0,27 (17,664)	
LS MW (SE)	4,01 (1,492)	-1,12 (1,832)	
95 %-KI	[1,068; 6,945]	[-4,733; 2,483]	
Veränderung zu Woche 8/9			
n/N (%)	89/117 (76)	63/84 (75)	LS MD 5,52 [1,141; 9,905]
MW (SD)	3,37 (20,686)	-2,60 (19,028)	
LS MW (SE)	3,81 (1,399)	-1,71 (1,711)	
95 %-KI	[1,050; 6,570]	[-5,087; 1,662]	
Veränderung zu Woche 12			
n/N (%)	65/116 (56)	40/84 (48)	LS MD 5,80 [1,518; 10,075]
MW (SD)	6,54 (20,478)	-4,67 (20,919)	
LS MW (SE)	3,67 (1,364)	-2,12 (1,670)	
95 %-KI	[0,979; 6,366]	[-5,419; 1,171]	
Veränderung zu Woche 15/16			
n/N (%)	61/114 (54)	29/80 (36)	LS MD 6,07 [1,803; 10,337]
MW (SD)	3,56 (22,895)	-4,00 (22,160)	
LS MW (SE)	3,53 (1,357)	-2,54 (1,668)	
95 %-KI	[0,855; 6,214]	[-5,826; 0,755]	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	46/112 (41)	27/76 (36)	LS MD 6,46 [2,053; 10,869]
MW (SD)	7,15 (21,919)	2,59 (17,973)	
LS MW (SE)	3,34 (1,394)	-3,12 (1,731)	
95 %-KI	[0,587; 6,088]	[-6,538; 0,291]	
Veränderung zu Woche 24			
n/N (%)	44/110 (40)	22/73 (30)	LS MD 6,73 [2,125; 11,344]
MW (SD)	3,36 (26,706)	-2,86 (21,833)	
LS MW (SE)	3,20 (1,451)	-3,53 (1,819)	
95 %-KI	[0,338; 6,061]	[-7,119; 0,049]	
Veränderung zu Woche 36			
n/N (%)	53/98 (54)	32/66 (48)	LS MD 7,67 [1,880; 13,466]
MW (SD)	4,79 (23,289)	-3,84 (18,721)	
LS MW (SE)	2,73 (1,800)	-4,95 (2,320)	
95 %-KI	[-0,811; 6,266]	[-9,504; -0,387]	
Veränderung zu Woche 48			
n/N (%)	11/88 (12)	5/58 (9)	LS MD 8,61 [1,173; 16,050]
MW (SD)	14,18 (24,645)	-12,00 (13,038)	
LS MW (SE)	2,26 (2,294)	-6,36 (3,000)	
95 %-KI	[-2,249; 6,759]	[-12,247; -0,465]	
<b>Letztes Platin-freies Intervall: ≤ 3 Monate</b>			
Baseline			
n/N (%)	86/112 (77)	74/105 (70)	-
MW (SD)	68,87 (18,547)	60,92 (21,075)	
Absolute Werte zum Studienende			
n/N (%)	6/69 (9)	6/44 (14)	-
MW (SD)	79,33 (27,171)	63,67 (24,873)	
Effekt über Studiendauer			
n	86	74	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	0,16 (1,583)	-6,45 (1,822)	LS MD 6,60 [1,774; 11,436] 0,0077  Hedges' g 0,43 [0,119; 0,748]
95 %-KI	[-2,972; 3,287]	[-10,045; -2,849]	
Veränderung zu Woche 3/4			
n/N (%)	65/110 (59)	52/99 (53)	LS MD 5,05 [-0,092; 10,198]
MW (SD)	0,12 (13,666)	1,19 (19,780)	
LS MW (SE)	0,41 (1,702)	-4,65 (1,934)	
95 %-KI	[-2,949; 3,764]	[-8,457; -0,834]	
Veränderung zu Woche 8/9			
n/N (%)	68/107 (64)	56/92 (61)	LS MD 5,75 [0,871; 10,627]
MW (SD)	-2,01 (15,765)	-2,18 (22,845)	
LS MW (SE)	0,30 (1,610)	-5,45 (1,831)	
95 %-KI	[-2,884; 3,475]	[-9,068; -1,839]	
Veränderung zu Woche 12			
n/N (%)	44/100 (44)	28/89 (31)	LS MD 6,24 [1,424; 11,048]
MW (SD)	0,64 (19,545)	-3,54 (25,243)	
LS MW (SE)	0,22 (1,582)	-6,02 (1,810)	
95 %-KI	[-2,910; 3,344]	[-9,592; -2,445]	
Veränderung zu Woche 15/16			
n/N (%)	48/98 (49)	16/84 (19)	LS MD 6,72 [1,874; 11,573]
MW (SD)	-0,48 (20,204)	-1,69 (23,177)	
LS MW (SE)	0,14 (1,588)	-6,58 (1,832)	
95 %-KI	[-2,999; 3,276]	[-10,201; -2,968]	
Veränderung zu Woche 20/21			
n/N (%)	32/94 (34)	17/76 (22)	LS MD 7,42 [2,341; 12,497]
MW (SD)	-0,47 (20,879)	9,76 (22,999)	
LS MW (SE)	0,03 (1,651)	-7,39 (1,935)	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,233; 3,285]	[-11,209; -3,576]	
Veränderung zu Woche 24			
n/N (%)	25/92 (27)	13/71 (18)	LS MD 7,91 [2,557; 13,254]
MW (SD)	-2,72 (20,846)	0,92 (25,158)	
LS MW (SE)	-0,05 (1,730)	-7,96 (2,052)	
95 %-KI	[-3,465; 3,361]	[-12,000; -3,916]	
Veränderung zu Woche 36			
n/N (%)	37/81 (46)	22/56 (39)	LS MD 9,58 [2,790; 16,362]
MW (SD)	-2,19 (22,265)	-4,64 (22,489)	
LS MW (SE)	-0,32 (2,170)	-9,90 (2,647)	
95 %-KI	[-4,588; 3,946]	[-15,100; -4,694]	
Veränderung zu Woche 48			
n/N (%)	5/69 (7)	5/44 (11)	LS MD 11,25 [2,551; 19,940]
MW (SD)	9,20 (34,860)	-8,40 (15,900)	
LS MW (SE)	-0,59 (2,765)	-11,84 (3,415)	
95 %-KI	[-6,024; 4,843]	[-18,545; -5,127]	
<b>Letztes Platin-freies Intervall: &gt; 3 Monate</b>			
Baseline			
n/N (%)	151/185 (82)	110/134 (82)	-
MW (SD)	65,65 (20,814)	69,21 (17,942)	
Absolute Werte zum Studienende			
n/N (%)	15/121 (12)	3/82 (4)	-
MW (SD)	67,87 (14,322)	68,67 (17,616)	
Effekt über Studiendauer			
n	151	110	LS MD 6,36 [2,923; 9,795] 0,0003
LS MW (SE)	2,48 (1,083)	-3,88 (1,348)	
95 %-KI	[0,348; 4,617]	[-6,531; -1,222]	Hedges' g 0,46 [0,215; 0,713]



MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	109/181 (60)	76/131 (58)	LS MD 4,71 [0,872; 8,553]
MW (SD)	4,06 (16,375)	-3,16 (16,928)	
LS MW (SE)	2,85 (1,217)	-1,86 (1,509)	
95 %-KI	[0,461; 5,248]	[-4,823; 1,108]	
Veränderung zu Woche 8/9			
n/N (%)	131/177 (74)	86/125 (69)	LS MD 5,42 [1,882; 8,948]
MW (SD)	2,21 (19,470)	-3,23 (19,858)	
LS MW (SE)	2,70 (1,127)	-2,72 (1,379)	
95 %-KI	[0,478; 4,914]	[-5,433; -0,006]	
Veränderung zu Woche 12			
n/N (%)	93/175 (53)	56/121 (46)	LS MD 5,91 [2,473; 9,341]
MW (SD)	6,85 (21,492)	-6,43 (16,906)	
LS MW (SE)	2,58 (1,092)	-3,32 (1,341)	
95 %-KI	[0,434; 4,736]	[-5,962; -0,683]	
Veränderung zu Woche 15/16			
n/N (%)	91/169 (54)	49/117 (42)	LS MD 6,40 [2,959; 9,840]
MW (SD)	2,52 (19,847)	-6,63 (21,742)	
LS MW (SE)	2,47 (1,084)	-3,93 (1,351)	
95 %-KI	[0,338; 4,609]	[-6,585; -1,266]	
Veränderung zu Woche 20/21			
n/N (%)	70/163 (43)	42/112 (38)	LS MD 7,10 [3,472; 10,732]
MW (SD)	6,81 (21,963)	-0,93 (14,663)	
LS MW (SE)	2,31 (1,119)	-4,79 (1,446)	
95 %-KI	[0,112; 4,518]	[-7,632; -1,942]	
Veränderung zu Woche 24			
n/N (%)	62/156 (40)	30/106 (28)	LS MD 7,59 [3,720; 11,468]
MW (SD)	4,89 (24,470)	-3,83 (14,338)	
LS MW (SE)	2,20 (1,174)	-5,39 (1,562)	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-0,106; 4,513]	[-8,460; -2,321]	
Veränderung zu Woche 36			
n/N (%)	77/136 (57)	37/96 (39)	LS MD 9,28 [4,093; 14,468]
MW (SD)	4,48 (18,945)	-10,89 (16,336)	
LS MW (SE)	1,82 (1,503)	-7,46 (2,150)	
95 %-KI	[-1,129; 4,774]	[-11,678; -3,239]	
Veränderung zu Woche 48			
n/N (%)	14/121 (12)	3/82 (4)	LS MD 10,97 [4,072; 17,863]
MW (SD)	5,07 (19,365)	-8,33 (12,583)	
LS MW (SE)	1,44 (1,959)	-9,53 (2,889)	
95 %-KI	[-2,402; 5,285]	[-15,195; -3,857]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Pegyliertes liposomales Doxorubicin</b>			
Baseline			
n/N (%)	95/120 (79)	67/90 (74)	-
MW (SD)	64,04 (21,050)	70,13 (17,012)	
Absolute Werte zum Studienende			
n/N (%)	12/80 (15)	5/50 (10)	-
MW (SD)	76,08 (12,731)	68,40 (24,603)	
Effekt über Studiendauer			
n	95	67	LS MD 6,42 [1,716; 11,124] 0,0078  Hedges' g 0,44 [0,122; 0,755]
LS MW (SE)	2,45 (1,451)	-3,97 (1,851)	
95 %-KI	[-0,417; 5,316]	[-7,625; -0,316]	
Veränderung zu Woche 3/4			
n/N (%)	66/116 (57)	48/87 (55)	LS MD 3,88 [-1,196; 8,954]
MW (SD)	5,45 (17,251)	-2,10 (16,607)	
LS MW (SE)	2,26 (1,591)	-1,62 (1,988)	
95 %-KI	[-0,875; 5,397]	[-5,535; 2,299]	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	80/114 (70)	52/79 (66)	LS MD 4,92 [0,134; 9,711]
MW (SD)	0,78 (16,978)	-5,44 (21,971)	
LS MW (SE)	2,34 (1,499)	-2,58 (1,869)	
95 %-KI	[-0,621; 5,298]	[-6,273; 1,105]	
Veränderung zu Woche 12			
n/N (%)	56/110 (51)	29/76 (38)	LS MD 5,65 [0,956; 10,350]
MW (SD)	6,38 (20,514)	-4,79 (17,817)	
LS MW (SE)	2,39 (1,462)	-3,26 (1,837)	
95 %-KI	[-0,496; 5,282]	[-6,887; 0,367]	
Veränderung zu Woche 15/16			
n/N (%)	59/109 (54)	24/73 (33)	LS MD 6,38 [1,682; 11,085]
MW (SD)	3,68 (22,170)	-8,08 (20,489)	
LS MW (SE)	2,45 (1,451)	-3,94 (1,849)	
95 %-KI	[-0,420; 5,314]	[-7,588; -0,286]	
Veränderung zu Woche 20/21			
n/N (%)	48/107 (45)	23/70 (33)	LS MD 7,43 [2,554; 12,300]
MW (SD)	7,33 (22,457)	0,30 (14,599)	
LS MW (SE)	2,52 (1,478)	-4,90 (1,942)	
95 %-KI	[-0,395; 5,443]	[-8,732; -1,073]	
Veränderung zu Woche 24			
n/N (%)	42/103 (41)	18/65 (28)	LS MD 8,16 [3,058; 13,257]
MW (SD)	4,98 (22,996)	3,56 (13,976)	
LS MW (SE)	2,58 (1,527)	-5,58 (2,053)	
95 %-KI	[-0,434; 5,591]	[-9,624; -1,534]	
Veränderung zu Woche 36			
n/N (%)	52/91 (57)	22/57 (39)	LS MD 10,66 [4,277; 17,048]
MW (SD)	2,56 (21,276)	-11,09 (18,761)	
LS MW (SE)	2,76 (1,843)	-7,90 (2,644)	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-0,862; 6,390]	[-13,094; -2,702]	
Veränderung zu Woche 48			
n/N (%)	11/80 (14)	4/50 (8)	LS MD 13,17 [5,013; 21,320]
MW (SD)	13,91 (20,676)	-8,00 (16,411)	
LS MW (SE)	2,95 (2,310)	-10,22 (3,421)	
95 %-KI	[-1,589; 7,489]	[-16,935; -3,498]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Paclitaxel</b>			
Baseline			
n/N (%)	97/116 (84)	81/95 (85)	-
MW (SD)	67,72 (19,654)	61,14 (22,303)	
Absolute Werte zum Studienende			
n/N (%)	3/75 (4)	1/53 (2)	-
MW (SD)	41,67 (24,664)	40,00 (NA)	
Effekt über Studiendauer			
n	97	81	LS MD 5,40 [1,060; 9,750] 0,0151  Hedges' g 0,37 [0,076; 0,671]
LS MW (SE)	1,73 (1,430)	-3,67 (1,646)	
95 %-KI	[-1,091; 4,557]	[-6,919; -0,425]	
Veränderung zu Woche 3/4			
n/N (%)	78/115 (68)	58/93 (62)	LS MD 3,64 [-1,150; 8,423]
MW (SD)	1,88 (14,510)	0,95 (19,427)	
LS MW (SE)	2,42 (1,575)	-1,22 (1,822)	
95 %-KI	[-0,683; 5,522]	[-4,803; 2,369]	
Veränderung zu Woche 8/9			
n/N (%)	82/112 (73)	61/90 (68)	LS MD 4,45 [0,012; 8,879]
MW (SD)	0,33 (20,426)	2,79 (21,242)	
LS MW (SE)	2,11 (1,467)	-2,34 (1,673)	
95 %-KI	[-0,789; 5,000]	[-5,639; 0,959]	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	55/110 (50)	40/87 (46)	LS MD 5,01 [0,676; 9,347]
MW (SD)	5,53 (22,228)	-5,90 (23,336)	
LS MW (SE)	1,89 (1,432)	-3,13 (1,636)	
95 %-KI	[-0,943; 4,714]	[-6,354; 0,102]	
Veränderung zu Woche 15/16			
n/N (%)	58/106 (55)	31/85 (36)	LS MD 5,58 [1,208; 9,948]
MW (SD)	1,16 (17,717)	-2,65 (25,098)	
LS MW (SE)	1,67 (1,435)	-3,91 (1,659)	
95 %-KI	[-1,168; 4,499]	[-7,185; -0,639]	
Veränderung zu Woche 20/21			
n/N (%)	41/102 (40)	28/82 (34)	LS MD 6,39 [1,746; 11,028]
MW (SD)	1,17 (22,716)	4,39 (21,760)	
LS MW (SE)	1,35 (1,501)	-5,04 (1,790)	
95 %-KI	[-1,609; 4,313]	[-8,562; -1,509]	
Veränderung zu Woche 24			
n/N (%)	33/98 (34)	20/80 (25)	LS MD 6,95 [1,986; 11,920]
MW (SD)	1,85 (25,112)	-5,70 (17,930)	
LS MW (SE)	1,13 (1,587)	-5,82 (1,939)	
95 %-KI	[-1,996; 4,259]	[-9,638; -2,005]	
Veränderung zu Woche 36			
n/N (%)	46/86 (53)	26/69 (38)	LS MD 8,89 [2,235; 15,554]
MW (SD)	1,28 (18,953)	-6,12 (21,024)	
LS MW (SE)	0,38 (2,059)	-8,52 (2,678)	
95 %-KI	[-3,668; 4,424]	[-13,778; -3,256]	
Veränderung zu Woche 48			
n/N (%)	3/75 (4)	1/53 (2)	LS MD 10,84 [2,007; 19,664]
MW (SD)	-11,67 (12,583)	0,00 (NA)	
LS MW (SE)	-0,38 (2,686)	-11,21 (3,594)	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-5,650; 4,898]	[-18,269; -4,155]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Topotecan</b>			
Baseline			
n/N (%)	45/61 (74)	36/54 (67)	-
MW (SD)	70,73 (18,189)	68,61 (15,448)	
Absolute Werte zum Studienende			
n/N (%)	6/35 (17)	3/23 (13)	-
MW (SD)	76,00 (14,738)	68,67 (17,616)	
Effekt über Studiendauer			
n	45	36	LS MD 7,59 [1,796; 13,388] 0,0109  Hedges' g 0,58 [0,132; 1,027]
LS MW (SE)	-0,55 (1,871)	-8,15 (2,247)	
95 %-KI	[-4,289; 3,181]	[-12,619; -3,673]	
Veränderung zu Woche 3/4			
n/N (%)	30/60 (50)	22/50 (44)	LS MD 8,64 [2,164; 15,115]
MW (SD)	-1,90 (12,864)	-6,00 (17,923)	
LS MW (SE)	0,18 (2,117)	-8,45 (2,510)	
95 %-KI	[-4,010; 4,379]	[-13,426; -3,484]	
Veränderung zu Woche 8/9			
n/N (%)	37/58 (64)	29/48 (60)	LS MD 8,18 [2,236; 14,127]
MW (SD)	1,73 (16,762)	-9,90 (15,633)	
LS MW (SE)	-0,14 (1,935)	-8,32 (2,299)	
95 %-KI	[-3,990; 3,713]	[-12,888; -3,751]	
Veränderung zu Woche 12			
n/N (%)	26/55 (47)	15/47 (32)	LS MD 7,86 [2,075; 13,645]
MW (SD)	0,15 (19,516)	-5,60 (14,476)	
LS MW (SE)	-0,36 (1,875)	-8,23 (2,238)	
95 %-KI	[-4,104; 3,375]	[-12,679; -3,771]	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	22/52 (42)	10/43 (23)	LS MD 7,54 [1,726; 13,353]
MW (SD)	-3,55 (19,116)	-7,60 (15,027)	
LS MW (SE)	-0,59 (1,876)	-8,13 (2,255)	
95 %-KI	[-4,335; 3,153]	[-12,619; -3,641]	
Veränderung zu Woche 20/21			
n/N (%)	13/48 (27)	8/36 (22)	LS MD 7,08 [0,909; 13,253]
MW (SD)	4,77 (15,216)	-0,38 (11,451)	
LS MW (SE)	-0,91 (1,983)	-8,00 (2,412)	
95 %-KI	[-4,861; 3,033]	[-12,783; -3,207]	
Veränderung zu Woche 24			
n/N (%)	12/47 (26)	5/32 (16)	LS MD 6,76 [0,141; 13,380]
MW (SD)	-2,92 (22,371)	-10,60 (28,023)	
LS MW (SE)	-1,14 (2,123)	-7,90 (2,600)	
95 %-KI	[-5,353; 3,073]	[-13,050; -2,750]	
Veränderung zu Woche 36			
n/N (%)	16/40 (40)	11/26 (42)	LS MD 5,66 [-3,329; 14,650]
MW (SD)	4,50 (21,376)	-9,27 (14,227)	
LS MW (SE)	-1,92 (2,874)	-7,58 (3,564)	
95 %-KI	[-7,583; 3,752]	[-14,602; -0,550]	
Veränderung zu Woche 48			
n/N (%)	5/35 (14)	3/23 (13)	LS MD 4,56 [-7,472; 16,593]
MW (SD)	-0,20 (29,115)	-11,67 (14,434)	
LS MW (SE)	-2,69 (3,843)	-7,25 (4,778)	
95 %-KI	[-10,259; 4,878]	[-16,661; 2,159]	
<b>Daten aus Studie: MIRASOL</b>			
Baseline			
n/N (%)	166/218 (76)	155/207 (75)	-
MW (SD)	65,86 (20,734)	65,26 (20,030)	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	10/140 (7)	6/110 (5)	-
MW (SD)	68,40 (19,523)	69,67 (20,539)	
Effekt über Studiendauer			
n	166	155	LS MD 7,00 [3,814; 10,188] < 0,0001  Hedges' g 0,48 [0,260; 0,704]
LS MW (SE)	2,35 (1,101)	-4,65 (1,189)	
95 %-KI	[0,182; 4,514]	[-6,993; -2,314]	
Veränderung zu Woche 3/4			
n/N (%)	112/213 (53)	105/200 (52)	LS MD 6,76 [3,250; 10,264]
MW (SD)	3,37 (17,476)	-2,79 (18,769)	
LS MW (SE)	3,16 (1,221)	-3,59 (1,302)	
95 %-KI	[0,764; 5,564]	[-6,152; -1,035]	
Veränderung zu Woche 8/9			
n/N (%)	136/210 (65)	121/188 (64)	LS MD 6,86 [3,605; 10,122]
MW (SD)	2,51 (19,654)	-2,73 (21,783)	
LS MW (SE)	2,81 (1,138)	-4,06 (1,205)	
95 %-KI	[0,569; 5,045]	[-6,426; -1,687]	
Veränderung zu Woche 12			
n/N (%)	93/205 (45)	72/183 (39)	LS MD 6,94 [3,756; 10,121]
MW (SD)	6,35 (23,451)	-4,64 (18,957)	
LS MW (SE)	2,56 (1,107)	-4,38 (1,180)	
95 %-KI	[0,379; 4,736]	[-6,703; -2,059]	
Veränderung zu Woche 15/16			
n/N (%)	93/199 (47)	54/178 (30)	LS MD 7,01 [3,819; 10,207]
MW (SD)	2,10 (21,083)	-5,00 (22,986)	
LS MW (SE)	2,31 (1,101)	-4,71 (1,194)	
95 %-KI	[0,140; 4,475]	[-7,054; -2,357]	



MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	64/190 (34)	49/165 (30)	LS MD 7,12 [3,760; 10,480]
MW (SD)	4,81 (24,709)	1,47 (18,288)	
LS MW (SE)	1,95 (1,138)	-5,17 (1,277)	
95 %-KI	[-0,287; 4,189]	[-7,678; -2,659]	
Veränderung zu Woche 24			
n/N (%)	54/184 (29)	37/155 (24)	LS MD 7,19 [3,626; 10,763]
MW (SD)	5,70 (27,539)	-1,84 (16,507)	
LS MW (SE)	1,70 (1,192)	-5,49 (1,373)	
95 %-KI	[-0,642; 4,045]	[-8,190; -2,796]	
Veränderung zu Woche 36			
n/N (%)	80/160 (50)	47/134 (35)	LS MD 7,45 [2,759; 12,142]
MW (SD)	1,55 (22,022)	-7,40 (17,523)	
LS MW (SE)	0,85 (1,512)	-6,61 (1,857)	
95 %-KI	[-2,122; 3,812]	[-10,250; -2,960]	
Veränderung zu Woche 48			
n/N (%)	8/140 (6)	5/110 (5)	LS MD 7,71 [1,543; 13,869]
MW (SD)	-2,50 (23,881)	-6,40 (12,837)	
LS MW (SE)	-0,01 (1,954)	-7,72 (2,468)	
95 %-KI	[-3,845; 3,823]	[-12,560; -2,875]	
<b>Daten aus Studie: FORWARD 1</b>			
Baseline			
n/N (%)	71/79 (90)	29/32 (91)	-
MW (SD)	69,07 (18,262)	69,14 (17,324)	
Absolute Werte zum Studienende			
n/N (%)	11/50 (22)	3/16 (19)	-
MW (SD)	73,64 (18,848)	56,67 (25,658)	
Effekt über Studiendauer			
n	71	29	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	0,15 (1,424)	-4,24 (2,354)	LS MD 4,38 [-1,071; 9,840] 0,1140  Hedges' g 0,36 [-0,078; 0,792]
95 %-KI	[-2,680; 2,979]	[-8,902; 0,432]	
Veränderung zu Woche 3/4			
n/N (%)	62/78 (79)	23/30 (77)	LS MD -1,85 [-7,823; 4,116]
MW (SD)	1,18 (11,049)	5,00 (13,899)	
LS MW (SE)	-0,73 (1,575)	1,12 (2,581)	
95 %-KI	[-3,846; 2,383]	[-3,975; 6,218]	
Veränderung zu Woche 8/9			
n/N (%)	63/74 (85)	21/29 (72)	LS MD 0,81 [-4,744; 6,355]
MW (SD)	-3,00 (14,633)	-3,33 (16,304)	
LS MW (SE)	-0,36 (1,463)	-1,16 (2,390)	
95 %-KI	[-3,258; 2,545]	[-5,895; 3,572]	
Veränderung zu Woche 12			
n/N (%)	44/70 (63)	12/27 (44)	LS MD 2,67 [-2,763; 8,096]
MW (SD)	1,68 (14,330)	-10,42 (25,625)	
LS MW (SE)	-0,09 (1,426)	-2,76 (2,338)	
95 %-KI	[-2,925; 2,738]	[-7,395; 1,875]	
Veränderung zu Woche 15/16			
n/N (%)	46/68 (68)	11/23 (48)	LS MD 4,53 [-0,936; 9,991]
MW (SD)	0,24 (17,588)	-7,45 (17,271)	
LS MW (SE)	0,17 (1,426)	-4,36 (2,358)	
95 %-KI	[-2,663; 3,002]	[-9,033; 0,317]	
Veränderung zu Woche 20/21			
n/N (%)	38/67 (57)	10/23 (43)	LS MD 7,19 [1,415; 12,958]
MW (SD)	4,05 (16,010)	5,50 (16,575)	
LS MW (SE)	0,54 (1,489)	-6,64 (2,508)	

MIRASOL + FORWARD 1	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-2,409; 3,499]	[-11,604; -1,679]	
Veränderung zu Woche 24			
n/N (%)	33/64 (52)	6/22 (27)	LS MD 9,05 [2,899; 15,196]
MW (SD)	-2,21 (14,260)	-5,83 (27,824)	
LS MW (SE)	0,81 (1,574)	-8,24 (2,686)	
95 %-KI	[-2,308; 3,924]	[-13,545; -2,934]	
Veränderung zu Woche 36			
n/N (%)	34/57 (60)	12/18 (67)	LS MD 15,43 [7,284; 23,573]
MW (SD)	4,12 (15,338)	-13,08 (23,998)	
LS MW (SE)	1,71 (2,046)	-13,72 (3,602)	
95 %-KI	[-2,320; 5,738]	[-20,809; -6,631]	
Veränderung zu Woche 48			
n/N (%)	11/50 (22)	3/16 (19)	LS MD 21,81 [11,072; 32,548]
MW (SD)	12,45 (21,842)	-11,67 (17,559)	
LS MW (SE)	2,61 (2,675)	-19,20 (4,771)	
95 %-KI	[-2,649; 7,870]	[-28,579; -9,821]	
<p><i>Analysepopulation: ITT/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Modell: Veränderung zu Baseline ~ Behandlung + Baseline-Wert * Zeit in Wochen + Behandlung * Zeit in Wochen + Ursprungsstudie + zufällige Effekte durch die Patientin</i></p> <p><i>Die Berechnung des LS MWs erfolgt durch ein MMRM mit dem oben angegebenen Modell. Basierend hierauf werden KI und p-Wert ermittelt. Hedges' g basiert ebenfalls auf den LS MW und ist somit auf das Modell angepasst.</i></p> <p><i>Es werden ausschließlich gemeinsame Analysezeitpunkte dargestellt.</i></p> <p><i>Ein LS MD und Hedges' g größer als Null bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

## 2. EORTC QLQ-C30

### 2.1 EORTC QLQ-C30 Appetitverlust

#### EORTC QLQ-C30 Appetitverlust: Subgruppenanalyse

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
<b>EORTC QLQ-C30 Appetitverlust</b>			
<b>Alter: &lt; 65 Jahre</b>			
Baseline			
n/N (%)	93/115 (81)	92/119 (77)	-
MW (SD)	24,73 (29,856)	22,46 (29,281)	
Absolute Werte zum Studienende			
n/N (%)	4/73 (5)	4/64 (6)	-
MW (SD)	25,00 (16,667)	16,67 (19,245)	
Effekt über Studiendauer			
n	93	92	LS MD -3,35 [-9,402; 2,701] 0,2760
LS MW (SE)	-0,74 (2,114)	2,61 (2,219)	
95 %-KI	[-4,911; 3,439]	[-1,764; 6,993]	Hedges' g -0,16 [-0,449; 0,129]
Veränderung zu Woche 3/4			
n/N (%)	59/113 (52)	61/115 (53)	LS MD -0,05 [-6,941; 6,841]
MW (SD)	-3,95 (32,214)	1,09 (27,867)	
LS MW (SE)	-1,67 (2,433)	-1,62 (2,518)	
95 %-KI	[-6,459; 3,118]	[-6,575; 3,334]	
Veränderung zu Woche 8/9			
n/N (%)	74/112 (66)	71/108 (66)	LS MD -1,50 [-7,757; 4,750]
MW (SD)	-2,70 (31,578)	1,41 (26,087)	
LS MW (SE)	-1,26 (2,213)	0,24 (2,272)	
95 %-KI	[-5,622; 3,104]	[-4,233; 4,723]	
Veränderung zu Woche 12			
n/N (%)	47/110 (43)	40/105 (38)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	-5,67 (40,120)	-1,67 (23,811)	LS MD -2,52 [-8,572; 3,529]
LS MW (SE)	-0,97 (2,131)	1,55 (2,204)	
95 %-KI	[-5,177; 3,235]	[-2,797; 5,899]	
Veränderung zu Woche 15/16			
n/N (%)	53/107 (50)	33/102 (32)	LS MD -3,54 [-9,611; 2,533]
MW (SD)	-4,40 (37,002)	4,04 (30,909)	
LS MW (SE)	-0,68 (2,117)	2,86 (2,232)	
95 %-KI	[-4,863; 3,497]	[-1,546; 7,259]	
Veränderung zu Woche 20/21			
n/N (%)	36/101 (36)	30/96 (31)	LS MD -4,99 [-11,476; 1,491]
MW (SD)	-3,70 (33,597)	-1,11 (36,602)	
LS MW (SE)	-0,27 (2,216)	4,72 (2,429)	
95 %-KI	[-4,643; 4,101]	[-0,064; 9,507]	
Veränderung zu Woche 24			
n/N (%)	25/99 (25)	19/91 (21)	LS MD -6,01 [-13,011; 0,991]
MW (SD)	-4,00 (37,663)	-3,51 (31,220)	
LS MW (SE)	0,02 (2,361)	6,03 (2,658)	
95 %-KI	[-4,634; 4,668]	[0,796; 11,258]	
Veränderung zu Woche 36			
n/N (%)	40/86 (47)	28/79 (35)	LS MD -9,50 [-19,206; 0,206]
MW (SD)	0,83 (27,722)	16,67 (32,075)	
LS MW (SE)	1,00 (3,176)	10,50 (3,783)	
95 %-KI	[-5,237; 7,246]	[3,073; 17,935]	
Veränderung zu Woche 48			
n/N (%)	4/73 (5)	3/64 (5)	LS MD -12,99 [-26,118; 0,140]
MW (SD)	0,00 (0,000)	11,11 (19,245)	
LS MW (SE)	1,99 (4,253)	14,98 (5,157)	
95 %-KI	[-6,361; 10,345]	[4,854; 25,107]	
<b>Alter: ≥ 65 Jahre</b>			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Baseline			
n/N (%)	83/103 (81)	66/88 (75)	-
MW (SD)	20,88 (27,894)	17,68 (28,175)	
Absolute Werte zum Studienende			
n/N (%)	6/67 (9)	2/46 (4)	-
MW (SD)	11,11 (17,213)	16,67 (23,570)	
Effekt über Studiendauer			
n	83	66	LS MD -7,89 [-14,010; -1,763] 0,0120  Hedges' g -0,42 [-0,746; -0,093]
LS MW (SE)	-1,30 (2,012)	6,59 (2,357)	
95 %-KI	[-5,278; 2,684]	[1,933; 11,246]	
Veränderung zu Woche 3/4			
n/N (%)	62/100 (62)	48/85 (56)	LS MD -5,12 [-12,076; 1,841]
MW (SD)	8,60 (27,617)	3,47 (24,056)	
LS MW (SE)	1,44 (2,308)	6,56 (2,677)	
95 %-KI	[-3,107; 5,991]	[1,287; 11,832]	
Veränderung zu Woche 8/9			
n/N (%)	71/98 (72)	53/80 (66)	LS MD -6,35 [-12,654; -0,044]
MW (SD)	-6,57 (26,198)	6,92 (25,619)	
LS MW (SE)	0,22 (2,100)	6,57 (2,408)	
95 %-KI	[-3,924; 4,372]	[1,821; 11,325]	
Veränderung zu Woche 12			
n/N (%)	49/95 (52)	31/78 (40)	LS MD -7,21 [-13,320; -1,101]
MW (SD)	-4,08 (27,749)	7,53 (26,819)	
LS MW (SE)	-0,63 (2,025)	6,58 (2,337)	
95 %-KI	[-4,634; 3,376]	[1,965; 11,199]	
Veränderung zu Woche 15/16			
n/N (%)	41/92 (45)	22/76 (29)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	-7,32 (24,166)	13,64 (26,546)	LS MD -8,07 [-14,226; -1,919]
LS MW (SE)	-1,48 (2,016)	6,59 (2,374)	
95 %-KI	[-5,470; 2,507]	[1,901; 11,281]	
Veränderung zu Woche 20/21			
n/N (%)	31/89 (35)	21/69 (30)	LS MD -9,30 [-15,921; -2,687]
MW (SD)	-4,30 (33,045)	7,94 (25,614)	
LS MW (SE)	-2,70 (2,118)	6,60 (2,603)	
95 %-KI	[-6,884; 1,486]	[1,471; 11,738]	
Veränderung zu Woche 24			
n/N (%)	28/85 (33)	19/64 (30)	LS MD -10,17 [-17,346; -2,985]
MW (SD)	-3,57 (26,198)	8,77 (26,856)	
LS MW (SE)	-3,55 (2,262)	6,61 (2,863)	
95 %-KI	[-8,013; 0,909]	[0,976; 12,252]	
Veränderung zu Woche 36			
n/N (%)	40/74 (54)	20/55 (36)	LS MD -13,12 [-23,179; -3,062]
MW (SD)	-3,33 (30,940)	5,00 (16,312)	
LS MW (SE)	-6,47 (3,056)	6,65 (4,117)	
95 %-KI	[-12,483; -0,466]	[-1,445; 14,737]	
Veränderung zu Woche 48			
n/N (%)	4/67 (6)	2/46 (4)	LS MD -16,08 [-29,728; -2,424]
MW (SD)	-8,33 (16,667)	16,67 (23,570)	
LS MW (SE)	-9,40 (4,096)	6,68 (5,633)	
95 %-KI	[-17,445; -1,351]	[-4,388; 17,744]	
<b>Region: USA</b>			
Baseline			
n/N (%)	49/65 (75)	34/51 (67)	-
MW (SD)	19,73 (24,456)	14,71 (22,006)	
Absolute Werte zum Studienende			
n/N (%)	2/39 (5)	3/27 (11)	-

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	16,67 (23,570)	22,22 (19,245)	
Effekt über Studiendauer			
n	49	34	LS MD -1,85 [-10,371; 6,667] 0,6662  Hedges' g -0,10 [-0,534; 0,341]
LS MW (SE)	2,39 (2,702)	4,24 (3,304)	
95 %-KI	[-2,997; 7,772]	[-2,336; 10,816]	
Veränderung zu Woche 3/4			
n/N (%)	34/64 (53)	21/49 (43)	LS MD 1,87 [-7,764; 11,508]
MW (SD)	6,86 (25,662)	4,76 (26,427)	
LS MW (SE)	4,58 (3,049)	2,71 (3,783)	
95 %-KI	[-1,460; 10,616]	[-4,781; 10,193]	
Veränderung zu Woche 8/9			
n/N (%)	42/62 (68)	30/46 (65)	LS MD 0,19 [-8,617; 8,990]
MW (SD)	-1,59 (26,496)	4,44 (27,310)	
LS MW (SE)	3,59 (2,793)	3,40 (3,430)	
95 %-KI	[-1,966; 9,139]	[-3,413; 10,213]	
Veränderung zu Woche 12			
n/N (%)	26/59 (44)	16/45 (36)	LS MD -0,99 [-9,529; 7,542]
MW (SD)	2,56 (26,538)	8,33 (31,032)	
LS MW (SE)	2,89 (2,709)	3,89 (3,313)	
95 %-KI	[-2,503; 8,289]	[-2,706; 10,479]	
Veränderung zu Woche 15/16			
n/N (%)	21/56 (38)	11/44 (25)	LS MD -2,17 [-10,726; 6,378]
MW (SD)	3,17 (23,345)	-3,03 (23,355)	
LS MW (SE)	2,20 (2,712)	4,37 (3,317)	
95 %-KI	[-3,205; 7,602]	[-2,229; 10,974]	
Veränderung zu Woche 20/21			
n/N (%)	13/54 (24)	9/40 (22)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	-5,13 (18,490)	3,70 (20,031)	LS MD -3,86 [-12,921; 5,202]
LS MW (SE)	1,21 (2,865)	5,07 (3,530)	
95 %-KI	[-4,487; 6,901]	[-1,940; 12,073]	
Veränderung zu Woche 24			
n/N (%)	9/53 (17)	6/38 (16)	LS MD -5,04 [-14,760; 4,681]
MW (SD)	11,11 (28,868)	0,00 (0,000)	
LS MW (SE)	0,51 (3,065)	5,55 (3,804)	
95 %-KI	[-5,560; 6,587]	[-1,980; 13,085]	
Veränderung zu Woche 36			
n/N (%)	22/43 (51)	10/33 (30)	LS MD -9,09 [-22,342; 4,171]
MW (SD)	-4,55 (31,363)	6,67 (14,055)	
LS MW (SE)	-1,87 (4,134)	7,22 (5,251)	
95 %-KI	[-10,013; 6,282]	[-3,128; 17,567]	
Veränderung zu Woche 48			
n/N (%)	2/39 (5)	3/27 (11)	LS MD -13,13 [-30,946; 4,684]
MW (SD)	-16,67 (23,570)	11,11 (19,245)	
LS MW (SE)	-4,24 (5,516)	8,89 (7,090)	
95 %-KI	[-15,105; 6,615]	[-5,074; 22,846]	
<b>Region: Rest der Welt</b>			
Baseline			
n/N (%)	127/153 (83)	124/156 (79)	-
MW (SD)	24,15 (30,480)	22,04 (30,321)	
Absolute Werte zum Studienende			
n/N (%)	8/101 (8)	3/83 (4)	-
MW (SD)	16,67 (17,817)	11,11 (19,245)	
Effekt über Studiendauer			
n	127	124	LS MD -6,71 [-11,798; -1,618] 0,0100 Hedges' g
LS MW (SE)	-2,13 (1,769)	4,58 (1,886)	
95 %-KI	[-5,612; 1,360]	[0,868; 8,296]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
			-0,33 [-0,576; -0,078]
Veränderung zu Woche 3/4			
n/N (%)	87/149 (58)	88/151 (58)	LS MD -3,49 [-9,275; 2,304]
MW (SD)	0,77 (32,140)	1,52 (26,217)	
LS MW (SE)	-1,82 (2,037)	1,66 (2,130)	
95 %-KI	[-5,830; 2,181]	[-2,525; 5,848]	
Veränderung zu Woche 8/9			
n/N (%)	103/148 (70)	94/142 (66)	LS MD -4,90 [-10,148; 0,346]
MW (SD)	-5,83 (30,043)	3,55 (25,619)	
LS MW (SE)	-1,96 (1,853)	2,94 (1,918)	
95 %-KI	[-5,605; 1,692]	[-0,831; 6,720]	
Veränderung zu Woche 12			
n/N (%)	70/146 (48)	55/138 (40)	LS MD -5,89 [-10,972; -0,812]
MW (SD)	-7,62 (36,414)	0,61 (23,562)	
LS MW (SE)	-2,05 (1,784)	3,84 (1,865)	
95 %-KI	[-5,564; 1,465]	[0,170; 7,515]	
Veränderung zu Woche 15/16			
n/N (%)	73/143 (51)	44/134 (33)	LS MD -6,88 [-11,992; -1,774]
MW (SD)	-8,22 (33,693)	10,61 (30,307)	
LS MW (SE)	-2,14 (1,771)	4,74 (1,898)	
95 %-KI	[-5,632; 1,348]	[1,003; 8,478]	
Veränderung zu Woche 20/21			
n/N (%)	54/136 (40)	42/125 (34)	LS MD -8,30 [-13,778; -2,819]
MW (SD)	-3,70 (35,858)	2,38 (34,838)	
LS MW (SE)	-2,27 (1,851)	6,02 (2,085)	
95 %-KI	[-5,919; 1,370]	[1,922; 10,125]	
Veränderung zu Woche 24			
n/N (%)	44/131 (34)	32/117 (27)	
MW (SD)	-6,82 (31,810)	3,12 (32,083)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-2,37 (1,969)	6,92 (2,295)	LS MD -9,29 [-15,226; -3,353]
95 %-KI	[-6,242; 1,507]	[2,412; 11,433]	
Veränderung zu Woche 36			
n/N (%)	58/117 (50)	38/101 (38)	LS MD -12,69 [-20,969; -4,404]
MW (SD)	0,00 (28,613)	13,16 (29,551)	
LS MW (SE)	-2,69 (2,643)	10,00 (3,301)	
95 %-KI	[-7,874; 2,504]	[3,521; 16,482]	
Veränderung zu Woche 48			
n/N (%)	6/101 (6)	2/83 (2)	LS MD -16,08 [-27,309; -4,860]
MW (SD)	0,00 (0,000)	16,67 (23,570)	
LS MW (SE)	-3,00 (3,536)	13,08 (4,513)	
95 %-KI	[-9,943; 3,937]	[4,223; 21,939]	
<b>Stadium bei der Diagnose: I-III</b>			
Baseline			
n/N (%)	112/141 (79)	111/144 (77)	-
MW (SD)	20,83 (29,040)	21,02 (29,104)	
Absolute Werte zum Studienende			
n/N (%)	6/91 (7)	4/76 (5)	-
MW (SD)	11,11 (17,213)	25,00 (16,667)	
Effekt über Studiendauer			
n	112	111	LS MD -7,48 [-12,894; -2,067] 0,0070
LS MW (SE)	-1,20 (1,894)	6,28 (1,990)	
95 %-KI	[-4,931; 2,539]	[2,363; 10,206]	Hedges' g -0,36 [-0,628; -0,099]
Veränderung zu Woche 3/4			
n/N (%)	75/137 (55)	79/138 (57)	LS MD -3,96 [-10,061; 2,137]
MW (SD)	0,89 (26,831)	3,38 (27,526)	
LS MW (SE)	-1,44 (2,156)	2,52 (2,231)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-5,684; 2,799]	[-1,868; 6,907]	
Veränderung zu Woche 8/9			
n/N (%)	94/136 (69)	86/129 (67)	LS MD -5,50 [-11,087; 0,082]
MW (SD)	-4,61 (29,975)	3,88 (25,266)	
LS MW (SE)	-1,33 (1,975)	4,17 (2,035)	
95 %-KI	[-5,226; 2,557]	[0,160; 8,175]	
Veränderung zu Woche 12			
n/N (%)	60/133 (45)	48/128 (38)	LS MD -6,58 [-11,998; -1,163]
MW (SD)	-5,56 (35,344)	2,78 (26,483)	
LS MW (SE)	-1,26 (1,908)	5,32 (1,980)	
95 %-KI	[-5,021; 2,503]	[1,420; 9,222]	
Veränderung zu Woche 15/16			
n/N (%)	62/130 (48)	35/125 (28)	LS MD -7,66 [-13,086; -2,231]
MW (SD)	-3,23 (31,772)	7,62 (31,401)	
LS MW (SE)	-1,18 (1,896)	6,47 (1,998)	
95 %-KI	[-4,923; 2,555]	[2,537; 10,413]	
Veränderung zu Woche 20/21			
n/N (%)	45/123 (37)	34/116 (29)	LS MD -9,20 [-14,943; -3,455]
MW (SD)	-2,22 (33,635)	1,96 (35,714)	
LS MW (SE)	-1,08 (1,976)	8,12 (2,149)	
95 %-KI	[-4,969; 2,817]	[3,894; 12,353]	
Veränderung zu Woche 24			
n/N (%)	33/121 (27)	27/109 (25)	LS MD -10,28 [-16,429; -4,126]
MW (SD)	-3,03 (32,664)	2,47 (33,238)	
LS MW (SE)	-1,00 (2,093)	9,28 (2,327)	
95 %-KI	[-5,120; 3,119]	[4,700; 13,853]	
Veränderung zu Woche 36			
n/N (%)	52/105 (50)	36/92 (39)	
MW (SD)	0,64 (30,601)	15,74 (29,262)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-0,74 (2,765)	13,23 (3,226)	LS MD -13,97 [-22,305; -5,643]
95 %-KI	[-6,173; 4,689]	[6,897; 19,567]	
Veränderung zu Woche 48			
n/N (%)	5/91 (5)	4/76 (5)	LS MD -17,67 [-28,815; -6,527]
MW (SD)	-6,67 (14,907)	16,67 (19,245)	
LS MW (SE)	-0,48 (3,666)	17,19 (4,348)	
95 %-KI	[-7,680; 6,714]	[8,653; 25,723]	
<b>Stadium bei der Diagnose: IV</b>			
Baseline			
n/N (%)	59/72 (82)	45/60 (75)	-
MW (SD)	27,12 (29,344)	19,26 (28,858)	
Absolute Werte zum Studienende			
n/N (%)	4/46 (9)	2/33 (6)	-
MW (SD)	25,00 (16,667)	0,00 (0,000)	
Effekt über Studiendauer			
n	59	45	LS MD -1,81 [-9,157; 5,534] 0,6256  Hedges' g -0,10 [-0,485; 0,291]
LS MW (SE)	-1,73 (2,361)	0,08 (2,834)	
95 %-KI	[-6,421; 2,963]	[-5,537; 5,703]	
Veränderung zu Woche 3/4			
n/N (%)	41/71 (58)	28/59 (47)	LS MD -0,08 [-8,630; 8,466]
MW (SD)	3,25 (36,366)	-2,38 (22,090)	
LS MW (SE)	0,81 (2,783)	0,89 (3,308)	
95 %-KI	[-4,684; 6,303]	[-5,632; 7,415]	
Veränderung zu Woche 8/9			
n/N (%)	46/69 (67)	36/56 (64)	LS MD -0,86 [-8,398; 6,682]
MW (SD)	-6,52 (26,869)	3,70 (28,483)	
LS MW (SE)	-0,33 (2,489)	0,53 (2,872)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-5,262; 4,602]	[-5,158; 6,215]	
Veränderung zu Woche 12			
n/N (%)	31/67 (46)	22/52 (42)	LS MD -1,40 [-8,677; 5,874]
MW (SD)	-6,45 (31,528)	3,03 (22,792)	
LS MW (SE)	-1,13 (2,381)	0,27 (2,777)	
95 %-KI	[-5,855; 3,601]	[-5,233; 5,782]	
Veränderung zu Woche 15/16			
n/N (%)	29/64 (45)	18/50 (36)	LS MD -1,95 [-9,363; 5,473]
MW (SD)	-10,34 (33,456)	7,41 (21,559)	
LS MW (SE)	-1,92 (2,367)	0,02 (2,876)	
95 %-KI	[-6,627; 2,778]	[-5,681; 5,722]	
Veränderung zu Woche 20/21			
n/N (%)	19/62 (31)	16/46 (35)	LS MD -2,72 [-10,997; 5,554]
MW (SD)	-7,02 (34,389)	4,17 (26,874)	
LS MW (SE)	-3,06 (2,509)	-0,34 (3,314)	
95 %-KI	[-8,039; 1,912]	[-6,891; 6,206]	
Veränderung zu Woche 24			
n/N (%)	18/59 (31)	10/44 (23)	LS MD -3,26 [-12,502; 5,972]
MW (SD)	-5,56 (32,839)	-0,00 (15,713)	
LS MW (SE)	-3,86 (2,709)	-0,60 (3,772)	
95 %-KI	[-9,219; 1,497]	[-8,034; 6,841]	
Veränderung zu Woche 36			
n/N (%)	27/52 (52)	11/41 (27)	LS MD -5,13 [-18,913; 8,657]
MW (SD)	-4,94 (27,275)	3,03 (10,050)	
LS MW (SE)	-6,60 (3,793)	-1,47 (5,806)	
95 %-KI	[-14,061; 0,871]	[-12,889; 9,955]	
Veränderung zu Woche 48			
n/N (%)	3/46 (7)	1/33 (3)	
MW (SD)	0,00 (0,000)	0,00 (NA)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-9,33 (5,178)	-2,34 (8,134)	LS MD -6,99 [-26,160; 12,178]
95 %-KI	[-19,513; 0,855]	[-18,336; 13,660]	
<b>BRCA Status: Positiv</b>			
Baseline			
n/N (%)	25/27 (93)	23/35 (66)	-
MW (SD)	25,33 (32,318)	31,88 (34,050)	
Absolute Werte zum Studienende			
n/N (%)	1/19 (5)	0/15 (0)	-
MW (SD)	33,33 (NA)	NA (NA)	
Effekt über Studiendauer			
n	25	23	LS MD -2,00 [-14,624; 10,624] 0,7511  Hedges' g -0,09 [-0,658; 0,476]
LS MW (SE)	-2,30 (4,218)	-0,30 (4,621)	
95 %-KI	[-10,814; 6,218]	[-9,587; 8,992]	
Veränderung zu Woche 3/4			
n/N (%)	16/27 (59)	18/35 (51)	LS MD 0,47 [-13,259; 14,205]
MW (SD)	6,25 (30,353)	-1,85 (21,305)	
LS MW (SE)	0,58 (4,716)	0,10 (4,983)	
95 %-KI	[-8,842; 9,998]	[-9,839; 10,049]	
Veränderung zu Woche 8/9			
n/N (%)	21/26 (81)	20/30 (67)	LS MD -0,73 [-13,404; 11,948]
MW (SD)	-4,76 (26,427)	-1,67 (27,519)	
LS MW (SE)	-0,82 (4,361)	-0,09 (4,532)	
95 %-KI	[-9,588; 7,950]	[-9,205; 9,023]	
Veränderung zu Woche 12			
n/N (%)	14/26 (54)	10/30 (33)	LS MD -1,57 [-14,083; 10,946]
MW (SD)	2,38 (38,038)	-6,67 (14,055)	
LS MW (SE)	-1,80 (4,238)	-0,23 (4,523)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-10,345; 6,753]	[-9,334; 8,879]	
Veränderung zu Woche 15/16			
n/N (%)	12/26 (46)	8/29 (28)	LS MD -2,41 [-15,255; 10,436]
MW (SD)	-11,11 (35,770)	4,17 (33,034)	
LS MW (SE)	-2,77 (4,228)	-0,36 (4,774)	
95 %-KI	[-11,309; 5,762]	[-9,939; 9,210]	
Veränderung zu Woche 20/21			
n/N (%)	10/25 (40)	4/25 (16)	LS MD -3,61 [-17,718; 10,498]
MW (SD)	-3,33 (42,889)	-16,67 (19,245)	
LS MW (SE)	-4,17 (4,411)	-0,56 (5,506)	
95 %-KI	[-13,042; 4,702]	[-11,517; 10,397]	
Veränderung zu Woche 24			
n/N (%)	8/25 (32)	4/24 (17)	LS MD -4,45 [-19,905; 11,003]
MW (SD)	-8,33 (38,832)	-16,67 (19,245)	
LS MW (SE)	-5,15 (4,664)	-0,70 (6,206)	
95 %-KI	[-14,488; 4,193]	[-13,002; 11,608]	
Veränderung zu Woche 36			
n/N (%)	10/21 (48)	5/20 (25)	LS MD -7,33 [-29,185; 14,519]
MW (SD)	-6,67 (26,294)	6,67 (14,907)	
LS MW (SE)	-8,50 (6,088)	-1,17 (9,216)	
95 %-KI	[-20,561; 3,562]	[-19,373; 17,040]	
Veränderung zu Woche 48			
n/N (%)	1/19 (5)	0/15 (0)	LS MD -10,22 [-39,786; 19,355]
MW (SD)	0,00 (NA)	NA (NA)	
LS MW (SE)	-11,85 (7,992)	-1,64 (12,638)	
95 %-KI	[-27,643; 3,941]	[-26,603; 23,332]	
<b>BRCA Status: Negativ/Unbekannt</b>			
Baseline			
n/N (%)	151/191 (79)	135/172 (78)	-



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	22,52 (28,428)	18,52 (27,520)	
Absolute Werte zum Studienende			
n/N (%)	9/121 (7)	6/95 (6)	-
MW (SD)	14,81 (17,568)	16,67 (18,257)	
Effekt über Studiendauer			
n	151	135	LS MD -5,77 [-10,416; -1,132] 0,0150  Hedges' g -0,29 [-0,524; -0,057]
LS MW (SE)	-0,63 (1,583)	5,15 (1,745)	
95 %-KI	[-3,743; 2,493]	[1,714; 8,584]	
Veränderung zu Woche 3/4			
n/N (%)	105/186 (56)	91/165 (55)	LS MD -2,28 [-7,594; 3,037]
MW (SD)	1,90 (30,602)	2,93 (27,057)	
LS MW (SE)	-0,10 (1,823)	2,18 (1,997)	
95 %-KI	[-3,680; 3,485]	[-1,743; 6,105]	
Veränderung zu Woche 8/9			
n/N (%)	124/184 (67)	104/158 (66)	LS MD -3,80 [-8,614; 1,008]
MW (SD)	-4,57 (29,551)	4,81 (25,618)	
LS MW (SE)	-0,33 (1,656)	3,48 (1,798)	
95 %-KI	[-3,587; 2,931]	[-0,060; 7,011]	
Veränderung zu Woche 12			
n/N (%)	82/179 (46)	61/153 (40)	LS MD -4,87 [-9,516; -0,225]
MW (SD)	-6,10 (33,591)	3,83 (26,596)	
LS MW (SE)	-0,49 (1,595)	4,38 (1,738)	
95 %-KI	[-3,629; 2,652]	[0,962; 7,802]	
Veränderung zu Woche 15/16			
n/N (%)	82/173 (47)	47/149 (32)	LS MD -5,94 [-10,593; -1,283]
MW (SD)	-4,88 (31,480)	8,51 (29,049)	
LS MW (SE)	-0,65 (1,585)	5,29 (1,752)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,772; 2,472]	[1,839; 8,737]	
Veränderung zu Woche 20/21			
n/N (%)	57/165 (35)	47/140 (34)	LS MD -7,46 [-12,428; -2,497]
MW (SD)	-4,09 (31,541)	4,26 (33,055)	
LS MW (SE)	-0,88 (1,663)	6,58 (1,897)	
95 %-KI	[-4,152; 2,392]	[2,853; 10,313]	
Veränderung zu Woche 24			
n/N (%)	45/159 (28)	34/131 (26)	LS MD -8,53 [-13,892; -3,168]
MW (SD)	-2,96 (30,832)	4,90 (29,738)	
LS MW (SE)	-1,04 (1,774)	7,49 (2,070)	
95 %-KI	[-4,529; 2,447]	[3,421; 11,557]	
Veränderung zu Woche 36			
n/N (%)	70/139 (50)	43/114 (38)	LS MD -12,19 [-19,634; -4,744]
MW (SD)	-0,48 (29,756)	12,40 (28,194)	
LS MW (SE)	-1,59 (2,396)	10,60 (2,938)	
95 %-KI	[-6,296; 3,111]	[4,829; 16,364]	
Veränderung zu Woche 48			
n/N (%)	7/121 (6)	5/95 (5)	LS MD -15,85 [-25,933; -5,763]
MW (SD)	-4,76 (12,599)	13,33 (18,257)	
LS MW (SE)	-2,15 (3,214)	13,70 (4,008)	
95 %-KI	[-8,452; 4,161]	[5,838; 21,569]	
<b>Baseline ECOG PS: 0</b>			
Baseline			
n/N (%)	100/128 (78)	97/113 (86)	-
MW (SD)	20,67 (26,709)	15,12 (24,066)	
Absolute Werte zum Studienende			
n/N (%)	7/87 (8)	3/72 (4)	-
MW (SD)	23,81 (16,265)	11,11 (19,245)	
Effekt über Studiendauer			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n	100	97	LS MD -4,28 [-9,926; 1,365] 0,1364  Hedges' g -0,21 [-0,493; 0,067]
LS MW (SE)	1,12 (1,971)	5,40 (2,062)	
95 %-KI	[-2,775; 5,005]	[1,331; 9,461]	
Veränderung zu Woche 3/4			
n/N (%)	70/127 (55)	64/111 (58)	LS MD -0,63 [-6,945; 5,688]
MW (SD)	1,90 (27,736)	6,25 (22,906)	
LS MW (SE)	1,99 (2,213)	2,62 (2,314)	
95 %-KI	[-2,362; 6,349]	[-1,932; 7,176]	
Veränderung zu Woche 8/9			
n/N (%)	84/126 (67)	75/108 (69)	LS MD -2,21 [-8,021; 3,605]
MW (SD)	-4,76 (26,958)	4,44 (24,711)	
LS MW (SE)	1,61 (2,047)	3,82 (2,113)	
95 %-KI	[-2,421; 5,649]	[-0,342; 7,985]	
Veränderung zu Woche 12			
n/N (%)	51/122 (42)	46/108 (43)	LS MD -3,31 [-8,962; 2,335]
MW (SD)	-5,23 (36,131)	3,62 (22,474)	
LS MW (SE)	1,35 (1,985)	4,66 (2,053)	
95 %-KI	[-2,568; 5,264]	[0,613; 8,710]	
Veränderung zu Woche 15/16			
n/N (%)	54/120 (45)	35/105 (33)	LS MD -4,42 [-10,075; 1,237]
MW (SD)	-0,00 (30,372)	13,33 (28,238)	
LS MW (SE)	1,08 (1,972)	5,50 (2,067)	
95 %-KI	[-2,810; 4,974]	[1,425; 9,578]	
Veränderung zu Woche 20/21			
n/N (%)	40/117 (34)	32/101 (32)	LS MD -6,00 [-11,957; -0,041]
MW (SD)	-2,50 (28,632)	9,38 (27,086)	
LS MW (SE)	0,70 (2,042)	6,70 (2,212)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,325; 4,729]	[2,343; 11,058]	
Veränderung zu Woche 24			
n/N (%)	27/112 (24)	22/96 (23)	LS MD -7,10 [-13,456; -0,752]
MW (SD)	-4,94 (32,951)	9,09 (25,577)	
LS MW (SE)	0,44 (2,147)	7,54 (2,388)	
95 %-KI	[-3,793; 4,666]	[2,841; 12,240]	
Veränderung zu Woche 36			
n/N (%)	49/99 (49)	35/87 (40)	LS MD -10,90 [-19,383; -2,407]
MW (SD)	-1,36 (28,020)	9,52 (27,501)	
LS MW (SE)	-0,48 (2,765)	10,42 (3,289)	
95 %-KI	[-5,908; 4,957]	[3,959; 16,880]	
Veränderung zu Woche 48			
n/N (%)	5/87 (6)	3/72 (4)	LS MD -14,69 [-25,963; -3,409]
MW (SD)	-6,67 (14,907)	0,00 (0,000)	
LS MW (SE)	-1,39 (3,612)	13,30 (4,423)	
95 %-KI	[-8,479; 5,705]	[4,615; 21,983]	
<b>Baseline ECOG PS: 1</b>			
Baseline			
n/N (%)	76/90 (84)	60/91 (66)	-
MW (SD)	25,88 (31,552)	27,78 (32,571)	
Absolute Werte zum Studienende			
n/N (%)	3/53 (6)	3/37 (8)	-
MW (SD)	0,00 (0,000)	22,22 (19,245)	
Effekt über Studiendauer			
n	76	60	LS MD -8,50 [-15,480; -1,513] 0,0175
LS MW (SE)	-3,71 (2,260)	4,78 (2,714)	
95 %-KI	[-8,190; 0,762]	[-0,584; 10,149]	Hedges' g -0,42 [-0,759; -0,074]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	51/86 (59)	44/87 (51)	LS MD -3,95 [-12,002; 4,108]
MW (SD)	3,27 (34,160)	-3,03 (29,481)	
LS MW (SE)	-2,73 (2,675)	1,21 (3,094)	
95 %-KI	[-8,006; 2,536]	[-4,884; 7,308]	
Veränderung zu Woche 8/9			
n/N (%)	61/84 (73)	48/78 (62)	LS MD -6,03 [-13,211; 1,155]
MW (SD)	-4,37 (31,900)	3,47 (27,710)	
LS MW (SE)	-3,18 (2,380)	2,85 (2,749)	
95 %-KI	[-7,886; 1,521]	[-2,585; 8,275]	
Veränderung zu Woche 12			
n/N (%)	45/83 (54)	24/74 (32)	LS MD -7,48 [-14,431; -0,539]
MW (SD)	-4,44 (32,255)	2,78 (27,657)	
LS MW (SE)	-3,50 (2,275)	3,99 (2,675)	
95 %-KI	[-8,001; 1,008]	[-1,301; 9,278]	
Veränderung zu Woche 15/16			
n/N (%)	40/79 (51)	20/72 (28)	LS MD -8,94 [-15,994; -1,889]
MW (SD)	-13,33 (32,730)	-1,67 (29,568)	
LS MW (SE)	-3,81 (2,269)	5,13 (2,754)	
95 %-KI	[-8,303; 0,683]	[-0,313; 10,576]	
Veränderung zu Woche 20/21			
n/N (%)	27/73 (37)	18/63 (29)	LS MD -11,02 [-18,788; -3,258]
MW (SD)	-6,17 (39,264)	-3,70 (32,113)	
LS MW (SE)	-4,26 (2,428)	6,76 (3,105)	
95 %-KI	[-9,058; 0,542]	[0,640; 12,890]	
Veränderung zu Woche 24			
n/N (%)	26/72 (36)	15/58 (26)	LS MD -12,48 [-21,060; -3,899]
MW (SD)	-2,56 (31,160)	-2,22 (29,457)	
LS MW (SE)	-4,57 (2,641)	7,91 (3,477)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-9,782; 0,639]	[1,059; 14,757]	
Veränderung zu Woche 36			
n/N (%)	31/61 (51)	13/46 (28)	LS MD -17,47 [-30,002; -4,948]
MW (SD)	-1,08 (31,604)	17,95 (25,875)	
LS MW (SE)	-5,65 (3,761)	11,83 (5,178)	
95 %-KI	[-13,042; 1,748]	[1,650; 22,006]	
Veränderung zu Woche 48			
n/N (%)	3/53 (6)	2/37 (5)	LS MD -22,47 [-39,745; -5,194]
MW (SD)	0,00 (0,000)	33,33 (0,000)	
LS MW (SE)	-6,72 (5,166)	15,75 (7,164)	
95 %-KI	[-16,874; 3,430]	[1,670; 29,825]	
<b>Anzahl vorheriger Therapielinien: 1</b>			
Baseline			
n/N (%)	24/31 (77)	23/29 (79)	-
MW (SD)	19,44 (25,851)	10,14 (18,627)	
Absolute Werte zum Studienende			
n/N (%)	1/22 (5)	0/14 (0)	-
MW (SD)	33,33 (NA)	NA (NA)	
Effekt über Studiendauer			
n	24	23	LS MD -16,58 [-27,786; -5,372] 0,0047
LS MW (SE)	-4,48 (3,779)	12,10 (4,007)	
95 %-KI	[-12,128; 3,162]	[4,029; 20,163]	
Veränderung zu Woche 3/4			
n/N (%)	16/31 (52)	15/29 (52)	LS MD -7,62 [-20,593; 5,360]
MW (SD)	-4,17 (26,874)	0,00 (21,822)	
LS MW (SE)	-7,15 (4,478)	0,47 (4,693)	
95 %-KI	[-16,073; 1,780]	[-8,863; 9,804]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	20/31 (65)	18/26 (69)	LS MD -11,39 [-23,058; 0,283]
MW (SD)	-6,67 (23,195)	7,41 (24,403)	
LS MW (SE)	-6,03 (4,043)	5,36 (4,135)	
95 %-KI	[-14,146; 2,094]	[-2,924; 13,647]	
Veränderung zu Woche 12			
n/N (%)	14/31 (45)	12/24 (50)	LS MD -14,03 [-25,254; -2,799]
MW (SD)	-14,29 (25,198)	8,33 (20,719)	
LS MW (SE)	-5,24 (3,854)	8,79 (3,967)	
95 %-KI	[-13,020; 2,538]	[0,802; 16,769]	
Veränderung zu Woche 15/16			
n/N (%)	15/31 (48)	11/22 (50)	LS MD -16,67 [-27,880; -5,453]
MW (SD)	-8,89 (15,258)	24,24 (33,635)	
LS MW (SE)	-4,46 (3,778)	12,21 (4,012)	
95 %-KI	[-12,100; 3,187]	[4,133; 20,286]	
Veränderung zu Woche 20/21			
n/N (%)	11/30 (37)	9/22 (41)	LS MD -20,44 [-32,365; -8,509]
MW (SD)	-3,03 (17,979)	25,93 (36,430)	
LS MW (SE)	-3,34 (3,875)	17,10 (4,426)	
95 %-KI	[-11,153; 4,481]	[8,244; 25,958]	
Veränderung zu Woche 24			
n/N (%)	9/30 (30)	11/20 (55)	LS MD -23,08 [-35,962; -10,190]
MW (SD)	-11,11 (16,667)	18,18 (34,524)	
LS MW (SE)	-2,55 (4,080)	20,52 (4,912)	
95 %-KI	[-10,739; 5,636]	[10,743; 30,306]	
Veränderung zu Woche 36			
n/N (%)	15/26 (58)	6/18 (33)	LS MD -32,13 [-50,203; -14,048]
MW (SD)	4,44 (33,014)	27,78 (38,968)	
LS MW (SE)	0,14 (5,395)	32,26 (7,262)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-10,544; 10,820]	[17,911; 46,616]	
Veränderung zu Woche 48			
n/N (%)	0/22 (0)	0/14 (0)	LS MD -41,17 [-65,893; -16,456]
MW (SD)	NA (NA)	NA (NA)	
LS MW (SE)	2,83 (7,228)	44,00 (10,078)	
95 %-KI	[-11,440; 17,096]	[24,110; 63,895]	
<b>Anzahl vorheriger Therapielinien: 2</b>			
Baseline			
n/N (%)	76/89 (85)	64/83 (77)	-
MW (SD)	25,00 (28,868)	20,83 (29,991)	
Absolute Werte zum Studienende			
n/N (%)	4/59 (7)	2/50 (4)	-
MW (SD)	16,67 (19,245)	16,67 (23,570)	
Effekt über Studiendauer			
n	76	64	LS MD -3,71 [-10,465; 3,055] 0,2803  Hedges' g -0,18 [-0,517; 0,149]
LS MW (SE)	-1,32 (2,225)	2,39 (2,588)	
95 %-KI	[-5,721; 3,089]	[-2,727; 7,506]	
Veränderung zu Woche 3/4			
n/N (%)	54/86 (63)	45/80 (56)	LS MD -1,53 [-9,261; 6,198]
MW (SD)	3,70 (29,437)	2,22 (27,889)	
LS MW (SE)	-0,10 (2,578)	1,43 (2,950)	
95 %-KI	[-5,178; 4,984]	[-4,377; 7,245]	
Veränderung zu Woche 8/9			
n/N (%)	64/85 (75)	51/77 (66)	LS MD -2,51 [-9,460; 4,447]
MW (SD)	-5,73 (27,574)	3,92 (27,201)	
LS MW (SE)	-0,64 (2,332)	1,86 (2,631)	
95 %-KI	[-5,253; 3,965]	[-3,333; 7,057]	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	39/83 (47)	31/75 (41)	LS MD -3,19 [-9,920; 3,543]
MW (SD)	-4,27 (34,352)	6,45 (23,443)	
LS MW (SE)	-1,03 (2,242)	2,16 (2,555)	
95 %-KI	[-5,463; 3,411]	[-2,889; 7,214]	
Veränderung zu Woche 15/16			
n/N (%)	42/80 (52)	20/74 (27)	LS MD -3,87 [-10,676; 2,934]
MW (SD)	-7,94 (38,119)	3,33 (28,408)	
LS MW (SE)	-1,41 (2,229)	2,46 (2,615)	
95 %-KI	[-5,822; 3,004]	[-2,707; 7,631]	
Veränderung zu Woche 20/21			
n/N (%)	32/78 (41)	21/68 (31)	LS MD -4,85 [-12,242; 2,550]
MW (SD)	-5,21 (37,011)	1,59 (30,689)	
LS MW (SE)	-1,96 (2,344)	2,89 (2,917)	
95 %-KI	[-6,590; 2,679]	[-2,861; 8,642]	
Veränderung zu Woche 24			
n/N (%)	27/74 (36)	13/65 (20)	LS MD -5,53 [-13,623; 2,566]
MW (SD)	-3,70 (35,001)	-5,13 (22,958)	
LS MW (SE)	-2,34 (2,509)	3,19 (3,245)	
95 %-KI	[-7,290; 2,614]	[-3,199; 9,579]	
Veränderung zu Woche 36			
n/N (%)	34/65 (52)	19/58 (33)	LS MD -7,87 [-19,435; 3,699]
MW (SD)	-3,92 (33,600)	12,28 (33,721)	
LS MW (SE)	-3,65 (3,424)	4,22 (4,775)	
95 %-KI	[-10,382; 3,083]	[-5,166; 13,602]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	1/50 (2)	LS MD -10,21 [-26,032; 5,617]
MW (SD)	0,00 (0,000)	33,33 (NA)	
LS MW (SE)	-4,96 (4,616)	5,25 (6,584)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-14,030; 4,108]	[-7,690; 18,183]	
<b>Anzahl vorheriger Therapielinien: 3</b>			
Baseline			
n/N (%)	76/98 (78)	71/95 (75)	-
MW (SD)	21,93 (30,088)	23,47 (30,023)	
Absolute Werte zum Studienende			
n/N (%)	5/59 (8)	4/46 (9)	-
MW (SD)	13,33 (18,257)	16,67 (19,245)	
Effekt über Studiendauer			
n	76	71	LS MD -3,50 [-10,310; 3,309] 0,3112  Hedges' g -0,17 [-0,491; 0,157]
LS MW (SE)	0,61 (2,363)	4,11 (2,516)	
95 %-KI	[-4,065; 5,283]	[-0,863; 9,083]	
Veränderung zu Woche 3/4			
n/N (%)	51/96 (53)	49/91 (54)	LS MD -0,52 [-8,062; 7,031]
MW (SD)	3,27 (32,833)	2,72 (26,209)	
LS MW (SE)	1,88 (2,637)	2,40 (2,786)	
95 %-KI	[-3,314; 7,084]	[-3,092; 7,892]	
Veränderung zu Woche 8/9			
n/N (%)	61/94 (65)	55/85 (65)	LS MD -1,84 [-8,819; 5,133]
MW (SD)	-2,73 (32,372)	2,42 (25,543)	
LS MW (SE)	1,32 (2,435)	3,16 (2,568)	
95 %-KI	[-3,493; 6,128]	[-1,910; 8,231]	
Veränderung zu Woche 12			
n/N (%)	43/91 (47)	28/84 (33)	LS MD -2,77 [-9,576; 4,031]
MW (SD)	-2,33 (36,656)	-4,76 (28,276)	
LS MW (SE)	0,92 (2,368)	3,69 (2,507)	
95 %-KI	[-3,763; 5,603]	[-1,261; 8,646]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	37/88 (42)	24/82 (29)	LS MD -3,70 [-10,535; 3,132]
MW (SD)	-1,80 (29,340)	4,17 (26,580)	
LS MW (SE)	0,52 (2,369)	4,22 (2,528)	
95 %-KI	[-4,162; 5,208]	[-0,771; 9,220]	
Veränderung zu Woche 20/21			
n/N (%)	24/82 (29)	21/75 (28)	LS MD -5,03 [-12,249; 2,190]
MW (SD)	-2,78 (33,932)	-6,35 (29,096)	
LS MW (SE)	-0,04 (2,486)	4,99 (2,696)	
95 %-KI	[-4,955; 4,867]	[-0,335; 10,305]	
Veränderung zu Woche 24			
n/N (%)	17/80 (21)	14/70 (20)	LS MD -5,96 [-13,661; 1,743]
MW (SD)	-0,00 (33,333)	-2,38 (27,625)	
LS MW (SE)	-0,44 (2,641)	5,52 (2,897)	
95 %-KI	[-5,651; 4,768]	[-0,192; 11,226]	
Veränderung zu Woche 36			
n/N (%)	31/69 (45)	23/58 (40)	LS MD -9,15 [-19,422; 1,131]
MW (SD)	-1,08 (21,915)	7,25 (14,058)	
LS MW (SE)	-1,80 (3,488)	7,34 (3,926)	
95 %-KI	[-8,662; 5,056]	[-0,376; 15,060]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	4/46 (9)	LS MD -12,33 [-25,949; 1,286]
MW (SD)	-8,33 (16,667)	8,33 (16,667)	
LS MW (SE)	-3,16 (4,602)	9,17 (5,230)	
95 %-KI	[-12,208; 5,879]	[-1,110; 19,443]	
<b>Vorherige Verabreichung von Bevacizumab: Ja</b>			
Baseline			
n/N (%)	104/134 (78)	99/132 (75)	-
MW (SD)	23,40 (28,208)	21,55 (29,857)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	3/79 (4)	3/62 (5)	-
MW (SD)	11,11 (19,245)	22,22 (19,245)	
Effekt über Studiendauer			
n	104	99	LS MD -2,84 [-8,653; 2,963] 0,3353  Hedges' g -0,14 [-0,411; 0,140]
LS MW (SE)	2,69 (2,001)	5,53 (2,164)	
95 %-KI	[-1,262; 6,637]	[1,266; 9,798]	
Veränderung zu Woche 3/4			
n/N (%)	68/130 (52)	69/127 (54)	LS MD -0,46 [-7,022; 6,101]
MW (SD)	5,39 (31,338)	4,83 (25,098)	
LS MW (SE)	3,38 (2,290)	3,84 (2,430)	
95 %-KI	[-1,131; 7,882]	[-0,944; 8,617]	
Veränderung zu Woche 8/9			
n/N (%)	85/130 (65)	75/119 (63)	LS MD -1,58 [-7,518; 4,360]
MW (SD)	-1,57 (29,505)	4,44 (25,311)	
LS MW (SE)	3,05 (2,082)	4,63 (2,182)	
95 %-KI	[-1,052; 7,158]	[0,332; 8,931]	
Veränderung zu Woche 12			
n/N (%)	54/126 (43)	38/114 (33)	LS MD -2,36 [-8,142; 3,419]
MW (SD)	-2,47 (37,674)	1,75 (28,943)	
LS MW (SE)	2,83 (2,011)	5,19 (2,135)	
95 %-KI	[-1,141; 6,795]	[0,978; 9,399]	
Veränderung zu Woche 15/16			
n/N (%)	56/122 (46)	32/112 (29)	LS MD -3,14 [-9,017; 2,729]
MW (SD)	-2,38 (32,941)	7,29 (30,214)	
LS MW (SE)	2,60 (2,009)	5,75 (2,203)	
95 %-KI	[-1,363; 6,565]	[1,403; 10,087]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	39/114 (34)	28/103 (27)	LS MD -4,26 [-10,676; 2,151]
MW (SD)	0,85 (31,051)	-0,00 (37,406)	
LS MW (SE)	2,28 (2,125)	6,54 (2,476)	
95 %-KI	[-1,910; 6,466]	[1,668; 11,413]	
Veränderung zu Woche 24			
n/N (%)	28/109 (26)	17/95 (18)	LS MD -5,05 [-12,072; 1,981]
MW (SD)	4,76 (28,276)	3,92 (38,877)	
LS MW (SE)	2,05 (2,279)	7,10 (2,761)	
95 %-KI	[-2,434; 6,539]	[1,669; 12,527]	
Veränderung zu Woche 36			
n/N (%)	43/93 (46)	22/79 (28)	LS MD -7,73 [-17,741; 2,283]
MW (SD)	2,33 (23,452)	12,12 (26,318)	
LS MW (SE)	1,28 (3,110)	9,01 (4,062)	
95 %-KI	[-4,832; 7,387]	[1,030; 16,984]	
Veränderung zu Woche 48			
n/N (%)	3/79 (4)	2/62 (3)	LS MD -10,41 [-24,057; 3,230]
MW (SD)	-11,11 (19,245)	16,67 (23,570)	
LS MW (SE)	0,50 (4,181)	10,92 (5,585)	
95 %-KI	[-7,707; 8,713]	[-0,050; 21,883]	
<b>Vorherige Verabreichung von Bevacizumab: Nein</b>			
Baseline			
n/N (%)	72/84 (86)	59/75 (79)	-
MW (SD)	22,22 (30,128)	18,64 (27,173)	
Absolute Werte zum Studienende			
n/N (%)	7/61 (11)	3/48 (6)	-
MW (SD)	19,05 (17,817)	11,11 (19,245)	
Effekt über Studiendauer			
n	72	59	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-5,93 (2,121)	2,86 (2,408)	LS MD -8,79 [-15,148; -2,438] 0,0071  Hedges' g -0,48 [-0,829; -0,130]
95 %-KI	[-10,134; -1,735]	[-1,908; 7,624]	
Veränderung zu Woche 3/4			
n/N (%)	53/83 (64)	40/73 (55)	LS MD -4,40 [-11,769; 2,975]
MW (SD)	-1,26 (29,208)	-2,50 (27,619)	
LS MW (SE)	-5,08 (2,469)	-0,68 (2,805)	
95 %-KI	[-9,949; -0,213]	[-6,212; 4,845]	
Veränderung zu Woche 8/9			
n/N (%)	60/80 (75)	49/69 (71)	LS MD -6,21 [-12,871; 0,456]
MW (SD)	-8,89 (28,035)	2,72 (27,077)	
LS MW (SE)	-5,43 (2,237)	0,78 (2,523)	
95 %-KI	[-9,853; -1,012]	[-4,208; 5,758]	
Veränderung zu Woche 12			
n/N (%)	42/79 (53)	33/69 (48)	LS MD -7,48 [-13,874; -1,076]
MW (SD)	-7,94 (29,273)	3,03 (21,022)	
LS MW (SE)	-5,68 (2,145)	1,80 (2,420)	
95 %-KI	[-9,924; -1,434]	[-2,989; 6,582]	
Veränderung zu Woche 15/16			
n/N (%)	38/77 (49)	23/66 (35)	LS MD -8,74 [-15,095; -2,390]
MW (SD)	-10,53 (30,120)	8,70 (28,810)	
LS MW (SE)	-5,92 (2,120)	2,82 (2,407)	
95 %-KI	[-10,123; -1,726]	[-1,945; 7,581]	
Veränderung zu Woche 20/21			
n/N (%)	28/76 (37)	23/62 (37)	LS MD -10,55 [-17,220; -3,886]
MW (SD)	-10,71 (35,199)	5,80 (25,922)	
LS MW (SE)	-6,28 (2,205)	4,28 (2,547)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-10,638; -1,914]	[-0,756; 9,309]	
Veränderung zu Woche 24			
n/N (%)	25/75 (33)	21/60 (35)	LS MD -11,82 [-18,947; -4,693]
MW (SD)	-13,33 (33,333)	1,59 (19,653)	
LS MW (SE)	-6,52 (2,341)	5,30 (2,741)	
95 %-KI	[-11,146; -1,898]	[-0,110; 10,706]	
Veränderung zu Woche 36			
n/N (%)	37/67 (55)	26/55 (47)	LS MD -16,17 [-25,894; -6,437]
MW (SD)	-5,41 (34,706)	11,54 (28,193)	
LS MW (SE)	-7,37 (3,142)	8,80 (3,801)	
95 %-KI	[-13,546; -1,187]	[1,325; 16,274]	
Veränderung zu Woche 48			
n/N (%)	5/61 (8)	3/48 (6)	LS MD -20,51 [-33,657; -7,365]
MW (SD)	0,00 (0,000)	11,11 (19,245)	
LS MW (SE)	-8,21 (4,215)	12,30 (5,164)	
95 %-KI	[-16,492; 0,072]	[2,155; 22,446]	
<b>Letztes Platin-freies Intervall: ≤ 3 Monate</b>			
Baseline			
n/N (%)	67/83 (81)	62/91 (68)	-
MW (SD)	22,89 (31,360)	24,73 (32,467)	
Absolute Werte zum Studienende			
n/N (%)	3/55 (5)	5/39 (13)	-
MW (SD)	22,22 (19,245)	13,33 (18,257)	
Effekt über Studiendauer			
n	67	62	LS MD -4,70 [-12,218; 2,827] 0,2189
LS MW (SE)	-2,05 (2,573)	2,65 (2,798)	
95 %-KI	[-7,145; 3,048]	[-2,888; 8,183]	Hedges' g -0,22 [-0,563; 0,130]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	49/82 (60)	46/86 (53)	LS MD -1,30 [-9,614; 7,021]
MW (SD)	0,68 (35,675)	2,90 (28,826)	
LS MW (SE)	1,71 (2,890)	3,01 (3,071)	
95 %-KI	[-3,989; 7,417]	[-3,046; 9,066]	
Veränderung zu Woche 8/9			
n/N (%)	51/81 (63)	46/80 (57)	LS MD -2,86 [-10,514; 4,798]
MW (SD)	-2,61 (29,697)	2,90 (27,058)	
LS MW (SE)	-0,01 (2,648)	2,84 (2,825)	
95 %-KI	[-5,252; 5,224]	[-2,741; 8,428]	
Veränderung zu Woche 12			
n/N (%)	33/78 (42)	24/78 (31)	LS MD -3,95 [-11,438; 3,537]
MW (SD)	-8,08 (39,114)	0,00 (29,488)	
LS MW (SE)	-1,22 (2,573)	2,73 (2,773)	
95 %-KI	[-6,321; 3,874]	[-2,759; 8,213]	
Veränderung zu Woche 15/16			
n/N (%)	33/76 (43)	14/75 (19)	LS MD -5,04 [-12,624; 2,537]
MW (SD)	-4,04 (43,106)	7,14 (26,726)	
LS MW (SE)	-2,43 (2,586)	2,61 (2,826)	
95 %-KI	[-7,556; 2,690]	[-2,980; 8,201]	
Veränderung zu Woche 20/21			
n/N (%)	22/72 (31)	14/67 (21)	LS MD -6,60 [-14,749; 1,539]
MW (SD)	-9,09 (37,348)	-11,90 (33,607)	
LS MW (SE)	-4,16 (2,751)	2,44 (3,073)	
95 %-KI	[-9,602; 1,279]	[-3,624; 8,512]	
Veränderung zu Woche 24			
n/N (%)	15/72 (21)	12/62 (19)	LS MD -7,70 [-16,495; 1,099]
MW (SD)	-8,89 (40,760)	-11,11 (21,711)	
LS MW (SE)	-5,37 (2,956)	2,33 (3,344)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-11,206; 0,464]	[-4,267; 8,921]	
Veränderung zu Woche 36			
n/N (%)	27/63 (43)	18/50 (36)	LS MD -11,45 [-23,529; 0,639]
MW (SD)	-8,64 (27,100)	5,56 (12,783)	
LS MW (SE)	-9,52 (4,025)	1,93 (4,653)	
95 %-KI	[-17,435; -1,602]	[-7,225; 11,079]	
Veränderung zu Woche 48			
n/N (%)	2/55 (4)	4/39 (10)	LS MD -15,19 [-31,389; 1,004]
MW (SD)	0,00 (0,000)	8,33 (16,667)	
LS MW (SE)	-13,67 (5,385)	1,53 (6,253)	
95 %-KI	[-24,251; -3,080]	[-10,765; 13,819]	
<b>Letztes Platin-freies Intervall: &gt; 3 Monate</b>			
Baseline			
n/N (%)	109/135 (81)	96/116 (83)	-
MW (SD)	22,94 (27,479)	17,71 (26,024)	
Absolute Werte zum Studienende			
n/N (%)	7/85 (8)	1/71 (1)	-
MW (SD)	14,29 (17,817)	33,33 (NA)	
Effekt über Studiendauer			
n	109	96	LS MD -6,15 [-11,527; -0,777] 0,0251
LS MW (SE)	-0,54 (1,826)	5,62 (2,020)	
95 %-KI	[-4,140; 3,067]	[1,632; 9,598]	
Veränderung zu Woche 3/4			
n/N (%)	72/131 (55)	63/114 (55)	LS MD -2,01 [-8,213; 4,189]
MW (SD)	3,70 (26,570)	1,59 (24,266)	
LS MW (SE)	-1,42 (2,110)	0,59 (2,339)	
95 %-KI	[-5,570; 2,732]	[-4,007; 5,193]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	94/129 (73)	78/108 (72)	LS MD -3,81 [-9,399; 1,784]
MW (SD)	-5,67 (28,769)	4,27 (25,402)	
LS MW (SE)	-1,04 (1,921)	2,77 (2,086)	
95 %-KI	[-4,822; 2,749]	[-1,337; 6,879]	
Veränderung zu Woche 12			
n/N (%)	63/127 (50)	47/105 (45)	LS MD -5,06 [-10,450; 0,322]
MW (SD)	-3,17 (31,517)	3,55 (23,296)	
LS MW (SE)	-0,77 (1,847)	4,30 (2,009)	
95 %-KI	[-4,410; 2,874]	[0,335; 8,257]	
Veränderung zu Woche 15/16			
n/N (%)	61/123 (50)	41/103 (40)	LS MD -6,32 [-11,708; -0,933]
MW (SD)	-6,56 (24,206)	8,13 (30,533)	
LS MW (SE)	-0,50 (1,827)	5,82 (2,029)	
95 %-KI	[-4,105; 3,104]	[1,822; 9,820]	
Veränderung zu Woche 20/21			
n/N (%)	45/118 (38)	37/98 (38)	LS MD -8,12 [-13,861; -2,372]
MW (SD)	-1,48 (30,941)	8,11 (30,837)	
LS MW (SE)	-0,12 (1,896)	8,00 (2,214)	
95 %-KI	[-3,856; 3,621]	[3,640; 12,357]	
Veränderung zu Woche 24			
n/N (%)	38/112 (34)	26/93 (28)	LS MD -9,37 [-15,582; -3,164]
MW (SD)	-1,75 (27,886)	8,97 (30,634)	
LS MW (SE)	0,15 (2,007)	9,52 (2,434)	
95 %-KI	[-3,802; 4,103]	[4,736; 14,311]	
Veränderung zu Woche 36			
n/N (%)	53/97 (55)	30/84 (36)	LS MD -13,68 [-22,348; -5,016]
MW (SD)	2,52 (29,849)	15,56 (32,440)	
LS MW (SE)	1,07 (2,663)	14,75 (3,520)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-4,162; 6,299]	[7,838; 21,663]	
Veränderung zu Woche 48			
n/N (%)	6/85 (7)	1/71 (1)	LS MD -17,99 [-29,771; -6,211]
MW (SD)	-5,56 (13,608)	33,33 (NA)	
LS MW (SE)	1,99 (3,549)	19,98 (4,841)	
95 %-KI	[-4,980; 8,955]	[10,474; 29,482]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Pegyliertes liposomales Doxorubicin</b>			
Baseline			
n/N (%)	62/80 (78)	57/76 (75)	-
MW (SD)	22,04 (24,845)	15,20 (23,629)	
Absolute Werte zum Studienende			
n/N (%)	3/51 (6)	3/41 (7)	-
MW (SD)	22,22 (19,245)	11,11 (19,245)	
Effekt über Studiendauer			
n	62	57	LS MD -10,91 [-19,001; -2,814] 0,0087  Hedges' g -0,49 [-0,856; -0,125]
LS MW (SE)	0,50 (2,744)	11,41 (2,994)	
95 %-KI	[-4,938; 5,942]	[5,483; 17,336]	
Veränderung zu Woche 3/4			
n/N (%)	42/76 (55)	42/74 (57)	LS MD -6,72 [-15,769; 2,335]
MW (SD)	-4,76 (25,044)	6,35 (26,786)	
LS MW (SE)	-1,14 (3,133)	5,57 (3,318)	
95 %-KI	[-7,327; 5,040]	[-0,971; 12,118]	
Veränderung zu Woche 8/9			
n/N (%)	52/76 (68)	44/66 (67)	LS MD -8,55 [-16,852; -0,251]
MW (SD)	0,00 (28,006)	9,85 (24,463)	
LS MW (SE)	-0,42 (2,873)	8,13 (3,026)	
95 %-KI	[-6,108; 5,262]	[2,143; 14,114]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	33/75 (44)	23/64 (36)	LS MD -9,84 [-17,910; -1,760]
MW (SD)	-6,06 (35,799)	10,14 (23,430)	
LS MW (SE)	0,08 (2,771)	9,92 (2,958)	
95 %-KI	[-5,411; 5,573]	[4,060; 15,772]	
Veränderung zu Woche 15/16			
n/N (%)	33/74 (45)	19/62 (31)	LS MD -11,12 [-19,239; -3,000]
MW (SD)	-3,03 (37,605)	24,56 (31,115)	
LS MW (SE)	0,59 (2,745)	11,70 (3,011)	
95 %-KI	[-4,856; 6,027]	[5,746; 17,664]	
Veränderung zu Woche 20/21			
n/N (%)	27/72 (38)	18/59 (31)	LS MD -12,95 [-21,594; -4,313]
MW (SD)	-6,17 (35,850)	14,81 (30,726)	
LS MW (SE)	1,31 (2,840)	14,26 (3,283)	
95 %-KI	[-4,318; 6,930]	[7,776; 20,743]	
Veränderung zu Woche 24			
n/N (%)	21/69 (30)	16/54 (30)	LS MD -14,24 [-23,521; -4,954]
MW (SD)	-12,70 (34,118)	10,42 (26,440)	
LS MW (SE)	1,81 (2,993)	16,05 (3,586)	
95 %-KI	[-4,106; 7,727]	[8,977; 23,118]	
Veränderung zu Woche 36			
n/N (%)	30/60 (50)	16/48 (33)	LS MD -18,64 [-31,294; -5,985]
MW (SD)	0,00 (33,903)	20,83 (31,914)	
LS MW (SE)	3,54 (3,906)	22,18 (5,050)	
95 %-KI	[-4,147; 11,226]	[12,247; 32,111]	
Veränderung zu Woche 48			
n/N (%)	2/51 (4)	2/41 (5)	LS MD -23,04 [-39,998; -6,085]
MW (SD)	0,00 (0,000)	16,67 (23,570)	
LS MW (SE)	5,27 (5,155)	28,31 (6,833)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-4,866; 15,403]	[14,878; 41,743]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Paclitaxel</b>			
Baseline			
n/N (%)	75/88 (85)	69/82 (84)	-
MW (SD)	27,56 (33,501)	26,57 (33,127)	
Absolute Werte zum Studienende			
n/N (%)	1/56 (2)	1/49 (2)	-
MW (SD)	33,33 (NA)	0,00 (NA)	
Effekt über Studiendauer			
n	75	69	LS MD -0,20 [-6,088; 5,688] 0,9464  Hedges' g -0,01 [-0,338; 0,316]
LS MW (SE)	-2,33 (2,020)	-2,13 (2,193)	
95 %-KI	[-6,327; 1,668]	[-6,466; 2,208]	
Veränderung zu Woche 3/4			
n/N (%)	55/87 (63)	49/81 (60)	LS MD 2,06 [-5,000; 9,110]
MW (SD)	6,67 (34,783)	-2,72 (26,209)	
LS MW (SE)	0,68 (2,425)	-1,38 (2,643)	
95 %-KI	[-4,098; 5,455]	[-6,580; 3,827]	
Veränderung zu Woche 8/9			
n/N (%)	63/86 (73)	54/79 (68)	LS MD 1,03 [-5,155; 7,222]
MW (SD)	-6,35 (33,256)	-2,47 (25,781)	
LS MW (SE)	-0,68 (2,137)	-1,72 (2,298)	
95 %-KI	[-4,904; 3,538]	[-6,252; 2,817]	
Veränderung zu Woche 12			
n/N (%)	42/84 (50)	36/77 (47)	LS MD 0,32 [-5,584; 6,222]
MW (SD)	-5,56 (37,479)	-1,85 (28,668)	
LS MW (SE)	-1,64 (2,034)	-1,96 (2,190)	
95 %-KI	[-5,661; 2,388]	[-6,284; 2,373]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	45/81 (56)	28/76 (37)	LS MD -0,40 [-6,321; 5,530]
MW (SD)	-8,15 (31,905)	-1,19 (26,422)	
LS MW (SE)	-2,59 (2,028)	-2,19 (2,212)	
95 %-KI	[-6,603; 1,424]	[-6,569; 2,180]	
Veränderung zu Woche 20/21			
n/N (%)	29/77 (38)	26/73 (36)	LS MD -1,42 [-7,893; 5,060]
MW (SD)	-1,15 (36,168)	-8,97 (33,410)	
LS MW (SE)	-3,95 (2,185)	-2,53 (2,461)	
95 %-KI	[-8,267; 0,364]	[-7,389; 2,320]	
Veränderung zu Woche 24			
n/N (%)	21/74 (28)	19/72 (26)	LS MD -2,13 [-9,293; 5,030]
MW (SD)	1,59 (34,118)	-3,51 (33,138)	
LS MW (SE)	-4,90 (2,393)	-2,77 (2,753)	
95 %-KI	[-9,623; -0,187]	[-8,195; 2,648]	
Veränderung zu Woche 36			
n/N (%)	35/64 (55)	24/63 (38)	LS MD -4,58 [-15,172; 6,008]
MW (SD)	-2,86 (29,563)	4,17 (24,696)	
LS MW (SE)	-8,17 (3,472)	-3,59 (4,153)	
95 %-KI	[-14,997; -1,349]	[-11,750; 4,569]	
Veränderung zu Woche 48			
n/N (%)	1/56 (2)	1/49 (2)	LS MD -7,03 [-21,787; 7,721]
MW (SD)	0,00 (NA)	0,00 (NA)	
LS MW (SE)	-11,44 (4,809)	-4,41 (5,813)	
95 %-KI	[-20,889; -1,994]	[-15,829; 7,012]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Topotecan</b>			
Baseline			
n/N (%)	39/50 (78)	32/49 (65)	-
MW (SD)	15,38 (23,996)	16,67 (25,400)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	6/33 (18)	2/20 (10)	-
MW (SD)	11,11 (17,213)	33,33 (0,000)	
Effekt über Studiendauer			
n	39	32	LS MD -8,96 [-19,174; 1,249] 0,0844  Hedges' g -0,41 [-0,884; 0,061]
LS MW (SE)	-0,45 (3,408)	8,51 (3,860)	
95 %-KI	[-7,255; 6,359]	[0,818; 16,212]	
Veränderung zu Woche 3/4			
n/N (%)	24/50 (48)	18/45 (40)	LS MD -1,47 [-12,096; 9,158]
MW (SD)	5,56 (27,217)	5,56 (23,570)	
LS MW (SE)	0,54 (3,546)	2,01 (4,045)	
95 %-KI	[-6,523; 7,600]	[-6,038; 10,052]	
Veränderung zu Woche 8/9			
n/N (%)	30/48 (62)	26/43 (60)	LS MD -4,67 [-14,943; 5,601]
MW (SD)	-8,89 (19,443)	6,41 (26,699)	
LS MW (SE)	0,12 (3,440)	4,79 (3,882)	
95 %-KI	[-6,748; 6,982]	[-2,950; 12,526]	
Veränderung zu Woche 12			
n/N (%)	21/46 (46)	12/42 (29)	LS MD -6,91 [-17,093; 3,268]
MW (SD)	-1,59 (24,667)	0,00 (14,213)	
LS MW (SE)	-0,18 (3,407)	6,73 (3,842)	
95 %-KI	[-6,982; 6,626]	[-0,928; 14,397]	
Veränderung zu Woche 15/16			
n/N (%)	16/44 (36)	8/40 (20)	LS MD -9,15 [-19,374; 1,066]
MW (SD)	-4,17 (16,667)	0,00 (17,817)	
LS MW (SE)	-0,47 (3,410)	8,68 (3,864)	
95 %-KI	[-7,283; 6,337]	[0,976; 16,386]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	11/41 (27)	7/33 (21)	LS MD -12,36 [-22,860; -1,852]
MW (SD)	-6,06 (13,484)	14,29 (17,817)	
LS MW (SE)	-0,89 (3,475)	11,46 (4,004)	
95 %-KI	[-7,826; 6,037]	[3,494; 19,429]	
Veränderung zu Woche 24			
n/N (%)	11/41 (27)	3/29 (10)	LS MD -14,60 [-25,450; -3,745]
MW (SD)	3,03 (17,979)	0,00 (0,000)	
LS MW (SE)	-1,19 (3,561)	13,41 (4,170)	
95 %-KI	[-8,282; 5,904]	[5,125; 21,692]	
Veränderung zu Woche 36			
n/N (%)	15/36 (42)	8/23 (35)	LS MD -22,28 [-35,112; -9,454]
MW (SD)	0,00 (17,817)	16,67 (17,817)	
LS MW (SE)	-2,20 (4,075)	20,08 (5,076)	
95 %-KI	[-10,271; 5,870]	[10,054; 30,110]	
Veränderung zu Woche 48			
n/N (%)	5/33 (15)	2/20 (10)	LS MD -29,97 [-45,618; -14,319]
MW (SD)	-6,67 (14,907)	16,67 (23,570)	
LS MW (SE)	-3,21 (4,836)	26,76 (6,315)	
95 %-KI	[-12,757; 6,333]	[14,304; 39,208]	
<p><i>Analysepopulation: ITT</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023</i></p> <p><i>Modell: Veränderung zu Baseline ~ Behandlung + Baseline-Wert * Zeit in Wochen + Behandlung * Zeit in Wochen + zufällige Effekte durch die Patientin</i></p> <p><i>Die Berechnung des LS-MWs erfolgt durch ein MMRM mit dem oben angegebenen Modell. Basierend hierauf werden KI und p-Wert ermittelt. Hedges' g basiert ebenfalls auf den LS-MW und ist somit auf das Modell angepasst.</i></p> <p><i>Es werden ausschließlich gemeinsame Analysezeitpunkte dargestellt.</i></p> <p><i>Ein LS MD und Hedges' g kleiner als Null bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			



## 2.2 EORTC QLQ-C30 Verstopfung

### EORTC QLQ-C30 Verstopfung: Subgruppenanalyse

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
<b>EORTC QLQ-C30 Verstopfung</b>			
<b>Alter: &lt; 65 Jahre</b>			
Baseline			
n/N (%)	93/115 (81)	92/119 (77)	-
MW (SD)	23,30 (32,147)	28,99 (31,726)	
Absolute Werte zum Studienende			
n/N (%)	4/73 (5)	4/64 (6)	-
MW (SD)	25,00 (31,914)	8,33 (16,667)	
Effekt über Studiendauer			
n	93	92	LS MD -0,79 [-7,020; 5,437] 0,8023
LS MW (SE)	-3,69 (2,175)	-2,90 (2,280)	
95 %-KI	[-7,986; 0,603]	[-7,398; 1,599]	Hedges' g -0,04 [-0,325; 0,251]
Veränderung zu Woche 3/4			
n/N (%)	59/113 (52)	61/115 (53)	LS MD 0,03 [-6,970; 7,039]
MW (SD)	-6,21 (30,622)	-8,74 (27,823)	
LS MW (SE)	-3,87 (2,469)	-3,90 (2,557)	
95 %-KI	[-8,728; 0,992]	[-8,935; 1,130]	
Veränderung zu Woche 8/9			
n/N (%)	74/112 (66)	71/108 (66)	LS MD -0,33 [-6,743; 6,084]
MW (SD)	-1,35 (30,440)	-2,35 (32,034)	
LS MW (SE)	-3,79 (2,264)	-3,46 (2,329)	
95 %-KI	[-8,255; 0,675]	[-8,052; 1,130]	
Veränderung zu Woche 12			
n/N (%)	47/110 (43)	40/105 (38)	
MW (SD)	-3,55 (29,679)	-4,17 (24,093)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-3,74 (2,189)	-3,15 (2,266)	LS MD -0,58 [-6,811; 5,643]
95 %-KI	[-8,057; 0,586]	[-7,622; 1,319]	
Veränderung zu Woche 15/16			
n/N (%)	53/107 (50)	33/102 (32)	LS MD -0,84 [-7,087; 5,409]
MW (SD)	-4,40 (35,828)	-5,05 (27,790)	
LS MW (SE)	-3,68 (2,178)	-2,84 (2,291)	
95 %-KI	[-7,981; 0,619]	[-7,363; 1,678]	
Veränderung zu Woche 20/21			
n/N (%)	36/101 (36)	30/96 (31)	LS MD -1,20 [-7,832; 5,427]
MW (SD)	3,70 (33,597)	-6,67 (26,839)	
LS MW (SE)	-3,60 (2,272)	-2,40 (2,474)	
95 %-KI	[-8,085; 0,878]	[-7,275; 2,473]	
Veränderung zu Woche 24			
n/N (%)	25/99 (25)	19/91 (21)	LS MD -1,46 [-8,569; 5,655]
MW (SD)	-1,33 (37,859)	-12,28 (27,690)	
LS MW (SE)	-3,55 (2,408)	-2,09 (2,687)	
95 %-KI	[-8,294; 1,196]	[-7,380; 3,196]	
Veränderung zu Woche 36			
n/N (%)	40/86 (47)	28/79 (35)	LS MD -2,33 [-11,999; 7,338]
MW (SD)	-4,17 (36,349)	-2,38 (40,500)	
LS MW (SE)	-3,36 (3,183)	-1,03 (3,751)	
95 %-KI	[-9,618; 2,893]	[-8,400; 6,336]	
Veränderung zu Woche 48			
n/N (%)	4/73 (5)	3/64 (5)	LS MD -3,20 [-16,152; 9,745]
MW (SD)	-16,67 (43,033)	-11,11 (19,245)	
LS MW (SE)	-3,18 (4,218)	0,03 (5,067)	
95 %-KI	[-11,460; 5,108]	[-9,924; 9,979]	
<b>Alter: ≥ 65 Jahre</b>			
Baseline			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	83/103 (81)	66/88 (75)	-
MW (SD)	21,69 (28,243)	28,79 (31,965)	
Absolute Werte zum Studienende			
n/N (%)	6/67 (9)	2/46 (4)	-
MW (SD)	16,67 (18,257)	33,33 (47,140)	
Effekt über Studiendauer			
n	83	66	LS MD -0,30 [-6,428; 5,829] 0,9232  Hedges' g -0,02 [-0,339; 0,307]
LS MW (SE)	-1,39 (2,005)	-1,09 (2,356)	
95 %-KI	[-5,356; 2,576]	[-5,746; 3,565]	
Veränderung zu Woche 3/4			
n/N (%)	62/100 (62)	49/85 (58)	LS MD -2,97 [-10,040; 4,106]
MW (SD)	4,30 (28,620)	-1,36 (23,530)	
LS MW (SE)	-1,43 (2,328)	1,53 (2,719)	
95 %-KI	[-6,019; 3,153]	[-3,821; 6,889]	
Veränderung zu Woche 8/9			
n/N (%)	71/98 (72)	53/80 (66)	LS MD -1,78 [-8,126; 4,571]
MW (SD)	-4,23 (25,153)	-3,14 (36,552)	
LS MW (SE)	-1,41 (2,100)	0,36 (2,425)	
95 %-KI	[-5,561; 2,733]	[-4,423; 5,150]	
Veränderung zu Woche 12			
n/N (%)	49/95 (52)	31/78 (40)	LS MD -0,94 [-7,067; 5,178]
MW (SD)	-5,44 (26,655)	-3,23 (29,002)	
LS MW (SE)	-1,40 (2,018)	-0,46 (2,342)	
95 %-KI	[-5,391; 2,590]	[-5,083; 4,171]	
Veränderung zu Woche 15/16			
n/N (%)	41/92 (45)	22/76 (29)	
MW (SD)	-4,07 (28,082)	3,03 (25,006)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-1,39 (2,009)	-1,28 (2,373)	LS MD -0,11 [-6,272; 6,048]
95 %-KI	[-5,362; 2,588]	[-5,964; 3,413]	
Veränderung zu Woche 20/21			
n/N (%)	30/89 (34)	21/69 (30)	LS MD 1,08 [-5,574; 7,730]
MW (SD)	-1,11 (25,496)	7,94 (23,345)	
LS MW (SE)	-1,37 (2,124)	-2,45 (2,605)	
95 %-KI	[-5,564; 2,828]	[-7,584; 2,692]	
Veränderung zu Woche 24			
n/N (%)	28/85 (33)	19/64 (30)	LS MD 1,91 [-5,346; 9,168]
MW (SD)	-7,14 (24,607)	-5,26 (29,945)	
LS MW (SE)	-1,35 (2,283)	-3,27 (2,874)	
95 %-KI	[-5,857; 3,148]	[-8,925; 2,394]	
Veränderung zu Woche 36			
n/N (%)	40/74 (54)	20/55 (36)	LS MD 4,77 [-5,565; 15,097]
MW (SD)	2,50 (29,610)	-8,33 (23,878)	
LS MW (SE)	-1,31 (3,148)	-6,07 (4,176)	
95 %-KI	[-7,497; 4,880]	[-14,281; 2,132]	
Veränderung zu Woche 48			
n/N (%)	4/67 (6)	2/46 (4)	LS MD 7,62 [-6,518; 21,761]
MW (SD)	0,00 (27,217)	-33,33 (0,000)	
LS MW (SE)	-1,26 (4,262)	-8,88 (5,747)	
95 %-KI	[-9,636; 7,111]	[-20,174; 2,407]	
<b>Region: USA</b>			
Baseline			
n/N (%)	49/65 (75)	34/51 (67)	-
MW (SD)	18,37 (26,406)	27,45 (32,277)	
Absolute Werte zum Studienende			
n/N (%)	2/39 (5)	3/27 (11)	-
MW (SD)	16,67 (23,570)	33,33 (33,333)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Effekt über Studiendauer			
n	49	34	LS MD 1,28 [-8,060; 10,623] 0,7854  Hedges' g 0,06 [-0,376; 0,499]
LS MW (SE)	0,66 (2,930)	-0,62 (3,617)	
95 %-KI	[-5,174; 6,504]	[-7,814; 6,580]	
Veränderung zu Woche 3/4			
n/N (%)	34/64 (53)	21/49 (43)	LS MD -0,02 [-10,622; 10,576]
MW (SD)	2,94 (32,169)	-12,70 (24,667)	
LS MW (SE)	0,76 (3,317)	0,78 (4,172)	
95 %-KI	[-5,806; 7,328]	[-7,471; 9,038]	
Veränderung zu Woche 8/9			
n/N (%)	42/62 (68)	30/46 (65)	LS MD 0,57 [-9,057; 10,193]
MW (SD)	0,79 (28,023)	5,56 (36,181)	
LS MW (SE)	0,72 (3,033)	0,15 (3,743)	
95 %-KI	[-5,311; 6,745]	[-7,285; 7,584]	
Veränderung zu Woche 12			
n/N (%)	26/59 (44)	16/45 (36)	LS MD 0,98 [-8,351; 10,313]
MW (SD)	3,85 (25,520)	0,00 (27,217)	
LS MW (SE)	0,69 (2,939)	-0,29 (3,613)	
95 %-KI	[-5,166; 6,539]	[-7,482; 6,894]	
Veränderung zu Woche 15/16			
n/N (%)	21/56 (38)	11/44 (25)	LS MD 1,39 [-7,999; 10,788]
MW (SD)	-4,76 (33,806)	-9,09 (21,556)	
LS MW (SE)	0,66 (2,941)	-0,74 (3,640)	
95 %-KI	[-5,202; 6,515]	[-7,980; 6,504]	
Veränderung zu Woche 20/21			
n/N (%)	13/54 (24)	9/40 (22)	
MW (SD)	5,13 (18,490)	-7,41 (14,699)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	0,61 (3,109)	-1,37 (3,944)	LS MD 1,98 [-8,089; 12,059]
95 %-KI	[-5,565; 6,791]	[-9,194; 6,451]	
Veränderung zu Woche 24			
n/N (%)	9/53 (17)	6/38 (16)	LS MD 2,40 [-8,511; 13,307]
MW (SD)	-3,70 (20,031)	-11,11 (27,217)	
LS MW (SE)	0,58 (3,329)	-1,82 (4,311)	
95 %-KI	[-6,014; 7,179]	[-10,343; 6,712]	
Veränderung zu Woche 36			
n/N (%)	22/43 (51)	10/33 (30)	LS MD 3,82 [-11,404; 19,035]
MW (SD)	4,55 (27,785)	-20,00 (35,832)	
LS MW (SE)	0,48 (4,505)	-3,34 (6,147)	
95 %-KI	[-8,401; 9,357]	[-15,447; 8,774]	
Veränderung zu Woche 48			
n/N (%)	2/39 (5)	3/27 (11)	LS MD 5,23 [-15,402; 25,867]
MW (SD)	-16,67 (23,570)	-22,22 (19,245)	
LS MW (SE)	0,37 (6,024)	-4,86 (8,406)	
95 %-KI	[-11,486; 12,234]	[-21,408; 11,692]	
<b>Region: Rest der Welt</b>			
Baseline			
n/N (%)	127/153 (83)	124/156 (79)	-
MW (SD)	24,15 (31,616)	29,30 (31,692)	
Absolute Werte zum Studienende			
n/N (%)	8/101 (8)	3/83 (4)	-
MW (SD)	20,83 (24,801)	0,00 (0,000)	
Effekt über Studiendauer			
n	127	124	LS MD -1,00 [-6,048; 4,041] 0,6955 Hedges' g
LS MW (SE)	-3,66 (1,750)	-2,66 (1,867)	
95 %-KI	[-7,111; -0,214]	[-6,337; 1,018]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
			-0,05 [-0,297; 0,198]
Veränderung zu Woche 3/4			
n/N (%)	87/149 (58)	89/151 (59)	LS MD -1,49 [-7,206; 4,229]
MW (SD)	-2,30 (29,110)	-3,75 (26,323)	
LS MW (SE)	-3,83 (2,006)	-2,34 (2,103)	
95 %-KI	[-7,770; 0,119]	[-6,469; 1,796]	
Veränderung zu Woche 8/9			
n/N (%)	103/148 (70)	94/142 (66)	LS MD -1,28 [-6,472; 3,922]
MW (SD)	-4,21 (27,881)	-5,32 (32,902)	
LS MW (SE)	-3,75 (1,830)	-2,48 (1,900)	
95 %-KI	[-7,356; -0,152]	[-6,219; 1,262]	
Veränderung zu Woche 12			
n/N (%)	70/146 (48)	55/138 (40)	LS MD -1,13 [-6,162; 3,911]
MW (SD)	-7,62 (28,472)	-4,85 (25,993)	
LS MW (SE)	-3,70 (1,764)	-2,58 (1,849)	
95 %-KI	[-7,179; -0,229]	[-6,219; 1,063]	
Veränderung zu Woche 15/16			
n/N (%)	73/143 (51)	44/134 (33)	LS MD -0,98 [-6,039; 4,087]
MW (SD)	-4,11 (32,368)	0,00 (27,842)	
LS MW (SE)	-3,65 (1,752)	-2,68 (1,879)	
95 %-KI	[-7,106; -0,201]	[-6,378; 1,022]	
Veränderung zu Woche 20/21			
n/N (%)	53/136 (39)	42/125 (34)	LS MD -0,76 [-6,180; 4,654]
MW (SD)	0,63 (32,351)	0,79 (28,023)	
LS MW (SE)	-3,58 (1,830)	-2,82 (2,055)	
95 %-KI	[-7,186; 0,021]	[-6,863; 1,223]	
Veränderung zu Woche 24			
n/N (%)	44/131 (34)	32/117 (27)	
MW (SD)	-4,55 (33,404)	-8,33 (29,329)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-3,53 (1,945)	-2,92 (2,254)	LS MD -0,61 [-6,467; 5,241]
95 %-KI	[-7,359; 0,294]	[-7,350; 1,512]	
Veränderung zu Woche 36			
n/N (%)	58/117 (50)	38/101 (38)	LS MD -0,10 [-8,216; 8,014]
MW (SD)	-2,87 (34,924)	-0,88 (33,321)	
LS MW (SE)	-3,36 (2,598)	-3,26 (3,218)	
95 %-KI	[-8,462; 1,740]	[-9,577; 3,057]	
Veränderung zu Woche 48			
n/N (%)	6/101 (6)	2/83 (2)	LS MD 0,41 [-10,553; 11,376]
MW (SD)	-5,56 (38,968)	-16,67 (23,570)	
LS MW (SE)	-3,19 (3,465)	-3,60 (4,386)	
95 %-KI	[-9,991; 3,612]	[-12,209; 5,007]	
<b>Stadium bei der Diagnose: I-III</b>			
Baseline			
n/N (%)	112/141 (79)	111/144 (77)	-
MW (SD)	23,51 (31,840)	29,73 (32,209)	
Absolute Werte zum Studienende			
n/N (%)	6/91 (7)	4/76 (5)	-
MW (SD)	22,22 (17,213)	25,00 (31,914)	
Effekt über Studiendauer			
n	112	111	LS MD -0,44 [-5,769; 4,887] 0,8706
LS MW (SE)	-2,76 (1,858)	-2,32 (1,958)	
95 %-KI	[-6,420; 0,907]	[-6,174; 1,543]	Hedges' g -0,02 [-0,284; 0,241]
Veränderung zu Woche 3/4			
n/N (%)	75/137 (55)	79/138 (57)	LS MD -2,76 [-8,820; 3,306]
MW (SD)	-2,22 (28,650)	-5,06 (26,735)	
LS MW (SE)	-3,57 (2,135)	-0,81 (2,218)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-7,768; 0,633]	[-5,172; 3,551]	
Veränderung zu Woche 8/9			
n/N (%)	94/136 (69)	86/129 (67)	LS MD -1,74 [-7,257; 3,773]
MW (SD)	-2,48 (26,881)	-0,39 (32,937)	
LS MW (SE)	-3,21 (1,945)	-1,47 (2,010)	
95 %-KI	[-7,043; 0,618]	[-5,428; 2,488]	
Veränderung zu Woche 12			
n/N (%)	60/133 (45)	48/128 (38)	LS MD -1,03 [-6,367; 4,303]
MW (SD)	-8,89 (28,035)	-3,47 (28,550)	
LS MW (SE)	-2,96 (1,873)	-1,93 (1,949)	
95 %-KI	[-6,656; 0,729]	[-5,772; 1,909]	
Veränderung zu Woche 15/16			
n/N (%)	62/130 (48)	35/125 (28)	LS MD -0,32 [-5,664; 5,021]
MW (SD)	-0,54 (33,329)	-1,90 (22,785)	
LS MW (SE)	-2,71 (1,860)	-2,39 (1,966)	
95 %-KI	[-6,382; 0,953]	[-6,268; 1,482]	
Veränderung zu Woche 20/21			
n/N (%)	44/123 (36)	34/116 (29)	LS MD 0,69 [-4,980; 6,366]
MW (SD)	-0,76 (33,325)	-1,96 (24,538)	
LS MW (SE)	-2,36 (1,944)	-3,05 (2,121)	
95 %-KI	[-6,189; 1,471]	[-7,228; 1,123]	
Veränderung zu Woche 24			
n/N (%)	33/121 (27)	27/109 (25)	LS MD 1,40 [-4,697; 7,504]
MW (SD)	-1,01 (30,601)	-11,11 (30,662)	
LS MW (SE)	-2,11 (2,067)	-3,51 (2,306)	
95 %-KI	[-6,179; 1,959]	[-8,049; 1,022]	
Veränderung zu Woche 36			
n/N (%)	52/105 (50)	36/92 (39)	
MW (SD)	-0,64 (33,327)	-7,41 (33,910)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-1,26 (2,770)	-5,10 (3,235)	LS MD 3,84 [-4,535; 12,213]
95 %-KI	[-6,698; 4,183]	[-11,449; 1,257]	
Veränderung zu Woche 48			
n/N (%)	5/91 (5)	4/76 (5)	LS MD 6,27 [-5,007; 17,556]
MW (SD)	-13,33 (38,006)	-16,67 (19,245)	
LS MW (SE)	-0,40 (3,702)	-6,68 (4,387)	
95 %-KI	[-7,672; 6,864]	[-15,291; 1,935]	
<b>Stadium bei der Diagnose: IV</b>			
Baseline			
n/N (%)	59/72 (82)	45/60 (75)	-
MW (SD)	20,90 (27,611)	28,15 (30,941)	
Absolute Werte zum Studienende			
n/N (%)	4/46 (9)	2/33 (6)	-
MW (SD)	16,67 (33,333)	0,00 (0,000)	
Effekt über Studiendauer			
n	59	45	LS MD 0,43 [-7,595; 8,449] 0,9162
LS MW (SE)	-3,28 (2,589)	-3,71 (3,085)	
95 %-KI	[-8,425; 1,857]	[-9,830; 2,409]	Hedges' g 0,02 [-0,367; 0,409]
Veränderung zu Woche 3/4			
n/N (%)	41/71 (58)	29/59 (49)	LS MD 4,27 [-4,812; 13,351]
MW (SD)	1,63 (33,293)	-9,20 (23,395)	
LS MW (SE)	-1,90 (2,943)	-6,17 (3,514)	
95 %-KI	[-7,710; 3,917]	[-13,101; 0,769]	
Veränderung zu Woche 8/9			
n/N (%)	46/69 (67)	36/56 (64)	LS MD 2,54 [-5,679; 10,760]
MW (SD)	-3,62 (30,003)	-12,04 (32,025)	
LS MW (SE)	-2,52 (2,689)	-5,06 (3,138)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-7,849; 2,808]	[-11,276; 1,154]	
Veränderung zu Woche 12			
n/N (%)	31/67 (46)	22/52 (42)	LS MD 1,33 [-6,653; 9,312]
MW (SD)	0,00 (22,771)	-4,55 (21,320)	
LS MW (SE)	-2,96 (2,601)	-4,29 (3,048)	
95 %-KI	[-8,120; 2,205]	[-10,335; 1,759]	
Veränderung zu Woche 15/16			
n/N (%)	29/64 (45)	18/50 (36)	LS MD 0,12 [-7,958; 8,197]
MW (SD)	-12,64 (30,097)	-7,41 (29,273)	
LS MW (SE)	-3,39 (2,596)	-3,51 (3,117)	
95 %-KI	[-8,549; 1,759]	[-9,696; 2,668]	
Veränderung zu Woche 20/21			
n/N (%)	19/62 (31)	16/46 (35)	LS MD -1,61 [-10,371; 7,151]
MW (SD)	5,26 (22,942)	-0,00 (29,814)	
LS MW (SE)	-4,02 (2,731)	-2,41 (3,469)	
95 %-KI	[-9,433; 1,395]	[-9,267; 4,449]	
Veränderung zu Woche 24			
n/N (%)	18/59 (31)	10/44 (23)	LS MD -2,82 [-12,381; 6,740]
MW (SD)	-9,26 (33,927)	-6,67 (21,082)	
LS MW (SE)	-4,46 (2,915)	-1,64 (3,853)	
95 %-KI	[-10,223; 1,311]	[-9,237; 5,966]	
Veränderung zu Woche 36			
n/N (%)	27/52 (52)	11/41 (27)	LS MD -6,97 [-20,520; 6,578]
MW (SD)	-1,23 (33,945)	0,00 (36,515)	
LS MW (SE)	-5,95 (3,924)	1,02 (5,651)	
95 %-KI	[-13,681; 1,772]	[-10,103; 12,135]	
Veränderung zu Woche 48			
n/N (%)	3/46 (7)	1/33 (3)	
MW (SD)	0,00 (33,333)	-33,33 (NA)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-7,45 (5,241)	3,67 (7,783)	LS MD -11,12 [-29,581; 7,338]
95 %-KI	[-17,762; 2,856]	[-11,640; 18,976]	
<b>BRCA Status: Positiv</b>			
Baseline			
n/N (%)	25/27 (93)	23/35 (66)	-
MW (SD)	24,00 (32,660)	42,03 (30,513)	
Absolute Werte zum Studienende			
n/N (%)	1/19 (5)	0/15 (0)	-
MW (SD)	66,67 (NA)	NA (NA)	
Effekt über Studiendauer			
n	25	23	LS MD 15,44 [1,918; 28,970] 0,0262  Hedges' g 0,66 [0,079; 1,245]
LS MW (SE)	2,73 (4,426)	-12,71 (4,960)	
95 %-KI	[-6,197; 11,664]	[-22,691; -2,730]	
Veränderung zu Woche 3/4			
n/N (%)	16/27 (59)	18/35 (51)	LS MD 14,05 [-0,496; 28,587]
MW (SD)	-4,17 (23,960)	-16,67 (26,197)	
LS MW (SE)	2,77 (4,862)	-11,27 (5,290)	
95 %-KI	[-6,948; 12,495]	[-21,848; -0,697]	
Veränderung zu Woche 8/9			
n/N (%)	21/26 (81)	20/30 (67)	LS MD 14,72 [1,114; 28,335]
MW (SD)	7,94 (29,636)	-18,33 (33,289)	
LS MW (SE)	2,75 (4,545)	-11,97 (4,890)	
95 %-KI	[-6,386; 11,894]	[-21,814; -2,127]	
Veränderung zu Woche 12			
n/N (%)	14/26 (54)	10/30 (33)	LS MD 15,20 [1,752; 28,648]
MW (SD)	2,38 (30,562)	-3,33 (18,922)	
LS MW (SE)	2,74 (4,439)	-12,46 (4,877)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,212; 11,693]	[-22,287; -2,632]	
Veränderung zu Woche 15/16			
n/N (%)	12/26 (46)	8/29 (28)	LS MD 15,68 [1,975; 29,375]
MW (SD)	-11,11 (21,711)	0,00 (25,198)	
LS MW (SE)	2,73 (4,439)	-12,95 (5,091)	
95 %-KI	[-6,229; 11,683]	[-23,171; -2,726]	
Veränderung zu Woche 20/21			
n/N (%)	10/25 (40)	4/25 (16)	LS MD 16,35 [1,611; 31,097]
MW (SD)	-3,33 (24,595)	0,00 (0,000)	
LS MW (SE)	2,71 (4,620)	-13,65 (5,733)	
95 %-KI	[-6,580; 11,994]	[-25,073; -2,221]	
Veränderung zu Woche 24			
n/N (%)	8/25 (32)	4/24 (17)	LS MD 16,83 [0,939; 32,719]
MW (SD)	4,17 (21,362)	0,00 (0,000)	
LS MW (SE)	2,69 (4,861)	-14,14 (6,361)	
95 %-KI	[-7,041; 12,428]	[-26,764; -1,508]	
Veränderung zu Woche 36			
n/N (%)	10/21 (48)	5/20 (25)	LS MD 18,46 [-3,121; 40,037]
MW (SD)	3,33 (29,187)	-13,33 (18,257)	
LS MW (SE)	2,65 (6,217)	-15,81 (9,143)	
95 %-KI	[-9,674; 14,967]	[-33,878; 2,254]	
Veränderung zu Woche 48			
n/N (%)	1/19 (5)	0/15 (0)	LS MD 20,09 [-8,599; 48,773]
MW (SD)	33,33 (NA)	NA (NA)	
LS MW (SE)	2,60 (8,047)	-17,49 (12,377)	
95 %-KI	[-13,303; 18,501]	[-41,940; 6,964]	
<b>BRCA Status: Negativ/Unbekannt</b>			
Baseline			
n/N (%)	151/191 (79)	135/172 (78)	-

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	22,30 (29,993)	26,67 (31,491)	
Absolute Werte zum Studienende			
n/N (%)	9/121 (7)	6/95 (6)	-
MW (SD)	14,81 (17,568)	16,67 (27,889)	
Effekt über Studiendauer			
n	151	135	LS MD -2,50 [-7,109; 2,102] 0,2855
LS MW (SE)	-3,31 (1,568)	-0,80 (1,733)	
95 %-KI	[-6,395; -0,220]	[-4,215; 2,608]	Hedges' g -0,13 [-0,359; 0,106]
Veränderung zu Woche 3/4			
n/N (%)	105/186 (56)	92/165 (56)	LS MD -3,09 [-8,384; 2,205]
MW (SD)	-0,32 (30,834)	-3,26 (25,706)	
LS MW (SE)	-3,37 (1,811)	-0,28 (1,993)	
95 %-KI	[-6,930; 0,188]	[-4,196; 3,634]	
Veränderung zu Woche 8/9			
n/N (%)	124/184 (67)	104/158 (66)	LS MD -2,83 [-7,616; 1,948]
MW (SD)	-4,57 (27,327)	0,32 (33,332)	
LS MW (SE)	-3,34 (1,641)	-0,51 (1,790)	
95 %-KI	[-6,573; -0,113]	[-4,030; 3,012]	
Veränderung zu Woche 12			
n/N (%)	82/179 (46)	61/153 (40)	LS MD -2,65 [-7,267; 1,958]
MW (SD)	-5,69 (27,619)	-3,83 (27,283)	
LS MW (SE)	-3,32 (1,579)	-0,67 (1,728)	
95 %-KI	[-6,433; -0,214]	[-4,070; 2,732]	
Veränderung zu Woche 15/16			
n/N (%)	82/173 (47)	47/149 (32)	LS MD -2,48 [-7,094; 2,143]
MW (SD)	-3,25 (33,787)	-2,13 (27,279)	
LS MW (SE)	-3,30 (1,570)	-0,83 (1,740)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,396; -0,212]	[-4,254; 2,596]	
Veränderung zu Woche 20/21			
n/N (%)	56/165 (34)	47/140 (34)	LS MD -2,22 [-7,147; 2,709]
MW (SD)	2,38 (31,047)	-0,71 (27,355)	
LS MW (SE)	-3,28 (1,650)	-1,06 (1,882)	
95 %-KI	[-6,524; -0,030]	[-4,759; 2,644]	
Veränderung zu Woche 24			
n/N (%)	45/159 (28)	34/131 (26)	LS MD -2,04 [-7,367; 3,287]
MW (SD)	-5,93 (32,790)	-9,80 (30,184)	
LS MW (SE)	-3,26 (1,764)	-1,22 (2,054)	
95 %-KI	[-6,726; 0,211]	[-5,255; 2,819]	
Veränderung zu Woche 36			
n/N (%)	70/139 (50)	43/114 (38)	LS MD -1,43 [-8,846; 5,995]
MW (SD)	-1,43 (33,782)	-3,88 (35,790)	
LS MW (SE)	-3,19 (2,398)	-1,77 (2,920)	
95 %-KI	[-7,899; 1,516]	[-7,498; 3,965]	
Veränderung zu Woche 48			
n/N (%)	7/121 (6)	5/95 (5)	LS MD -0,81 [-10,881; 9,260]
MW (SD)	-14,29 (32,530)	-20,00 (18,257)	
LS MW (SE)	-3,13 (3,227)	-2,31 (3,988)	
95 %-KI	[-9,458; 3,207]	[-10,141; 5,512]	
<b>Baseline ECOG PS: 0</b>			
Baseline			
n/N (%)	100/128 (78)	97/113 (86)	-
MW (SD)	18,33 (27,778)	27,84 (29,923)	
Absolute Werte zum Studienende			
n/N (%)	7/87 (8)	3/72 (4)	-
MW (SD)	23,81 (25,198)	33,33 (33,333)	
Effekt über Studiendauer			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n	100	97	LS MD 0,76 [-4,770; 6,287] 0,7869  Hedges' g 0,04 [-0,241; 0,318]
LS MW (SE)	0,60 (1,915)	-0,16 (2,026)	
95 %-KI	[-3,179; 4,381]	[-4,154; 3,838]	
Veränderung zu Woche 3/4			
n/N (%)	70/127 (55)	64/111 (58)	LS MD 1,06 [-5,270; 7,393]
MW (SD)	1,43 (27,473)	-5,73 (24,165)	
LS MW (SE)	0,57 (2,195)	-0,49 (2,333)	
95 %-KI	[-3,747; 4,891]	[-5,079; 4,100]	
Veränderung zu Woche 8/9			
n/N (%)	84/126 (67)	75/108 (69)	LS MD 0,93 [-4,816; 6,677]
MW (SD)	1,19 (25,055)	-2,22 (31,160)	
LS MW (SE)	0,58 (2,004)	-0,35 (2,098)	
95 %-KI	[-3,366; 4,534]	[-4,480; 3,787]	
Veränderung zu Woche 12			
n/N (%)	51/122 (42)	46/108 (43)	LS MD 0,84 [-4,707; 6,385]
MW (SD)	-0,00 (26,667)	-1,45 (27,177)	
LS MW (SE)	0,59 (1,932)	-0,25 (2,023)	
95 %-KI	[-3,218; 4,404]	[-4,235; 3,744]	
Veränderung zu Woche 15/16			
n/N (%)	54/120 (45)	35/105 (33)	LS MD 0,75 [-4,791; 6,285]
MW (SD)	-1,23 (28,197)	2,86 (26,036)	
LS MW (SE)	0,60 (1,917)	-0,15 (2,032)	
95 %-KI	[-3,181; 4,384]	[-4,153; 3,862]	
Veränderung zu Woche 20/21			
n/N (%)	40/117 (34)	32/101 (32)	LS MD 0,62 [-5,243; 6,476]
MW (SD)	6,67 (21,616)	5,21 (25,554)	
LS MW (SE)	0,61 (1,997)	-0,00 (2,187)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,323; 4,551]	[-4,309; 4,305]	
Veränderung zu Woche 24			
n/N (%)	27/112 (24)	22/96 (23)	LS MD 0,52 [-5,765; 6,815]
MW (SD)	-1,23 (28,467)	-10,61 (27,958)	
LS MW (SE)	0,62 (2,117)	0,10 (2,379)	
95 %-KI	[-3,547; 4,793]	[-4,582; 4,779]	
Veränderung zu Woche 36			
n/N (%)	49/99 (49)	35/87 (40)	LS MD 0,21 [-8,409; 8,830]
MW (SD)	3,40 (33,503)	-6,67 (35,054)	
LS MW (SE)	0,65 (2,811)	0,44 (3,359)	
95 %-KI	[-4,871; 6,177]	[-6,156; 7,041]	
Veränderung zu Woche 48			
n/N (%)	5/87 (6)	3/72 (4)	LS MD -0,10 [-11,728; 11,520]
MW (SD)	-13,33 (38,006)	-22,22 (19,245)	
LS MW (SE)	0,68 (3,742)	0,79 (4,580)	
95 %-KI	[-6,664; 8,030]	[-8,206; 9,779]	
<b>Baseline ECOG PS: 1</b>			
Baseline			
n/N (%)	76/90 (84)	60/91 (66)	-
MW (SD)	28,07 (32,684)	31,11 (34,645)	
Absolute Werte zum Studienende			
n/N (%)	3/53 (6)	3/37 (8)	-
MW (SD)	11,11 (19,245)	0,00 (0,000)	
Effekt über Studiendauer			
n	76	60	LS MD -1,03 [-8,262; 6,211] 0,7796
LS MW (SE)	-6,72 (2,355)	-5,69 (2,799)	
95 %-KI	[-11,379; -2,052]	[-11,224; -0,156]	Hedges' g -0,05 [-0,387; 0,290]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	51/86 (59)	45/87 (52)	LS MD -2,95 [-11,071; 5,165]
MW (SD)	-3,92 (33,097)	-5,19 (29,263)	
LS MW (SE)	-6,76 (2,703)	-3,81 (3,107)	
95 %-KI	[-12,088; -1,431]	[-9,931; 2,317]	
Veränderung zu Woche 8/9			
n/N (%)	61/84 (73)	48/78 (62)	LS MD -2,07 [-9,451; 5,315]
MW (SD)	-8,20 (30,826)	-3,47 (38,432)	
LS MW (SE)	-6,74 (2,452)	-4,67 (2,819)	
95 %-KI	[-11,586; -1,893]	[-10,240; 0,898]	
Veränderung zu Woche 12			
n/N (%)	45/83 (54)	24/74 (32)	LS MD -1,45 [-8,645; 5,747]
MW (SD)	-9,63 (28,974)	-8,33 (24,574)	
LS MW (SE)	-6,73 (2,366)	-5,28 (2,762)	
95 %-KI	[-11,409; -2,042]	[-10,739; 0,186]	
Veränderung zu Woche 15/16			
n/N (%)	40/79 (51)	20/72 (28)	LS MD -0,83 [-8,132; 6,472]
MW (SD)	-8,33 (37,553)	-10,00 (26,710)	
LS MW (SE)	-6,71 (2,364)	-5,88 (2,836)	
95 %-KI	[-11,391; -2,031]	[-11,487; -0,276]	
Veränderung zu Woche 20/21			
n/N (%)	26/73 (36)	18/63 (29)	LS MD 0,05 [-7,879; 7,988]
MW (SD)	-6,41 (38,895)	-11,11 (25,565)	
LS MW (SE)	-6,69 (2,504)	-6,75 (3,144)	
95 %-KI	[-11,641; -1,741]	[-12,948; -0,544]	
Veränderung zu Woche 24			
n/N (%)	26/72 (36)	15/58 (26)	LS MD 0,67 [-7,982; 9,330]
MW (SD)	-7,69 (34,393)	-6,67 (31,371)	
LS MW (SE)	-6,68 (2,690)	-7,35 (3,473)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-11,986; -1,368]	[-14,191; -0,510]	
Veränderung zu Woche 36			
n/N (%)	31/61 (51)	13/46 (28)	LS MD 2,80 [-9,419; 15,012]
MW (SD)	-7,53 (31,867)	0,00 (33,333)	
LS MW (SE)	-6,63 (3,690)	-9,43 (5,003)	
95 %-KI	[-13,886; 0,628]	[-19,259; 0,408]	
Veränderung zu Woche 48			
n/N (%)	3/53 (6)	2/37 (5)	LS MD 4,92 [-11,662; 21,501]
MW (SD)	0,00 (33,333)	-16,67 (23,570)	
LS MW (SE)	-6,58 (4,974)	-11,50 (6,822)	
95 %-KI	[-16,355; 3,194]	[-24,905; 1,906]	
<b>Anzahl vorheriger Therapielinien: 1</b>			
Baseline			
n/N (%)	24/31 (77)	23/29 (79)	-
MW (SD)	19,44 (32,477)	15,94 (22,178)	
Absolute Werte zum Studienende			
n/N (%)	1/22 (5)	0/14 (0)	-
MW (SD)	33,33 (NA)	NA (NA)	
Effekt über Studiendauer			
n	24	23	LS MD -3,49 [-13,063; 6,073] 0,4646
LS MW (SE)	0,78 (3,231)	4,27 (3,469)	
95 %-KI	[-5,765; 7,322]	[-2,726; 11,273]	Hedges' g -0,21 [-0,785; 0,362]
Veränderung zu Woche 3/4			
n/N (%)	16/31 (52)	15/29 (52)	LS MD 3,27 [-8,846; 15,380]
MW (SD)	8,33 (31,032)	-2,22 (19,787)	
LS MW (SE)	1,07 (4,152)	-2,20 (4,468)	
95 %-KI	[-7,178; 9,317]	[-11,060; 6,665]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	20/31 (65)	18/26 (69)	LS MD 0,42 [-9,946; 10,790]
MW (SD)	-6,67 (29,814)	3,70 (19,433)	
LS MW (SE)	0,95 (3,580)	0,53 (3,743)	
95 %-KI	[-6,225; 8,119]	[-6,958; 8,008]	
Veränderung zu Woche 12			
n/N (%)	14/31 (45)	12/24 (50)	LS MD -1,57 [-11,266; 8,127]
MW (SD)	-4,76 (28,815)	-8,33 (32,177)	
LS MW (SE)	0,86 (3,328)	2,43 (3,479)	
95 %-KI	[-5,852; 7,574]	[-4,572; 9,434]	
Veränderung zu Woche 15/16			
n/N (%)	15/31 (48)	11/22 (50)	LS MD -3,56 [-13,134; 6,012]
MW (SD)	-2,22 (29,457)	12,12 (26,968)	
LS MW (SE)	0,78 (3,231)	4,34 (3,473)	
95 %-KI	[-5,767; 7,318]	[-2,671; 11,344]	
Veränderung zu Woche 20/21			
n/N (%)	11/30 (37)	9/22 (41)	LS MD -6,41 [-16,755; 3,943]
MW (SD)	9,09 (21,556)	14,81 (17,568)	
LS MW (SE)	0,65 (3,385)	7,06 (3,903)	
95 %-KI	[-6,167; 7,473]	[-0,766; 14,884]	
Veränderung zu Woche 24			
n/N (%)	9/30 (30)	11/20 (55)	LS MD -8,40 [-19,864; 3,069]
MW (SD)	0,00 (23,570)	-6,06 (20,101)	
LS MW (SE)	0,57 (3,677)	8,96 (4,440)	
95 %-KI	[-6,789; 7,923]	[0,113; 17,816]	
Veränderung zu Woche 36			
n/N (%)	15/26 (58)	6/18 (33)	LS MD -15,23 [-32,637; 2,187]
MW (SD)	2,22 (29,457)	16,67 (27,889)	
LS MW (SE)	0,27 (5,386)	15,50 (7,016)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-10,371; 10,918]	[1,627; 29,370]	
Veränderung zu Woche 48			
n/N (%)	0/22 (0)	0/14 (0)	LS MD -22,05 [-46,783; 2,677]
MW (SD)	NA (NA)	NA (NA)	
LS MW (SE)	-0,02 (7,587)	22,03 (10,032)	
95 %-KI	[-14,993; 14,952]	[2,226; 41,838]	
<b>Anzahl vorheriger Therapielinien: 2</b>			
Baseline			
n/N (%)	76/89 (85)	64/83 (77)	-
MW (SD)	23,25 (30,802)	29,69 (33,130)	
Absolute Werte zum Studienende			
n/N (%)	4/59 (7)	2/50 (4)	-
MW (SD)	33,33 (27,217)	0,00 (0,000)	
Effekt über Studiendauer			
n	76	64	LS MD 0,23 [-6,257; 6,722] 0,9436  Hedges' g 0,01 [-0,320; 0,345]
LS MW (SE)	-4,39 (2,136)	-4,62 (2,485)	
95 %-KI	[-8,620; -0,164]	[-9,536; 0,287]	
Veränderung zu Woche 3/4			
n/N (%)	54/86 (63)	46/80 (57)	LS MD -2,61 [-10,007; 4,779]
MW (SD)	-3,70 (30,141)	-0,72 (26,749)	
LS MW (SE)	-4,96 (2,469)	-2,34 (2,820)	
95 %-KI	[-9,823; -0,088]	[-7,896; 3,213]	
Veränderung zu Woche 8/9			
n/N (%)	64/85 (75)	51/77 (66)	LS MD -1,33 [-8,006; 5,336]
MW (SD)	-4,17 (27,539)	-9,15 (34,045)	
LS MW (SE)	-4,70 (2,237)	-3,37 (2,524)	
95 %-KI	[-9,123; -0,281]	[-8,351; 1,617]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	39/83 (47)	31/75 (41)	LS MD -0,44 [-6,904; 6,025]
MW (SD)	-5,13 (24,825)	-6,45 (24,973)	
LS MW (SE)	-4,53 (2,152)	-4,09 (2,454)	
95 %-KI	[-8,784; -0,266]	[-8,937; 0,766]	
Veränderung zu Woche 15/16			
n/N (%)	42/80 (52)	20/74 (27)	LS MD 0,46 [-6,077; 6,988]
MW (SD)	-9,52 (30,609)	-0,00 (28,613)	
LS MW (SE)	-4,35 (2,140)	-4,80 (2,510)	
95 %-KI	[-8,584; -0,112]	[-9,765; 0,158]	
Veränderung zu Woche 20/21			
n/N (%)	32/78 (41)	21/68 (31)	LS MD 1,73 [-5,348; 8,817]
MW (SD)	-0,00 (26,774)	-4,76 (32,121)	
LS MW (SE)	-4,09 (2,250)	-5,83 (2,790)	
95 %-KI	[-8,542; 0,353]	[-11,333; -0,326]	
Veränderung zu Woche 24			
n/N (%)	27/74 (36)	13/65 (20)	LS MD 2,63 [-5,104; 10,364]
MW (SD)	-7,41 (29,719)	-10,26 (34,385)	
LS MW (SE)	-3,92 (2,406)	-6,55 (3,096)	
95 %-KI	[-8,667; 0,831]	[-12,645; -0,450]	
Veränderung zu Woche 36			
n/N (%)	34/65 (52)	19/58 (33)	LS MD 5,70 [-5,288; 16,686]
MW (SD)	-1,96 (33,776)	-3,51 (24,582)	
LS MW (SE)	-3,31 (3,276)	-9,01 (4,529)	
95 %-KI	[-9,751; 3,131]	[-17,910; -0,109]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	1/50 (2)	LS MD 8,77 [-6,223; 23,760]
MW (SD)	-0,00 (47,140)	-33,33 (NA)	
LS MW (SE)	-2,70 (4,410)	-11,47 (6,229)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-11,368; 5,963]	[-23,710; 0,767]	
<b>Anzahl vorheriger Therapielinien: 3</b>			
Baseline			
n/N (%)	76/98 (78)	71/95 (75)	-
MW (SD)	22,81 (29,419)	32,39 (32,353)	
Absolute Werte zum Studienende			
n/N (%)	5/59 (8)	4/46 (9)	-
MW (SD)	6,67 (14,907)	25,00 (31,914)	
Effekt über Studiendauer			
n	76	71	LS MD 0,44 [-7,023; 7,913] 0,9064  Hedges' g 0,02 [-0,304; 0,343]
LS MW (SE)	-1,84 (2,577)	-2,29 (2,738)	
95 %-KI	[-6,940; 3,251]	[-7,700; 3,122]	
Veränderung zu Woche 3/4			
n/N (%)	51/96 (53)	49/91 (54)	LS MD -0,49 [-8,697; 7,708]
MW (SD)	-0,65 (29,432)	-10,88 (26,691)	
LS MW (SE)	-1,51 (2,839)	-1,02 (3,006)	
95 %-KI	[-7,110; 4,088]	[-6,942; 4,910]	
Veränderung zu Woche 8/9			
n/N (%)	61/94 (65)	55/85 (65)	LS MD -0,08 [-7,716; 7,564]
MW (SD)	-0,00 (27,889)	1,21 (36,831)	
LS MW (SE)	-1,66 (2,645)	-1,58 (2,792)	
95 %-KI	[-6,885; 3,566]	[-7,097; 3,930]	
Veränderung zu Woche 12			
n/N (%)	43/91 (47)	28/84 (33)	LS MD 0,22 [-7,250; 7,683]
MW (SD)	-3,88 (31,040)	1,19 (24,816)	
LS MW (SE)	-1,76 (2,581)	-1,98 (2,730)	
95 %-KI	[-6,867; 3,341]	[-7,376; 3,416]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	37/88 (42)	24/82 (29)	LS MD 0,51 [-6,981; 8,000]
MW (SD)	0,90 (35,561)	-9,72 (23,008)	
LS MW (SE)	-1,87 (2,583)	-2,38 (2,748)	
95 %-KI	[-6,975; 3,240]	[-7,808; 3,055]	
Veränderung zu Woche 20/21			
n/N (%)	23/82 (28)	21/75 (28)	LS MD 0,93 [-6,932; 8,788]
MW (SD)	-0,00 (37,605)	-3,17 (20,829)	
LS MW (SE)	-2,02 (2,696)	-2,94 (2,907)	
95 %-KI	[-7,342; 3,311]	[-8,682; 2,795]	
Veränderung zu Woche 24			
n/N (%)	17/80 (21)	14/70 (20)	LS MD 1,22 [-7,109; 9,550]
MW (SD)	-1,96 (38,135)	-9,52 (30,462)	
LS MW (SE)	-2,12 (2,847)	-3,34 (3,101)	
95 %-KI	[-7,736; 3,497]	[-9,452; 2,772]	
Veränderung zu Woche 36			
n/N (%)	31/69 (45)	23/58 (40)	LS MD 2,22 [-8,658; 13,107]
MW (SD)	-1,08 (34,943)	-11,59 (40,959)	
LS MW (SE)	-2,48 (3,681)	-4,70 (4,113)	
95 %-KI	[-9,715; 4,763]	[-12,786; 3,385]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	4/46 (9)	LS MD 3,23 [-11,028; 17,485]
MW (SD)	-16,67 (19,245)	-16,67 (19,245)	
LS MW (SE)	-2,83 (4,795)	-6,06 (5,418)	
95 %-KI	[-12,256; 6,591]	[-16,708; 4,586]	
<b>Vorherige Verabreichung von Bevacizumab: Ja</b>			
Baseline			
n/N (%)	104/134 (78)	99/132 (75)	-
MW (SD)	20,83 (26,759)	28,96 (31,460)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	3/79 (4)	3/62 (5)	-
MW (SD)	33,33 (0,000)	11,11 (19,245)	
Effekt über Studiendauer			
n	104	99	LS MD -0,67 [-6,678; 5,338] 0,8260  Hedges' g -0,03 [-0,306; 0,244]
LS MW (SE)	-0,32 (2,062)	0,35 (2,227)	
95 %-KI	[-4,394; 3,744]	[-4,044; 4,736]	
Veränderung zu Woche 3/4			
n/N (%)	68/130 (52)	69/127 (54)	LS MD -2,66 [-9,413; 4,096]
MW (SD)	2,45 (28,399)	-4,83 (29,856)	
LS MW (SE)	-0,61 (2,338)	2,05 (2,492)	
95 %-KI	[-5,215; 3,990]	[-2,856; 6,949]	
Veränderung zu Woche 8/9			
n/N (%)	85/130 (65)	75/119 (63)	LS MD -1,73 [-7,867; 4,417]
MW (SD)	-0,00 (25,717)	2,67 (33,225)	
LS MW (SE)	-0,48 (2,139)	1,25 (2,248)	
95 %-KI	[-4,694; 3,739]	[-3,182; 5,677]	
Veränderung zu Woche 12			
n/N (%)	54/126 (43)	38/114 (33)	LS MD -1,07 [-7,056; 4,913]
MW (SD)	-0,00 (27,472)	-5,26 (29,537)	
LS MW (SE)	-0,38 (2,071)	0,69 (2,201)	
95 %-KI	[-4,469; 3,703]	[-3,650; 5,028]	
Veränderung zu Woche 15/16			
n/N (%)	56/122 (46)	32/112 (29)	LS MD -0,42 [-6,488; 5,652]
MW (SD)	-4,17 (31,180)	1,04 (29,916)	
LS MW (SE)	-0,29 (2,069)	0,13 (2,264)	
95 %-KI	[-4,372; 3,795]	[-4,333; 4,592]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	38/114 (33)	28/103 (27)	LS MD 0,52 [-6,077; 7,108]
MW (SD)	1,75 (27,886)	-5,95 (25,746)	
LS MW (SE)	-0,15 (2,181)	-0,67 (2,528)	
95 %-KI	[-4,453; 4,146]	[-5,643; 4,306]	
Veränderung zu Woche 24			
n/N (%)	28/109 (26)	17/95 (18)	LS MD 1,17 [-6,022; 8,360]
MW (SD)	2,38 (27,108)	-9,80 (30,652)	
LS MW (SE)	-0,06 (2,330)	-1,23 (2,806)	
95 %-KI	[-4,647; 4,529]	[-6,744; 4,289]	
Veränderung zu Woche 36			
n/N (%)	43/93 (46)	22/79 (28)	LS MD 3,41 [-6,729; 13,548]
MW (SD)	-0,78 (32,111)	-1,52 (26,181)	
LS MW (SE)	0,27 (3,140)	-3,14 (4,087)	
95 %-KI	[-5,902; 6,433]	[-11,171; 4,882]	
Veränderung zu Woche 48			
n/N (%)	3/79 (4)	2/62 (3)	LS MD 5,65 [-8,105; 19,405]
MW (SD)	-11,11 (50,918)	-16,67 (23,570)	
LS MW (SE)	0,59 (4,191)	-5,06 (5,599)	
95 %-KI	[-7,641; 8,820]	[-16,054; 5,933]	
<b>Vorherige Verabreichung von Bevacizumab: Nein</b>			
Baseline			
n/N (%)	72/84 (86)	59/75 (79)	-
MW (SD)	25,00 (34,826)	28,81 (32,435)	
Absolute Werte zum Studienende			
n/N (%)	7/61 (11)	3/48 (6)	-
MW (SD)	14,29 (26,227)	22,22 (38,490)	
Effekt über Studiendauer			
n	72	59	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-5,63 (2,143)	-6,10 (2,431)	LS MD 0,47 [-5,943; 6,888] 0,8843  Hedges' g 0,03 [-0,319; 0,370]
95 %-KI	[-9,872; -1,384]	[-10,911; -1,290]	
Veränderung zu Woche 3/4			
n/N (%)	53/83 (64)	41/73 (56)	LS MD 1,47 [-5,943; 8,883]
MW (SD)	-5,03 (31,620)	-6,50 (18,588)	
LS MW (SE)	-5,61 (2,486)	-7,08 (2,824)	
95 %-KI	[-10,512; -0,712]	[-12,648; -1,516]	
Veränderung zu Woche 8/9			
n/N (%)	60/80 (75)	49/69 (71)	LS MD 1,06 [-5,664; 7,781]
MW (SD)	-6,67 (30,563)	-10,88 (33,602)	
LS MW (SE)	-5,62 (2,257)	-6,68 (2,548)	
95 %-KI	[-10,078; -1,159]	[-11,710; -1,644]	
Veränderung zu Woche 12			
n/N (%)	42/79 (53)	33/69 (48)	LS MD 0,77 [-5,693; 7,233]
MW (SD)	-10,32 (28,023)	-2,02 (21,952)	
LS MW (SE)	-5,62 (2,166)	-6,39 (2,445)	
95 %-KI	[-9,910; -1,336]	[-11,231; -1,556]	
Veränderung zu Woche 15/16			
n/N (%)	38/77 (49)	23/66 (35)	LS MD 0,48 [-5,931; 6,896]
MW (SD)	-4,39 (34,806)	-5,80 (21,678)	
LS MW (SE)	-5,63 (2,143)	-6,11 (2,430)	
95 %-KI	[-9,871; -1,384]	[-10,919; -1,301]	
Veränderung zu Woche 20/21			
n/N (%)	28/76 (37)	23/62 (37)	LS MD 0,07 [-6,640; 6,781]
MW (SD)	1,19 (33,311)	5,80 (25,922)	
LS MW (SE)	-5,63 (2,228)	-5,70 (2,560)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-10,041; -1,227]	[-10,764; -0,646]	
Veränderung zu Woche 24			
n/N (%)	25/75 (33)	21/60 (35)	LS MD -0,22 [-7,370; 6,935]
MW (SD)	-12,00 (34,534)	-7,94 (27,698)	
LS MW (SE)	-5,64 (2,363)	-5,42 (2,745)	
95 %-KI	[-10,306; -0,972]	[-10,838; -0,005]	
Veränderung zu Woche 36			
n/N (%)	37/67 (55)	26/55 (47)	LS MD -1,21 [-10,881; 8,470]
MW (SD)	-0,90 (34,682)	-7,69 (40,340)	
LS MW (SE)	-5,65 (3,158)	-4,45 (3,770)	
95 %-KI	[-11,867; 0,558]	[-11,862; 2,964]	
Veränderung zu Woche 48			
n/N (%)	5/61 (8)	3/48 (6)	LS MD -2,19 [-15,212; 10,826]
MW (SD)	-6,67 (27,889)	-22,22 (19,245)	
LS MW (SE)	-5,67 (4,227)	-3,48 (5,100)	
95 %-KI	[-13,975; 2,635]	[-13,498; 6,545]	
<b>Letztes Platin-freies Intervall: ≤ 3 Monate</b>			
Baseline			
n/N (%)	67/83 (81)	62/91 (68)	-
MW (SD)	20,90 (30,059)	34,41 (31,920)	
Absolute Werte zum Studienende			
n/N (%)	3/55 (5)	5/39 (13)	-
MW (SD)	11,11 (19,245)	20,00 (29,814)	
Effekt über Studiendauer			
n	67	62	LS MD -2,65 [-10,678; 5,387] 0,5156
LS MW (SE)	-5,97 (2,734)	-3,33 (2,950)	
95 %-KI	[-11,387; -0,557]	[-9,163; 2,511]	Hedges' g -0,12 [-0,461; 0,230]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	49/82 (60)	46/86 (53)	LS MD -3,77 [-12,527; 4,988]
MW (SD)	-4,08 (32,370)	-7,97 (29,131)	
LS MW (SE)	-6,13 (3,015)	-2,36 (3,205)	
95 %-KI	[-12,078; -0,177]	[-8,680; 3,965]	
Veränderung zu Woche 8/9			
n/N (%)	51/81 (63)	46/80 (57)	LS MD -3,25 [-11,416; 4,911]
MW (SD)	-5,23 (20,410)	-7,97 (40,482)	
LS MW (SE)	-6,06 (2,798)	-2,80 (2,981)	
95 %-KI	[-11,592; -0,520]	[-8,697; 3,091]	
Veränderung zu Woche 12			
n/N (%)	33/78 (42)	24/78 (31)	LS MD -2,89 [-10,898; 5,117]
MW (SD)	-7,07 (24,661)	0,00 (19,659)	
LS MW (SE)	-6,01 (2,733)	-3,12 (2,931)	
95 %-KI	[-11,419; -0,592]	[-8,915; 2,684]	
Veränderung zu Woche 15/16			
n/N (%)	33/76 (43)	14/75 (19)	LS MD -2,53 [-10,610; 5,553]
MW (SD)	-4,04 (38,871)	-4,76 (22,100)	
LS MW (SE)	-5,96 (2,747)	-3,43 (2,974)	
95 %-KI	[-11,396; -0,515]	[-9,311; 2,456]	
Veränderung zu Woche 20/21			
n/N (%)	21/72 (29)	14/67 (21)	LS MD -2,01 [-10,581; 6,558]
MW (SD)	1,59 (30,689)	4,76 (22,100)	
LS MW (SE)	-5,88 (2,898)	-3,87 (3,188)	
95 %-KI	[-11,615; -0,153]	[-10,170; 2,424]	
Veränderung zu Woche 24			
n/N (%)	15/72 (21)	12/62 (19)	LS MD -1,65 [-10,796; 7,497]
MW (SD)	-11,11 (29,991)	-5,56 (27,828)	
LS MW (SE)	-5,83 (3,086)	-4,18 (3,430)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-11,927; 0,258]	[-10,949; 2,579]	
Veränderung zu Woche 36			
n/N (%)	27/63 (43)	18/50 (36)	LS MD -0,41 [-12,552; 11,736]
MW (SD)	-8,64 (37,659)	-9,26 (37,583)	
LS MW (SE)	-5,66 (4,081)	-5,25 (4,629)	
95 %-KI	[-13,692; 2,367]	[-14,359; 3,850]	
Veränderung zu Woche 48			
n/N (%)	2/55 (4)	4/39 (10)	LS MD 0,83 [-15,166; 16,833]
MW (SD)	-33,33 (47,140)	-25,00 (16,667)	
LS MW (SE)	-5,49 (5,373)	-6,32 (6,130)	
95 %-KI	[-16,054; 5,072]	[-18,375; 5,727]	
<b>Letztes Platin-freies Intervall: &gt; 3 Monate</b>			
Baseline			
n/N (%)	109/135 (81)	96/116 (83)	-
MW (SD)	23,55 (30,531)	25,35 (31,249)	
Absolute Werte zum Studienende			
n/N (%)	7/85 (8)	1/71 (1)	-
MW (SD)	23,81 (25,198)	0,00 (NA)	
Effekt über Studiendauer			
n	109	96	LS MD 0,95 [-4,305; 6,207] 0,7216
LS MW (SE)	-0,58 (1,780)	-1,53 (1,983)	
95 %-KI	[-4,087; 2,936]	[-5,436; 2,384]	Hedges' g 0,05 [-0,224; 0,324]
Veränderung zu Woche 3/4			
n/N (%)	72/131 (55)	64/114 (56)	LS MD 0,67 [-5,466; 6,806]
MW (SD)	1,39 (28,216)	-3,65 (23,843)	
LS MW (SE)	-0,70 (2,083)	-1,37 (2,323)	
95 %-KI	[-4,795; 3,399]	[-5,935; 3,200]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	94/129 (73)	78/108 (72)	LS MD 0,79 [-4,696; 6,281]
MW (SD)	-1,42 (31,267)	0,43 (29,175)	
LS MW (SE)	-0,64 (1,880)	-1,44 (2,056)	
95 %-KI	[-4,349; 3,060]	[-5,487; 2,613]	
Veränderung zu Woche 12			
n/N (%)	63/127 (50)	47/105 (45)	LS MD 0,88 [-4,391; 6,146]
MW (SD)	-3,17 (29,763)	-5,67 (28,925)	
LS MW (SE)	-0,61 (1,801)	-1,48 (1,974)	
95 %-KI	[-4,159; 2,944]	[-5,377; 2,407]	
Veränderung zu Woche 15/16			
n/N (%)	61/123 (50)	41/103 (40)	LS MD 0,96 [-4,307; 6,233]
MW (SD)	-4,37 (28,852)	-0,81 (28,370)	
LS MW (SE)	-0,57 (1,781)	-1,53 (1,992)	
95 %-KI	[-4,083; 2,943]	[-5,459; 2,393]	
Veränderung zu Woche 20/21			
n/N (%)	45/118 (38)	37/98 (38)	LS MD 1,08 [-4,564; 6,734]
MW (SD)	1,48 (30,114)	-2,70 (27,642)	
LS MW (SE)	-0,52 (1,858)	-1,60 (2,182)	
95 %-KI	[-4,180; 3,146]	[-5,898; 2,694]	
Veränderung zu Woche 24			
n/N (%)	38/112 (34)	26/93 (28)	LS MD 1,17 [-4,971; 7,312]
MW (SD)	-1,75 (31,904)	-10,26 (29,468)	
LS MW (SE)	-0,48 (1,980)	-1,65 (2,409)	
95 %-KI	[-4,378; 3,419]	[-6,388; 3,088]	
Veränderung zu Woche 36			
n/N (%)	53/97 (55)	30/84 (36)	LS MD 1,46 [-7,248; 10,175]
MW (SD)	3,14 (30,145)	-2,22 (32,676)	
LS MW (SE)	-0,35 (2,683)	-1,81 (3,524)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-5,622; 4,919]	[-8,735; 5,105]	
Veränderung zu Woche 48			
n/N (%)	6/85 (7)	1/71 (1)	LS MD 1,76 [-10,178; 13,690]
MW (SD)	0,00 (29,814)	0,00 (NA)	
LS MW (SE)	-0,22 (3,617)	-1,98 (4,873)	
95 %-KI	[-7,325; 6,877]	[-11,546; 7,586]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Pegyliertes liposomales Doxorubicin</b>			
Baseline			
n/N (%)	62/80 (78)	57/76 (75)	-
MW (SD)	19,35 (28,661)	26,32 (31,958)	
Absolute Werte zum Studienende			
n/N (%)	3/51 (6)	3/41 (7)	-
MW (SD)	33,33 (33,333)	22,22 (38,490)	
Effekt über Studiendauer			
n	62	57	LS MD 0,13 [-6,900; 7,168] 0,9700  Hedges' g 0,01 [-0,353; 0,367]
LS MW (SE)	1,39 (2,367)	1,26 (2,621)	
95 %-KI	[-3,299; 6,089]	[-3,929; 6,451]	
Veränderung zu Woche 3/4			
n/N (%)	42/76 (55)	43/74 (58)	LS MD 2,26 [-5,981; 10,502]
MW (SD)	-0,79 (28,973)	-4,65 (23,661)	
LS MW (SE)	-0,53 (2,842)	-2,79 (3,048)	
95 %-KI	[-6,130; 5,079]	[-8,793; 3,221]	
Veränderung zu Woche 8/9			
n/N (%)	52/76 (68)	44/66 (67)	LS MD 1,33 [-5,982; 8,634]
MW (SD)	3,21 (29,711)	-4,55 (30,996)	
LS MW (SE)	0,32 (2,526)	-1,01 (2,683)	
95 %-KI	[-4,678; 5,315]	[-6,312; 4,297]	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	33/75 (44)	23/64 (36)	LS MD 0,67 [-6,345; 7,690]
MW (SD)	-3,03 (29,302)	-2,90 (26,425)	
LS MW (SE)	0,91 (2,400)	0,24 (2,587)	
95 %-KI	[-3,848; 5,666]	[-4,886; 5,360]	
Veränderung zu Woche 15/16			
n/N (%)	33/74 (45)	19/62 (31)	LS MD 0,02 [-7,051; 7,087]
MW (SD)	5,05 (38,298)	3,51 (33,138)	
LS MW (SE)	1,50 (2,368)	1,48 (2,641)	
95 %-KI	[-3,197; 6,197]	[-3,747; 6,711]	
Veränderung zu Woche 20/21			
n/N (%)	26/72 (36)	18/59 (31)	LS MD -0,92 [-8,627; 6,794]
MW (SD)	10,26 (32,344)	9,26 (25,063)	
LS MW (SE)	2,34 (2,489)	3,26 (2,956)	
95 %-KI	[-2,586; 7,273]	[-2,580; 9,100]	
Veränderung zu Woche 24			
n/N (%)	21/69 (30)	16/54 (30)	LS MD -1,57 [-10,060; 6,919]
MW (SD)	-1,59 (32,449)	-2,08 (22,669)	
LS MW (SE)	2,93 (2,679)	4,50 (3,307)	
95 %-KI	[-2,359; 8,227]	[-2,015; 11,025]	
Veränderung zu Woche 36			
n/N (%)	30/60 (50)	16/48 (33)	LS MD -3,81 [-16,190; 8,564]
MW (SD)	7,78 (31,175)	4,17 (43,674)	
LS MW (SE)	4,96 (3,752)	8,77 (4,942)	
95 %-KI	[-2,421; 12,340]	[-0,947; 18,492]	
Veränderung zu Woche 48			
n/N (%)	2/51 (4)	2/41 (5)	LS MD -6,06 [-23,172; 11,061]
MW (SD)	16,67 (23,570)	-33,33 (0,000)	
LS MW (SE)	6,98 (5,144)	13,04 (6,868)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,127; 17,097]	[-0,462; 26,542]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Paclitaxel</b>			
Baseline			
n/N (%)	75/88 (85)	69/82 (84)	-
MW (SD)	27,11 (33,195)	32,37 (31,814)	
Absolute Werte zum Studienende			
n/N (%)	1/56 (2)	1/49 (2)	-
MW (SD)	33,33 (NA)	0,00 (NA)	
Effekt über Studiendauer			
n	75	69	LS MD 0,11 [-6,827; 7,050] 0,9747  Hedges' g 0,01 [-0,322; 0,332]
LS MW (SE)	-6,73 (2,389)	-6,84 (2,565)	
95 %-KI	[-11,451; -2,001]	[-11,908; -1,767]	
Veränderung zu Woche 3/4			
n/N (%)	55/87 (63)	49/81 (60)	LS MD -3,53 [-11,256; 4,194]
MW (SD)	-2,42 (31,982)	-6,80 (31,165)	
LS MW (SE)	-6,48 (2,665)	-2,94 (2,869)	
95 %-KI	[-11,730; -1,221]	[-8,597; 2,708]	
Veränderung zu Woche 8/9			
n/N (%)	63/86 (73)	54/79 (68)	LS MD -1,88 [-8,999; 5,235]
MW (SD)	-8,99 (27,570)	-4,94 (36,862)	
LS MW (SE)	-6,59 (2,462)	-4,71 (2,625)	
95 %-KI	[-11,454; -1,724]	[-9,892; 0,477]	
Veränderung zu Woche 12			
n/N (%)	42/84 (50)	36/77 (47)	LS MD -0,73 [-7,662; 6,207]
MW (SD)	-7,14 (26,066)	-7,41 (27,730)	
LS MW (SE)	-6,67 (2,395)	-5,94 (2,557)	
95 %-KI	[-11,405; -1,932]	[-10,995; -0,887]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	45/81 (56)	28/76 (37)	LS MD 0,43 [-6,543; 7,396]
MW (SD)	-9,63 (25,248)	-5,95 (24,094)	
LS MW (SE)	-6,75 (2,396)	-7,17 (2,581)	
95 %-KI	[-11,487; -2,009]	[-12,275; -2,074]	
Veränderung zu Woche 20/21			
n/N (%)	29/77 (38)	26/73 (36)	LS MD 2,08 [-5,312; 9,464]
MW (SD)	-2,30 (29,454)	-7,69 (27,175)	
LS MW (SE)	-6,86 (2,514)	-8,94 (2,768)	
95 %-KI	[-11,826; -1,896]	[-14,400; -3,475]	
Veränderung zu Woche 24			
n/N (%)	21/74 (28)	19/72 (26)	LS MD 3,23 [-4,677; 11,138]
MW (SD)	-11,11 (28,545)	-15,79 (34,009)	
LS MW (SE)	-6,94 (2,669)	-10,17 (2,991)	
95 %-KI	[-12,205; -1,676]	[-16,065; -4,277]	
Veränderung zu Woche 36			
n/N (%)	35/64 (55)	24/63 (38)	LS MD 7,19 [-3,465; 17,842]
MW (SD)	-6,67 (37,747)	-13,89 (25,851)	
LS MW (SE)	-7,21 (3,521)	-14,40 (4,120)	
95 %-KI	[-14,135; -0,291]	[-22,499; -6,304]	
Veränderung zu Woche 48			
n/N (%)	1/56 (2)	1/49 (2)	LS MD 11,15 [-3,041; 25,335]
MW (SD)	-66,67 (NA)	-33,33 (NA)	
LS MW (SE)	-7,48 (4,642)	-18,63 (5,534)	
95 %-KI	[-16,605; 1,635]	[-29,503; -7,761]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Topotecan</b>			
Baseline			
n/N (%)	39/50 (78)	32/49 (65)	-
MW (SD)	18,80 (26,263)	26,04 (31,377)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	6/33 (18)	2/20 (10)	-
MW (SD)	11,11 (17,213)	16,67 (23,570)	
Effekt über Studiendauer			
n	39	32	LS MD -2,89 [-13,376; 7,595] 0,5840  Hedges' g -0,13 [-0,599; 0,337]
LS MW (SE)	0,13 (3,427)	3,02 (3,972)	
95 %-KI	[-6,725; 6,975]	[-4,905; 10,936]	
Veränderung zu Woche 3/4			
n/N (%)	24/50 (48)	18/45 (40)	LS MD -1,99 [-13,337; 9,357]
MW (SD)	2,78 (27,657)	-3,70 (15,713)	
LS MW (SE)	2,32 (3,713)	4,31 (4,336)	
95 %-KI	[-5,057; 9,705]	[-4,293; 12,921]	
Veränderung zu Woche 8/9			
n/N (%)	30/48 (62)	26/43 (60)	LS MD -2,37 [-13,018; 8,269]
MW (SD)	-0,00 (23,160)	5,13 (32,238)	
LS MW (SE)	1,38 (3,500)	3,76 (4,028)	
95 %-KI	[-5,597; 8,366]	[-4,264; 11,782]	
Veränderung zu Woche 12			
n/N (%)	21/46 (46)	12/42 (29)	LS MD -2,64 [-13,088; 7,800]
MW (SD)	-1,59 (30,689)	5,56 (19,245)	
LS MW (SE)	0,73 (3,430)	3,37 (3,945)	
95 %-KI	[-6,126; 7,580]	[-4,497; 11,239]	
Veränderung zu Woche 15/16			
n/N (%)	16/44 (36)	8/40 (20)	LS MD -2,91 [-13,414; 7,587]
MW (SD)	-8,33 (35,486)	0,00 (17,817)	
LS MW (SE)	0,07 (3,430)	2,98 (3,980)	
95 %-KI	[-6,787; 6,925]	[-4,953; 10,918]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	11/41 (27)	7/33 (21)	LS MD -3,30 [-14,312; 7,715]
MW (SD)	-9,09 (21,556)	0,00 (19,245)	
LS MW (SE)	-0,87 (3,552)	2,43 (4,227)	
95 %-KI	[-7,956; 6,214]	[-5,977; 10,832]	
Veränderung zu Woche 24			
n/N (%)	11/41 (27)	3/29 (10)	LS MD -3,57 [-15,215; 8,079]
MW (SD)	3,03 (34,816)	0,00 (0,000)	
LS MW (SE)	-1,53 (3,715)	2,04 (4,519)	
95 %-KI	[-8,922; 5,865]	[-6,925; 11,004]	
Veränderung zu Woche 36			
n/N (%)	15/36 (42)	8/23 (35)	LS MD -4,49 [-19,570; 10,586]
MW (SD)	-4,44 (21,331)	4,17 (33,034)	
LS MW (SE)	-3,78 (4,645)	0,71 (6,027)	
95 %-KI	[-12,965; 5,397]	[-11,188; 12,604]	
Veränderung zu Woche 48			
n/N (%)	5/33 (15)	2/20 (10)	LS MD -5,42 [-25,046; 14,214]
MW (SD)	-6,67 (27,889)	0,00 (0,000)	
LS MW (SE)	-6,04 (5,924)	-0,62 (7,954)	
95 %-KI	[-17,720; 5,642]	[-16,305; 15,058]	
<p><i>Analysepopulation: ITT</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023</i></p> <p><i>Modell: Veränderung zu Baseline ~ Behandlung + Baseline-Wert * Zeit in Wochen + Behandlung * Zeit in Wochen + zufällige Effekte durch die Patientin</i></p> <p><i>Die Berechnung des LS-MWs erfolgt durch ein MMRM mit dem oben angegebenen Modell. Basierend hierauf werden KI und p-Wert ermittelt. Hedges' g basiert ebenfalls auf den LS-MW und ist somit auf das Modell angepasst.</i></p> <p><i>Es werden ausschließlich gemeinsame Analysezeitpunkte dargestellt.</i></p> <p><i>Ein LS MD und Hedges' g kleiner als Null bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

## 2.3 EORTC QLQ-C30 Diarrhö

### EORTC QLQ-C30 Diarrhö: Subgruppenanalyse

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
<b>EORTC QLQ-C30 Diarrhö</b>			
<b>Alter: &lt; 65 Jahre</b>			
Baseline			
n/N (%)	95/115 (83)	92/119 (77)	-
MW (SD)	9,12 (22,515)	11,23 (20,540)	
Absolute Werte zum Studienende			
n/N (%)	4/73 (5)	4/64 (6)	-
MW (SD)	16,67 (19,245)	16,67 (19,245)	
Effekt über Studiendauer			
n	95	92	LS MD -3,48 [-8,216; 1,262] 0,1494
LS MW (SE)	1,15 (1,642)	4,63 (1,751)	
95 %-KI	[-2,093; 4,392]	[1,171; 8,082]	Hedges' g -0,21 [-0,499; 0,076]
Veränderung zu Woche 3/4			
n/N (%)	61/113 (54)	61/115 (53)	LS MD -2,54 [-7,947; 2,863]
MW (SD)	4,37 (14,241)	5,46 (21,240)	
LS MW (SE)	2,82 (1,892)	5,36 (1,986)	
95 %-KI	[-0,901; 6,547]	[1,457; 9,272]	
Veränderung zu Woche 8/9			
n/N (%)	76/112 (68)	72/108 (67)	LS MD -2,95 [-7,851; 1,944]
MW (SD)	1,32 (26,354)	4,17 (24,980)	
LS MW (SE)	2,09 (1,719)	5,04 (1,793)	
95 %-KI	[-1,303; 5,476]	[1,505; 8,574]	
Veränderung zu Woche 12			
n/N (%)	48/110 (44)	40/105 (38)	
MW (SD)	-1,39 (25,690)	4,17 (21,599)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	1,57 (1,655)	4,81 (1,740)	LS MD -3,24 [-7,979; 1,495]
95 %-KI	[-1,696; 4,837]	[1,381; 8,244]	
Veränderung zu Woche 15/16			
n/N (%)	55/107 (51)	32/102 (31)	LS MD -3,53 [-8,286; 1,226]
MW (SD)	4,85 (23,499)	7,29 (18,422)	
LS MW (SE)	1,05 (1,645)	4,58 (1,761)	
95 %-KI	[-2,192; 4,302]	[1,111; 8,059]	
Veränderung zu Woche 20/21			
n/N (%)	37/101 (37)	30/96 (31)	LS MD -3,94 [-9,028; 1,144]
MW (SD)	-0,90 (24,199)	-3,33 (13,419)	
LS MW (SE)	0,32 (1,724)	4,26 (1,915)	
95 %-KI	[-3,081; 3,718]	[0,488; 8,032]	
Veränderung zu Woche 24			
n/N (%)	25/99 (25)	19/91 (21)	LS MD -4,23 [-9,730; 1,270]
MW (SD)	1,33 (22,526)	3,51 (21,928)	
LS MW (SE)	-0,20 (1,838)	4,03 (2,094)	
95 %-KI	[-3,818; 3,423]	[-0,087; 8,152]	
Veränderung zu Woche 36			
n/N (%)	42/86 (49)	28/79 (35)	LS MD -5,22 [-12,872; 2,436]
MW (SD)	1,59 (25,452)	-1,19 (16,929)	
LS MW (SE)	-1,97 (2,481)	3,25 (2,974)	
95 %-KI	[-6,840; 2,910]	[-2,590; 9,095]	
Veränderung zu Woche 48			
n/N (%)	4/73 (5)	3/64 (5)	LS MD -6,21 [-16,577; 4,165]
MW (SD)	16,67 (19,245)	0,00 (0,000)	
LS MW (SE)	-3,73 (3,327)	2,47 (4,052)	
95 %-KI	[-10,268; 2,801]	[-5,484; 10,430]	
<b>Alter: ≥ 65 Jahre</b>			
Baseline			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	82/103 (80)	67/88 (76)	-
MW (SD)	9,76 (20,613)	7,46 (14,000)	
Absolute Werte zum Studienende			
n/N (%)	6/67 (9)	2/46 (4)	-
MW (SD)	11,11 (27,217)	16,67 (23,570)	
Effekt über Studiendauer			
n	82	67	LS MD 0,18 [-5,575; 5,936] 0,9507
LS MW (SE)	2,96 (1,899)	2,78 (2,202)	
95 %-KI	[-0,797; 6,713]	[-1,573; 7,128]	Hedges' g 0,01 [-0,313; 0,333]
Veränderung zu Woche 3/4			
n/N (%)	60/100 (60)	49/85 (58)	LS MD 0,76 [-5,671; 7,190]
MW (SD)	6,11 (27,782)	2,72 (19,048)	
LS MW (SE)	4,12 (2,144)	3,36 (2,458)	
95 %-KI	[-0,102; 8,349]	[-1,478; 8,206]	
Veränderung zu Woche 8/9			
n/N (%)	69/98 (70)	54/80 (68)	LS MD 0,50 [-5,391; 6,395]
MW (SD)	1,45 (22,459)	3,09 (28,424)	
LS MW (SE)	3,61 (1,971)	3,10 (2,238)	
95 %-KI	[-0,286; 7,498]	[-1,315; 7,522]	
Veränderung zu Woche 12			
n/N (%)	50/95 (53)	32/78 (41)	LS MD 0,32 [-5,415; 6,060]
MW (SD)	-3,33 (16,836)	7,29 (21,972)	
LS MW (SE)	3,24 (1,909)	2,92 (2,182)	
95 %-KI	[-0,531; 7,018]	[-1,391; 7,234]	
Veränderung zu Woche 15/16			
n/N (%)	41/92 (45)	22/76 (29)	
MW (SD)	-0,81 (26,339)	10,61 (27,958)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	2,88 (1,902)	2,74 (2,216)	LS MD 0,14 [-5,639; 5,924]
95 %-KI	[-0,880; 6,643]	[-1,639; 7,118]	
Veränderung zu Woche 20/21			
n/N (%)	30/89 (34)	21/69 (30)	LS MD -0,11 [-6,292; 6,062]
MW (SD)	-3,33 (29,491)	7,94 (27,698)	
LS MW (SE)	2,36 (1,987)	2,48 (2,410)	
95 %-KI	[-1,562; 6,290]	[-2,274; 7,232]	
Veränderung zu Woche 24			
n/N (%)	29/85 (34)	19/64 (30)	LS MD -0,29 [-6,951; 6,361]
MW (SD)	-4,60 (27,781)	10,53 (27,336)	
LS MW (SE)	2,00 (2,107)	2,30 (2,629)	
95 %-KI	[-2,156; 6,160]	[-2,882; 7,476]	
Veränderung zu Woche 36			
n/N (%)	41/74 (55)	19/55 (35)	LS MD -0,91 [-10,037; 8,213]
MW (SD)	1,63 (27,840)	1,75 (13,488)	
LS MW (SE)	0,76 (2,784)	1,67 (3,701)	
95 %-KI	[-4,713; 6,234]	[-5,599; 8,945]	
Veränderung zu Woche 48			
n/N (%)	4/67 (6)	2/46 (4)	LS MD -1,53 [-13,777; 10,718]
MW (SD)	0,00 (0,000)	0,00 (0,000)	
LS MW (SE)	-0,48 (3,683)	1,05 (5,010)	
95 %-KI	[-7,717; 6,755]	[-8,794; 10,890]	
<b>Region: USA</b>			
Baseline			
n/N (%)	48/65 (74)	34/51 (67)	-
MW (SD)	10,42 (20,807)	12,75 (18,376)	
Absolute Werte zum Studienende			
n/N (%)	2/39 (5)	3/27 (11)	-
MW (SD)	0,00 (0,000)	22,22 (19,245)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Effekt über Studiendauer			
n	48	34	LS MD -6,71 [-13,385; -0,027] 0,0491  Hedges' g -0,45 [-0,892; -0,002]
LS MW (SE)	-0,15 (2,121)	6,56 (2,592)	
95 %-KI	[-4,379; 4,086]	[1,395; 11,724]	
Veränderung zu Woche 3/4			
n/N (%)	33/64 (52)	21/49 (43)	LS MD -2,76 [-10,868; 5,339]
MW (SD)	5,05 (25,168)	6,35 (20,053)	
LS MW (SE)	3,14 (2,577)	5,91 (3,182)	
95 %-KI	[-1,951; 8,238]	[-0,382; 12,197]	
Veränderung zu Woche 8/9			
n/N (%)	41/62 (66)	30/46 (65)	LS MD -4,55 [-11,624; 2,526]
MW (SD)	0,00 (18,257)	0,00 (19,574)	
LS MW (SE)	1,65 (2,253)	6,20 (2,759)	
95 %-KI	[-2,822; 6,129]	[0,724; 11,681]	
Veränderung zu Woche 12			
n/N (%)	25/59 (42)	16/45 (36)	LS MD -5,80 [-12,517; 0,920]
MW (SD)	-1,33 (15,154)	10,42 (23,472)	
LS MW (SE)	0,61 (2,137)	6,41 (2,609)	
95 %-KI	[-3,649; 4,870]	[1,213; 11,605]	
Veränderung zu Woche 15/16			
n/N (%)	20/56 (36)	11/44 (25)	LS MD -7,05 [-13,761; -0,335]
MW (SD)	-0,00 (21,630)	21,21 (34,230)	
LS MW (SE)	-0,43 (2,131)	6,62 (2,606)	
95 %-KI	[-4,684; 3,819]	[1,424; 11,808]	
Veränderung zu Woche 20/21			
n/N (%)	12/54 (22)	9/40 (22)	
MW (SD)	-8,33 (25,126)	14,81 (37,680)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-1,92 (2,312)	6,91 (2,850)	LS MD -8,83 [-16,138; -1,528]
95 %-KI	[-6,517; 2,673]	[1,252; 12,570]	
Veränderung zu Woche 24			
n/N (%)	8/53 (15)	6/38 (16)	LS MD -10,08 [-18,153; -2,011]
MW (SD)	-8,33 (23,570)	22,22 (27,217)	
LS MW (SE)	-2,96 (2,549)	7,12 (3,164)	
95 %-KI	[-8,013; 2,084]	[0,854; 13,381]	
Veränderung zu Woche 36			
n/N (%)	22/43 (51)	10/33 (30)	LS MD -14,37 [-26,347; -2,385]
MW (SD)	-4,55 (11,708)	-6,67 (14,055)	
LS MW (SE)	-6,54 (3,756)	7,83 (4,737)	
95 %-KI	[-13,941; 0,860]	[-1,508; 17,159]	
Veränderung zu Woche 48			
n/N (%)	2/39 (5)	3/27 (11)	LS MD -18,65 [-35,409; -1,890]
MW (SD)	0,00 (0,000)	0,00 (0,000)	
LS MW (SE)	-10,12 (5,235)	8,53 (6,640)	
95 %-KI	[-20,424; 0,192]	[-4,541; 21,609]	
<b>Region: Rest der Welt</b>			
Baseline			
n/N (%)	129/153 (84)	125/156 (80)	-
MW (SD)	9,04 (21,950)	8,80 (18,032)	
Absolute Werte zum Studienende			
n/N (%)	8/101 (8)	3/83 (4)	-
MW (SD)	16,67 (25,198)	11,11 (19,245)	
Effekt über Studiendauer			
n	129	125	LS MD -0,37 [-4,599; 3,863] 0,8642 Hedges' g
LS MW (SE)	2,60 (1,467)	2,97 (1,570)	
95 %-KI	[-0,287; 5,493]	[-0,121; 6,062]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
			-0,02 [-0,267; 0,225]
Veränderung zu Woche 3/4			
n/N (%)	88/149 (59)	89/151 (59)	LS MD -1,18 [-5,893; 3,539]
MW (SD)	5,30 (20,768)	3,75 (20,374)	
LS MW (SE)	3,34 (1,655)	4,52 (1,738)	
95 %-KI	[0,087; 6,595]	[1,103; 7,934]	
Veränderung zu Woche 8/9			
n/N (%)	104/148 (70)	96/142 (68)	LS MD -0,82 [-5,156; 3,512]
MW (SD)	1,92 (26,613)	4,86 (28,193)	
LS MW (SE)	3,02 (1,525)	3,84 (1,588)	
95 %-KI	[0,014; 6,020]	[0,713; 6,965]	
Veränderung zu Woche 12			
n/N (%)	73/146 (50)	56/138 (41)	LS MD -0,57 [-4,794; 3,647]
MW (SD)	-2,74 (23,408)	4,17 (21,142)	
LS MW (SE)	2,79 (1,477)	3,36 (1,553)	
95 %-KI	[-0,119; 5,700]	[0,306; 6,421]	
Veränderung zu Woche 15/16			
n/N (%)	76/143 (53)	43/134 (32)	LS MD -0,32 [-4,570; 3,921]
MW (SD)	3,07 (25,634)	5,43 (17,714)	
LS MW (SE)	2,56 (1,468)	2,89 (1,579)	
95 %-KI	[-0,329; 5,456]	[-0,220; 5,997]	
Veränderung zu Woche 20/21			
n/N (%)	55/136 (40)	42/125 (34)	LS MD 0,03 [-4,485; 4,546]
MW (SD)	-0,61 (26,829)	-1,59 (14,636)	
LS MW (SE)	2,24 (1,524)	2,21 (1,716)	
95 %-KI	[-0,762; 5,240]	[-1,167; 5,585]	
Veränderung zu Woche 24			
n/N (%)	46/131 (35)	32/117 (27)	
MW (SD)	-0,72 (25,809)	4,17 (23,570)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	2,01 (1,607)	1,73 (1,870)	LS MD 0,28 [-4,568; 5,127]
95 %-KI	[-1,150; 5,175]	[-1,942; 5,409]	
Veränderung zu Woche 36			
n/N (%)	61/117 (52)	37/101 (37)	LS MD 1,13 [-5,445; 7,709]
MW (SD)	3,83 (29,875)	1,80 (15,607)	
LS MW (SE)	1,24 (2,092)	0,10 (2,619)	
95 %-KI	[-2,873; 5,343]	[-5,038; 5,244]	
Veränderung zu Woche 48			
n/N (%)	6/101 (6)	2/83 (2)	LS MD 1,98 [-6,799; 10,768]
MW (SD)	11,11 (17,213)	0,00 (0,000)	
LS MW (SE)	0,46 (2,750)	-1,53 (3,535)	
95 %-KI	[-4,939; 5,854]	[-8,466; 5,411]	
<b>Stadium bei der Diagnose: I-III</b>			
Baseline			
n/N (%)	113/141 (80)	112/144 (78)	-
MW (SD)	10,03 (23,096)	8,63 (17,755)	
Absolute Werte zum Studienende			
n/N (%)	6/91 (7)	4/76 (5)	-
MW (SD)	5,56 (13,608)	16,67 (19,245)	
Effekt über Studiendauer			
n	113	112	LS MD -0,07 [-4,351; 4,202] 0,9726
LS MW (SE)	2,96 (1,490)	3,03 (1,578)	
95 %-KI	[0,018; 5,896]	[-0,077; 6,140]	Hedges' g -0,00 [-0,266; 0,257]
Veränderung zu Woche 3/4			
n/N (%)	75/137 (55)	79/138 (57)	LS MD 0,46 [-4,406; 5,335]
MW (SD)	6,22 (22,390)	4,22 (17,996)	
LS MW (SE)	4,54 (1,718)	4,08 (1,785)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[1,163; 7,922]	[0,568; 7,587]	
Veränderung zu Woche 8/9			
n/N (%)	94/136 (69)	88/129 (68)	LS MD 0,23 [-4,197; 4,656]
MW (SD)	1,42 (26,736)	0,76 (22,589)	
LS MW (SE)	3,85 (1,563)	3,62 (1,616)	
95 %-KI	[0,771; 6,928]	[0,438; 6,803]	
Veränderung zu Woche 12			
n/N (%)	63/133 (47)	49/128 (38)	LS MD 0,06 [-4,217; 4,345]
MW (SD)	-2,12 (25,310)	6,12 (22,229)	
LS MW (SE)	3,36 (1,504)	3,30 (1,568)	
95 %-KI	[0,400; 6,330]	[0,210; 6,391]	
Veränderung zu Woche 15/16			
n/N (%)	64/130 (49)	34/125 (27)	LS MD -0,10 [-4,389; 4,187]
MW (SD)	3,65 (24,572)	9,80 (25,332)	
LS MW (SE)	2,88 (1,492)	2,98 (1,584)	
95 %-KI	[-0,062; 5,822]	[-0,141; 6,103]	
Veränderung zu Woche 20/21			
n/N (%)	46/123 (37)	34/116 (29)	LS MD -0,34 [-4,895; 4,222]
MW (SD)	-0,72 (29,388)	3,92 (19,703)	
LS MW (SE)	2,19 (1,557)	2,52 (1,714)	
95 %-KI	[-0,880; 5,255]	[-0,849; 5,897]	
Veränderung zu Woche 24			
n/N (%)	35/121 (29)	27/109 (25)	LS MD -0,50 [-5,408; 4,405]
MW (SD)	1,90 (25,492)	4,94 (22,079)	
LS MW (SE)	1,70 (1,655)	2,20 (1,866)	
95 %-KI	[-1,554; 4,960]	[-1,466; 5,874]	
Veränderung zu Woche 36			
n/N (%)	54/105 (51)	35/92 (38)	
MW (SD)	2,47 (26,582)	-1,90 (13,869)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	0,04 (2,216)	1,11 (2,628)	LS MD -1,07 [-7,818; 5,683]
95 %-KI	[-4,312; 4,393]	[-4,051; 6,267]	
Veränderung zu Woche 48			
n/N (%)	5/91 (5)	4/76 (5)	LS MD -1,63 [-10,738; 7,472]
MW (SD)	6,67 (14,907)	0,00 (0,000)	
LS MW (SE)	-1,62 (2,963)	0,01 (3,567)	
95 %-KI	[-7,438; 4,195]	[-6,990; 7,013]	
<b>Stadium bei der Diagnose: IV</b>			
Baseline			
n/N (%)	59/72 (82)	45/60 (75)	-
MW (SD)	7,91 (18,916)	11,85 (19,010)	
Absolute Werte zum Studienende			
n/N (%)	4/46 (9)	2/33 (6)	-
MW (SD)	25,00 (31,914)	16,67 (23,570)	
Effekt über Studiendauer			
n	59	45	LS MD -4,77 [-11,864; 2,328] 0,1855  Hedges' g -0,26 [-0,653; 0,126]
LS MW (SE)	1,17 (2,307)	5,94 (2,722)	
95 %-KI	[-3,411; 5,753]	[0,541; 11,337]	
Veränderung zu Woche 3/4			
n/N (%)	41/71 (58)	29/59 (49)	LS MD -3,93 [-11,821; 3,962]
MW (SD)	3,25 (20,823)	4,60 (24,759)	
LS MW (SE)	1,75 (2,580)	5,68 (3,038)	
95 %-KI	[-3,350; 6,847]	[-0,321; 11,677]	
Veränderung zu Woche 8/9			
n/N (%)	46/69 (67)	36/56 (64)	LS MD -4,31 [-11,539; 2,925]
MW (SD)	1,45 (19,822)	10,19 (31,692)	
LS MW (SE)	1,49 (2,384)	5,80 (2,752)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,237; 6,214]	[0,344; 11,246]	
Veränderung zu Woche 12			
n/N (%)	30/67 (45)	22/52 (42)	LS MD -4,57 [-11,629; 2,487]
MW (SD)	-2,22 (12,172)	4,55 (21,320)	
LS MW (SE)	1,31 (2,317)	5,88 (2,688)	
95 %-KI	[-3,292; 5,905]	[0,545; 11,210]	
Veränderung zu Woche 15/16			
n/N (%)	29/64 (45)	18/50 (36)	LS MD -4,83 [-11,975; 2,306]
MW (SD)	1,15 (25,947)	7,41 (14,260)	
LS MW (SE)	1,13 (2,312)	5,96 (2,748)	
95 %-KI	[-3,466; 5,717]	[0,511; 11,409]	
Veränderung zu Woche 20/21			
n/N (%)	18/62 (29)	16/46 (35)	LS MD -5,21 [-12,894; 2,471]
MW (SD)	-3,70 (19,433)	-4,17 (23,960)	
LS MW (SE)	0,87 (2,415)	6,08 (3,031)	
95 %-KI	[-3,923; 5,654]	[0,085; 12,069]	
Veränderung zu Woche 24			
n/N (%)	17/59 (29)	10/44 (23)	LS MD -5,48 [-13,792; 2,840]
MW (SD)	-7,84 (25,082)	6,67 (26,294)	
LS MW (SE)	0,68 (2,557)	6,16 (3,338)	
95 %-KI	[-4,375; 5,743]	[-0,427; 12,746]	
Veränderung zu Woche 36			
n/N (%)	28/52 (54)	11/41 (27)	LS MD -6,38 [-17,891; 5,130]
MW (SD)	0,00 (27,217)	3,03 (17,979)	
LS MW (SE)	0,06 (3,348)	6,44 (4,791)	
95 %-KI	[-6,532; 6,653]	[-2,985; 15,868]	
Veränderung zu Woche 48			
n/N (%)	3/46 (7)	1/33 (3)	
MW (SD)	11,11 (19,245)	0,00 (NA)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-0,56 (4,402)	6,72 (6,532)	LS MD -7,29 [-22,785; 8,214]
95 %-KI	[-9,221; 8,096]	[-6,123; 19,569]	
<b>BRCA Status: Positiv</b>			
Baseline			
n/N (%)	24/27 (89)	23/35 (66)	-
MW (SD)	8,33 (22,522)	13,04 (16,634)	
Absolute Werte zum Studienende			
n/N (%)	1/19 (5)	0/15 (0)	-
MW (SD)	33,33 (NA)	NA (NA)	
Effekt über Studiendauer			
n	24	23	LS MD 0,60 [-10,088; 11,287] 0,9105
LS MW (SE)	2,92 (3,592)	2,32 (3,885)	
95 %-KI	[-4,330; 10,177]	[-5,489; 10,137]	Hedges' g 0,03 [-0,539; 0,605]
Veränderung zu Woche 3/4			
n/N (%)	15/27 (56)	18/35 (51)	LS MD -1,54 [-13,170; 10,086]
MW (SD)	4,44 (17,213)	0,00 (25,565)	
LS MW (SE)	1,79 (4,007)	3,33 (4,185)	
95 %-KI	[-6,215; 9,798]	[-5,020; 11,687]	
Veränderung zu Woche 8/9			
n/N (%)	19/26 (73)	20/30 (67)	LS MD -0,49 [-11,207; 10,231]
MW (SD)	3,51 (29,175)	1,67 (27,519)	
LS MW (SE)	2,35 (3,707)	2,84 (3,796)	
95 %-KI	[-5,107; 9,805]	[-4,803; 10,477]	
Veränderung zu Woche 12			
n/N (%)	14/26 (54)	11/30 (37)	LS MD 0,25 [-10,344; 10,844]
MW (SD)	0,00 (0,000)	0,00 (21,082)	
LS MW (SE)	2,74 (3,606)	2,49 (3,801)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-4,537; 10,015]	[-5,166; 10,144]	
Veränderung zu Woche 15/16			
n/N (%)	11/26 (42)	8/29 (28)	LS MD 0,99 [-9,915; 11,891]
MW (SD)	3,03 (17,979)	0,00 (17,817)	
LS MW (SE)	3,13 (3,604)	2,14 (4,037)	
95 %-KI	[-4,146; 10,404]	[-5,954; 10,236]	
Veränderung zu Woche 20/21			
n/N (%)	9/25 (36)	4/25 (16)	LS MD 2,04 [-9,995; 14,078]
MW (SD)	11,11 (16,667)	0,00 (0,000)	
LS MW (SE)	3,69 (3,770)	1,64 (4,701)	
95 %-KI	[-3,895; 11,268]	[-7,707; 10,996]	
Veränderung zu Woche 24			
n/N (%)	7/25 (28)	4/24 (17)	LS MD 2,78 [-10,451; 16,010]
MW (SD)	14,29 (17,817)	0,00 (0,000)	
LS MW (SE)	4,08 (3,994)	1,30 (5,326)	
95 %-KI	[-3,919; 12,072]	[-9,261; 11,855]	
Veränderung zu Woche 36			
n/N (%)	10/21 (48)	4/20 (20)	LS MD 5,31 [-13,533; 24,152]
MW (SD)	10,00 (22,498)	0,00 (0,000)	
LS MW (SE)	5,41 (5,233)	0,10 (7,979)	
95 %-KI	[-4,954; 15,782]	[-15,663; 15,872]	
Veränderung zu Woche 48			
n/N (%)	1/19 (5)	0/15 (0)	LS MD 7,84 [-17,725; 33,403]
MW (SD)	33,33 (NA)	NA (NA)	
LS MW (SE)	6,75 (6,878)	-1,09 (10,970)	
95 %-KI	[-6,842; 20,346]	[-22,769; 20,594]	
<b>BRCA Status: Negativ/Unbekannt</b>			
Baseline			
n/N (%)	153/191 (80)	136/172 (79)	-

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	9,59 (21,519)	9,07 (18,355)	
Absolute Werte zum Studienende			
n/N (%)	9/121 (7)	6/95 (6)	-
MW (SD)	11,11 (23,570)	16,67 (18,257)	
Effekt über Studiendauer			
n	153	136	LS MD -2,36 [-6,240; 1,526] 0,2331  Hedges' g -0,14 [-0,372; 0,090]
LS MW (SE)	1,82 (1,320)	4,17 (1,466)	
95 %-KI	[-0,783; 4,415]	[1,287; 7,059]	
Veränderung zu Woche 3/4			
n/N (%)	106/186 (57)	92/165 (56)	LS MD -1,42 [-5,835; 3,004]
MW (SD)	5,35 (22,602)	5,07 (19,097)	
LS MW (SE)	3,49 (1,510)	4,90 (1,666)	
95 %-KI	[0,520; 6,456]	[1,629; 8,178]	
Veränderung zu Woche 8/9			
n/N (%)	126/184 (68)	106/158 (67)	LS MD -1,83 [-5,843; 2,192]
MW (SD)	1,06 (23,828)	4,09 (26,308)	
LS MW (SE)	2,76 (1,378)	4,59 (1,508)	
95 %-KI	[0,050; 5,471]	[1,620; 7,552]	
Veränderung zu Woche 12			
n/N (%)	84/179 (47)	61/153 (40)	LS MD -2,11 [-5,998; 1,774]
MW (SD)	-2,78 (23,261)	6,56 (21,790)	
LS MW (SE)	2,25 (1,329)	4,36 (1,460)	
95 %-KI	[-0,365; 4,867]	[1,489; 7,237]	
Veränderung zu Woche 15/16			
n/N (%)	85/173 (49)	46/149 (31)	LS MD -2,40 [-6,291; 1,494]
MW (SD)	2,35 (25,608)	10,14 (23,168)	
LS MW (SE)	1,74 (1,321)	4,14 (1,472)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-0,860; 4,343]	[1,244; 7,036]	
Veränderung zu Woche 20/21			
n/N (%)	58/165 (35)	47/140 (34)	LS MD -2,81 [-6,946; 1,329]
MW (SD)	-4,02 (27,272)	1,42 (21,933)	
LS MW (SE)	1,01 (1,382)	3,82 (1,585)	
95 %-KI	[-1,707; 3,734]	[0,704; 6,940]	
Veränderung zu Woche 24			
n/N (%)	47/159 (30)	34/131 (26)	LS MD -3,10 [-7,548; 1,357]
MW (SD)	-4,26 (25,648)	7,84 (26,026)	
LS MW (SE)	0,50 (1,470)	3,60 (1,723)	
95 %-KI	[-2,388; 3,396]	[0,213; 6,985]	
Veränderung zu Woche 36			
n/N (%)	73/139 (53)	43/114 (38)	LS MD -4,08 [-10,199; 2,042]
MW (SD)	0,46 (26,928)	0,00 (16,265)	
LS MW (SE)	-1,24 (1,968)	2,84 (2,418)	
95 %-KI	[-5,107; 2,621]	[-1,911; 7,582]	
Veränderung zu Woche 48			
n/N (%)	7/121 (6)	5/95 (5)	LS MD -5,06 [-13,312; 3,188]
MW (SD)	4,76 (12,599)	0,00 (0,000)	
LS MW (SE)	-2,99 (2,627)	2,07 (3,282)	
95 %-KI	[-8,145; 2,166]	[-4,368; 8,513]	
<b>Baseline ECOG PS: 0</b>			
Baseline			
n/N (%)	102/128 (80)	97/113 (86)	-
MW (SD)	7,19 (19,127)	10,65 (18,350)	
Absolute Werte zum Studienende			
n/N (%)	7/87 (8)	3/72 (4)	-
MW (SD)	19,05 (26,227)	22,22 (19,245)	
Effekt über Studiendauer			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n	102	97	LS MD -0,08 [-4,425; 4,273] 0,9725  Hedges' g -0,00 [-0,283; 0,273]
LS MW (SE)	2,27 (1,499)	2,35 (1,613)	
95 %-KI	[-0,688; 5,229]	[-0,835; 5,528]	
Veränderung zu Woche 3/4			
n/N (%)	71/127 (56)	64/111 (58)	LS MD 1,36 [-3,578; 6,307]
MW (SD)	4,69 (20,545)	3,12 (21,181)	
LS MW (SE)	4,25 (1,706)	2,88 (1,835)	
95 %-KI	[0,889; 7,604]	[-0,728; 6,493]	
Veränderung zu Woche 8/9			
n/N (%)	86/126 (68)	75/108 (69)	LS MD 0,74 [-3,762; 5,250]
MW (SD)	3,49 (18,456)	-0,89 (23,870)	
LS MW (SE)	3,40 (1,565)	2,65 (1,663)	
95 %-KI	[0,311; 6,480]	[-0,625; 5,928]	
Veränderung zu Woche 12			
n/N (%)	54/122 (44)	46/108 (43)	LS MD 0,31 [-4,049; 4,668]
MW (SD)	0,62 (20,973)	5,07 (23,272)	
LS MW (SE)	2,80 (1,511)	2,49 (1,609)	
95 %-KI	[-0,182; 5,781]	[-0,683; 5,663]	
Veränderung zu Woche 15/16			
n/N (%)	56/120 (47)	34/105 (32)	LS MD -0,12 [-4,481; 4,231]
MW (SD)	5,95 (22,117)	6,86 (21,366)	
LS MW (SE)	2,20 (1,500)	2,33 (1,617)	
95 %-KI	[-0,757; 5,164]	[-0,861; 5,518]	
Veränderung zu Woche 20/21			
n/N (%)	41/117 (35)	32/101 (32)	LS MD -0,74 [-5,347; 3,857]
MW (SD)	0,00 (21,082)	1,04 (24,662)	
LS MW (SE)	1,35 (1,558)	2,10 (1,734)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-1,720; 4,425]	[-1,318; 5,513]	
Veränderung zu Woche 24			
n/N (%)	28/112 (25)	22/96 (23)	LS MD -1,18 [-6,108; 3,749]
MW (SD)	2,38 (17,982)	1,52 (21,767)	
LS MW (SE)	0,76 (1,647)	1,94 (1,878)	
95 %-KI	[-2,488; 4,001]	[-1,759; 5,631]	
Veränderung zu Woche 36			
n/N (%)	52/99 (53)	35/87 (40)	LS MD -2,67 [-9,366; 4,030]
MW (SD)	-1,28 (18,625)	-0,95 (15,094)	
LS MW (SE)	-1,29 (2,163)	1,38 (2,616)	
95 %-KI	[-5,536; 2,962]	[-3,757; 6,520]	
Veränderung zu Woche 48			
n/N (%)	5/87 (6)	3/72 (4)	LS MD -4,16 [-13,147; 4,833]
MW (SD)	13,33 (18,257)	0,00 (0,000)	
LS MW (SE)	-3,33 (2,860)	0,83 (3,542)	
95 %-KI	[-8,945; 2,285]	[-6,127; 7,782]	
<b>Baseline ECOG PS: 1</b>			
Baseline			
n/N (%)	75/90 (83)	61/91 (67)	-
MW (SD)	12,44 (24,368)	8,20 (17,905)	
Absolute Werte zum Studienende			
n/N (%)	3/53 (6)	3/37 (8)	-
MW (SD)	0,00 (0,000)	11,11 (19,245)	
Effekt über Studiendauer			
n	75	61	LS MD -4,12 [-10,601; 2,369] 0,2115
LS MW (SE)	1,61 (2,119)	5,73 (2,490)	
95 %-KI	[-2,586; 5,807]	[0,804; 10,650]	Hedges' g -0,22 [-0,556; 0,122]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	50/86 (58)	45/87 (52)	LS MD -5,59 [-12,835; 1,650]
MW (SD)	6,00 (23,990)	5,93 (19,187)	
LS MW (SE)	1,68 (2,428)	7,28 (2,750)	
95 %-KI	[-3,105; 6,471]	[1,857; 12,695]	
Veränderung zu Woche 8/9			
n/N (%)	59/84 (70)	50/78 (64)	LS MD -4,91 [-11,509; 1,681]
MW (SD)	-1,69 (31,210)	10,67 (28,919)	
LS MW (SE)	1,65 (2,206)	6,56 (2,496)	
95 %-KI	[-2,711; 6,011]	[1,633; 11,495]	
Veränderung zu Woche 12			
n/N (%)	44/83 (53)	25/74 (34)	LS MD -4,44 [-10,878; 2,000]
MW (SD)	-6,06 (21,891)	5,33 (18,459)	
LS MW (SE)	1,63 (2,130)	6,07 (2,452)	
95 %-KI	[-2,589; 5,842]	[1,217; 10,914]	
Veränderung zu Woche 15/16			
n/N (%)	40/79 (51)	20/72 (28)	LS MD -3,96 [-10,513; 2,585]
MW (SD)	-2,50 (27,619)	11,67 (24,839)	
LS MW (SE)	1,60 (2,127)	5,57 (2,526)	
95 %-KI	[-2,608; 5,814]	[0,574; 10,560]	
Veränderung zu Woche 20/21			
n/N (%)	26/73 (36)	18/63 (29)	LS MD -3,28 [-10,422; 3,852]
MW (SD)	-5,13 (33,589)	1,85 (13,873)	
LS MW (SE)	1,57 (2,250)	4,85 (2,817)	
95 %-KI	[-2,878; 6,017]	[-0,700; 10,409]	
Veränderung zu Woche 24			
n/N (%)	26/72 (36)	15/58 (26)	LS MD -2,81 [-10,609; 4,989]
MW (SD)	-6,41 (31,297)	13,33 (27,603)	
LS MW (SE)	1,55 (2,414)	4,36 (3,120)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,217; 6,310]	[-1,788; 10,500]	
Veränderung zu Woche 36			
n/N (%)	31/61 (51)	12/46 (26)	LS MD -1,18 [-12,206; 9,845]
MW (SD)	6,45 (35,921)	2,78 (17,164)	
LS MW (SE)	1,47 (3,299)	2,65 (4,514)	
95 %-KI	[-5,021; 7,954]	[-6,225; 11,519]	
Veränderung zu Woche 48			
n/N (%)	3/53 (6)	2/37 (5)	LS MD 0,45 [-14,516; 15,413]
MW (SD)	0,00 (0,000)	0,00 (0,000)	
LS MW (SE)	1,39 (4,439)	0,94 (6,159)	
95 %-KI	[-7,337; 10,109]	[-11,165; 13,040]	
<b>Anzahl vorheriger Therapielinien: 1</b>			
Baseline			
n/N (%)	24/31 (77)	23/29 (79)	-
MW (SD)	8,33 (24,574)	7,25 (17,281)	
Absolute Werte zum Studienende			
n/N (%)	1/22 (5)	0/14 (0)	-
MW (SD)	0,00 (NA)	NA (NA)	
Effekt über Studiendauer			
n	24	23	LS MD -4,42 [-12,689; 3,844] 0,2867
LS MW (SE)	0,30 (2,843)	4,72 (2,975)	
95 %-KI	[-5,438; 6,042]	[-1,266; 10,715]	Hedges' g -0,31 [-0,884; 0,267]
Veränderung zu Woche 3/4			
n/N (%)	16/31 (52)	15/29 (52)	LS MD -2,77 [-11,742; 6,200]
MW (SD)	4,17 (11,386)	4,44 (24,774)	
LS MW (SE)	0,83 (3,114)	3,60 (3,259)	
95 %-KI	[-5,398; 7,066]	[-2,903; 10,113]	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	20/31 (65)	18/26 (69)	LS MD -3,47 [-11,915; 4,983]
MW (SD)	0,00 (18,732)	1,85 (21,305)	
LS MW (SE)	0,61 (2,940)	4,08 (3,027)	
95 %-KI	[-5,303; 6,524]	[-2,004; 10,156]	
Veränderung zu Woche 12			
n/N (%)	14/31 (45)	12/24 (50)	LS MD -3,95 [-12,228; 4,324]
MW (SD)	-9,52 (24,209)	5,56 (12,975)	
LS MW (SE)	0,45 (2,869)	4,41 (2,959)	
95 %-KI	[-5,332; 6,239]	[-1,554; 10,365]	
Veränderung zu Woche 15/16			
n/N (%)	15/31 (48)	11/22 (50)	LS MD -4,44 [-12,708; 3,830]
MW (SD)	0,00 (21,822)	-3,03 (10,050)	
LS MW (SE)	0,30 (2,843)	4,74 (2,977)	
95 %-KI	[-5,443; 6,037]	[-1,259; 10,730]	
Veränderung zu Woche 20/21			
n/N (%)	11/30 (37)	9/22 (41)	LS MD -5,13 [-13,679; 3,412]
MW (SD)	9,09 (15,570)	7,41 (14,699)	
LS MW (SE)	0,07 (2,887)	5,21 (3,145)	
95 %-KI	[-5,746; 5,892]	[-1,100; 11,513]	
Veränderung zu Woche 24			
n/N (%)	9/30 (30)	11/20 (55)	LS MD -5,62 [-14,549; 3,309]
MW (SD)	-7,41 (22,222)	3,03 (10,050)	
LS MW (SE)	-0,08 (2,972)	5,54 (3,351)	
95 %-KI	[-6,058; 5,890]	[-1,156; 12,229]	
Veränderung zu Woche 36			
n/N (%)	15/26 (58)	6/18 (33)	LS MD -7,29 [-18,471; 3,895]
MW (SD)	2,22 (8,607)	5,56 (13,608)	
LS MW (SE)	-0,62 (3,547)	6,67 (4,436)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-7,668; 6,426]	[-2,112; 15,445]	
Veränderung zu Woche 48			
n/N (%)	0/22 (0)	0/14 (0)	LS MD -8,96 [-23,300; 5,389]
MW (SD)	NA (NA)	NA (NA)	
LS MW (SE)	-1,16 (4,411)	7,80 (5,840)	
95 %-KI	[-9,877; 7,560]	[-3,732; 19,326]	
<b>Anzahl vorheriger Therapielinien: 2</b>			
Baseline			
n/N (%)	75/89 (84)	65/83 (78)	-
MW (SD)	8,89 (19,245)	10,77 (20,504)	
Absolute Werte zum Studienende			
n/N (%)	4/59 (7)	2/50 (4)	-
MW (SD)	16,67 (19,245)	16,67 (23,570)	
Effekt über Studiendauer			
n	75	65	LS MD 3,10 [-3,018; 9,227] 0,3178  Hedges' g 0,17 [-0,163; 0,503]
LS MW (SE)	4,79 (2,045)	1,68 (2,322)	
95 %-KI	[0,743; 8,836]	[-2,905; 6,274]	
Veränderung zu Woche 3/4			
n/N (%)	53/86 (62)	46/80 (57)	LS MD 1,93 [-4,818; 8,684]
MW (SD)	6,92 (24,771)	1,45 (17,151)	
LS MW (SE)	4,86 (2,281)	2,93 (2,552)	
95 %-KI	[0,360; 9,359]	[-2,105; 7,957]	
Veränderung zu Woche 8/9			
n/N (%)	63/85 (74)	53/77 (69)	LS MD 2,46 [-3,768; 8,689]
MW (SD)	3,17 (23,733)	3,77 (25,870)	
LS MW (SE)	4,83 (2,113)	2,37 (2,337)	
95 %-KI	[0,650; 9,005]	[-2,251; 6,984]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	39/83 (47)	31/75 (41)	LS MD 2,83 [-3,262; 8,922]
MW (SD)	0,00 (17,100)	1,08 (21,915)	
LS MW (SE)	4,81 (2,054)	1,98 (2,294)	
95 %-KI	[0,741; 8,870]	[-2,559; 6,509]	
Veränderung zu Woche 15/16			
n/N (%)	41/80 (51)	19/74 (26)	LS MD 3,20 [-2,960; 9,359]
MW (SD)	4,88 (32,112)	10,53 (15,919)	
LS MW (SE)	4,78 (2,048)	1,58 (2,344)	
95 %-KI	[0,730; 8,837]	[-3,048; 6,216]	
Veränderung zu Woche 20/21			
n/N (%)	31/78 (40)	21/68 (31)	LS MD 3,73 [-2,866; 10,321]
MW (SD)	-4,30 (23,947)	-1,59 (12,807)	
LS MW (SE)	4,75 (2,132)	1,02 (2,567)	
95 %-KI	[0,538; 8,966]	[-4,039; 6,087]	
Veränderung zu Woche 24			
n/N (%)	26/74 (35)	13/65 (20)	LS MD 4,10 [-3,004; 11,198]
MW (SD)	2,56 (29,699)	10,26 (25,036)	
LS MW (SE)	4,73 (2,249)	0,63 (2,809)	
95 %-KI	[0,290; 9,169]	[-4,899; 6,165]	
Veränderung zu Woche 36			
n/N (%)	34/65 (52)	19/58 (33)	LS MD 5,36 [-4,317; 15,043]
MW (SD)	3,92 (33,600)	7,02 (13,962)	
LS MW (SE)	4,65 (2,916)	-0,71 (3,958)	
95 %-KI	[-1,082; 10,389]	[-8,489; 7,070]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	1/50 (2)	LS MD 6,63 [-6,299; 19,559]
MW (SD)	16,67 (19,245)	0,00 (NA)	
LS MW (SE)	4,58 (3,815)	-2,05 (5,348)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-2,919; 12,074]	[-12,559; 8,455]	
<b>Anzahl vorheriger Therapielinien: 3</b>			
Baseline			
n/N (%)	78/98 (80)	71/95 (75)	-
MW (SD)	10,26 (22,986)	9,39 (16,118)	
Absolute Werte zum Studienende			
n/N (%)	5/59 (8)	4/46 (9)	-
MW (SD)	13,33 (29,814)	16,67 (19,245)	
Effekt über Studiendauer			
n	78	71	LS MD -5,50 [-10,778; -0,228] 0,0410  Hedges' g -0,34 [-0,661; -0,014]
LS MW (SE)	-0,23 (1,795)	5,27 (1,972)	
95 %-KI	[-3,780; 3,323]	[1,376; 9,174]	
Veränderung zu Woche 3/4			
n/N (%)	52/96 (54)	49/91 (54)	LS MD -3,99 [-10,170; 2,191]
MW (SD)	3,85 (21,546)	6,80 (21,495)	
LS MW (SE)	2,39 (2,130)	6,38 (2,301)	
95 %-KI	[-1,800; 6,589]	[1,853; 10,914]	
Veränderung zu Woche 8/9			
n/N (%)	62/94 (66)	55/85 (65)	LS MD -4,66 [-10,159; 0,842]
MW (SD)	-0,00 (26,993)	4,24 (28,728)	
LS MW (SE)	1,24 (1,895)	5,89 (2,043)	
95 %-KI	[-2,505; 4,977]	[1,862; 9,926]	
Veränderung zu Woche 12			
n/N (%)	45/91 (49)	29/84 (35)	LS MD -5,13 [-10,405; 0,153]
MW (SD)	-2,22 (23,995)	10,34 (23,744)	
LS MW (SE)	0,42 (1,809)	5,55 (1,965)	
95 %-KI	[-3,152; 4,002]	[1,668; 9,434]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	40/88 (45)	24/82 (29)	LS MD -5,59 [-10,892; -0,297]
MW (SD)	0,83 (15,991)	12,50 (29,180)	
LS MW (SE)	-0,39 (1,799)	5,21 (1,984)	
95 %-KI	[-3,946; 3,173]	[1,287; 9,129]	
Veränderung zu Woche 20/21			
n/N (%)	25/82 (30)	21/75 (28)	LS MD -6,26 [-11,993; -0,534]
MW (SD)	-4,00 (32,375)	1,59 (28,822)	
LS MW (SE)	-1,55 (1,918)	4,72 (2,172)	
95 %-KI	[-5,334; 2,244]	[0,433; 9,003]	
Veränderung zu Woche 24			
n/N (%)	19/80 (24)	14/70 (20)	LS MD -6,73 [-13,002; -0,461]
MW (SD)	-5,26 (20,071)	7,14 (32,499)	
LS MW (SE)	-2,36 (2,081)	4,38 (2,395)	
95 %-KI	[-6,461; 1,748]	[-0,343; 9,093]	
Veränderung zu Woche 36			
n/N (%)	34/69 (49)	22/58 (38)	LS MD -8,34 [-17,366; 0,694]
MW (SD)	-0,98 (23,904)	-7,58 (14,298)	
LS MW (SE)	-5,14 (2,953)	3,20 (3,489)	
95 %-KI	[-10,942; 0,668]	[-3,659; 10,058]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	4/46 (9)	LS MD -9,94 [-22,380; 2,498]
MW (SD)	0,00 (0,000)	0,00 (0,000)	
LS MW (SE)	-7,92 (4,054)	2,02 (4,815)	
95 %-KI	[-15,883; 0,048]	[-7,436; 11,483]	
<b>Vorherige Verabreichung von Bevacizumab: Ja</b>			
Baseline			
n/N (%)	106/134 (79)	100/132 (76)	-
MW (SD)	9,43 (20,447)	10,00 (18,041)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	3/79 (4)	3/62 (5)	-
MW (SD)	11,11 (19,245)	22,22 (19,245)	
Effekt über Studiendauer			
n	106	100	LS MD -2,73 [-7,816; 2,363] 0,2920  Hedges' g -0,15 [-0,421; 0,127]
LS MW (SE)	3,94 (1,734)	6,67 (1,912)	
95 %-KI	[0,517; 7,360]	[2,896; 10,434]	
Veränderung zu Woche 3/4			
n/N (%)	70/130 (54)	69/127 (54)	LS MD -1,84 [-7,671; 3,996]
MW (SD)	7,62 (24,192)	7,25 (21,290)	
LS MW (SE)	5,59 (2,016)	7,43 (2,176)	
95 %-KI	[1,623; 9,557]	[3,149; 11,706]	
Veränderung zu Woche 8/9			
n/N (%)	86/130 (66)	76/119 (64)	LS MD -2,25 [-7,476; 2,973]
MW (SD)	3,10 (24,322)	7,02 (28,965)	
LS MW (SE)	4,82 (1,816)	7,07 (1,933)	
95 %-KI	[1,241; 8,400]	[3,264; 10,880]	
Veränderung zu Woche 12			
n/N (%)	56/126 (44)	38/114 (33)	LS MD -2,54 [-7,606; 2,522]
MW (SD)	-0,60 (22,465)	9,65 (20,369)	
LS MW (SE)	4,28 (1,745)	6,82 (1,885)	
95 %-KI	[0,839; 7,725]	[3,108; 10,539]	
Veränderung zu Woche 15/16			
n/N (%)	59/122 (48)	32/112 (29)	LS MD -2,83 [-7,980; 2,316]
MW (SD)	4,52 (25,863)	12,50 (27,760)	
LS MW (SE)	3,74 (1,740)	6,58 (1,947)	
95 %-KI	[0,310; 7,176]	[2,737; 10,413]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	40/114 (35)	28/103 (27)	LS MD -3,25 [-8,909; 2,417]
MW (SD)	-1,67 (29,187)	3,57 (24,578)	
LS MW (SE)	2,97 (1,846)	6,22 (2,206)	
95 %-KI	[-0,664; 6,611]	[1,878; 10,561]	
Veränderung zu Woche 24			
n/N (%)	30/109 (28)	17/95 (18)	LS MD -3,54 [-9,784; 2,711]
MW (SD)	3,33 (26,767)	17,65 (29,149)	
LS MW (SE)	2,43 (1,989)	5,97 (2,477)	
95 %-KI	[-1,481; 6,351]	[1,102; 10,841]	
Veränderung zu Woche 36			
n/N (%)	46/93 (49)	22/79 (28)	LS MD -4,53 [-13,598; 4,535]
MW (SD)	3,62 (26,507)	1,52 (16,191)	
LS MW (SE)	0,59 (2,761)	5,12 (3,700)	
95 %-KI	[-4,835; 6,010]	[-2,147; 12,385]	
Veränderung zu Woche 48			
n/N (%)	3/79 (4)	2/62 (3)	LS MD -5,53 [-17,987; 6,934]
MW (SD)	11,11 (19,245)	0,00 (0,000)	
LS MW (SE)	-1,26 (3,747)	4,27 (5,121)	
95 %-KI	[-8,616; 6,098]	[-5,787; 14,321]	
<b>Vorherige Verabreichung von Bevacizumab: Nein</b>			
Baseline			
n/N (%)	71/84 (85)	59/75 (79)	-
MW (SD)	9,39 (23,356)	9,04 (18,394)	
Absolute Werte zum Studienende			
n/N (%)	7/61 (11)	3/48 (6)	-
MW (SD)	14,29 (26,227)	11,11 (19,245)	
Effekt über Studiendauer			
n	71	59	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-0,99 (1,557)	-0,30 (1,744)	LS MD -0,69 [-5,316; 3,938] 0,7687  Hedges' g -0,05 [-0,397; 0,294]
95 %-KI	[-4,072; 2,092]	[-3,752; 3,150]	
Veränderung zu Woche 3/4			
n/N (%)	51/83 (61)	41/73 (56)	LS MD -0,13 [-5,343; 5,078]
MW (SD)	1,96 (18,150)	-0,81 (17,461)	
LS MW (SE)	-0,06 (1,758)	0,07 (1,971)	
95 %-KI	[-3,533; 3,403]	[-3,818; 3,954]	
Veränderung zu Woche 8/9			
n/N (%)	59/80 (74)	50/69 (72)	LS MD -0,36 [-5,163; 4,438]
MW (SD)	-1,13 (24,733)	-1,33 (21,253)	
LS MW (SE)	-0,45 (1,622)	-0,08 (1,807)	
95 %-KI	[-3,654; 2,759]	[-3,656; 3,486]	
Veränderung zu Woche 12			
n/N (%)	42/79 (53)	34/69 (49)	LS MD -0,52 [-5,174; 4,127]
MW (SD)	-4,76 (20,258)	0,98 (22,451)	
LS MW (SE)	-0,72 (1,570)	-0,19 (1,749)	
95 %-KI	[-3,821; 2,391]	[-3,652; 3,269]	
Veränderung zu Woche 15/16			
n/N (%)	37/77 (48)	22/66 (33)	LS MD -0,68 [-5,311; 3,941]
MW (SD)	-0,90 (22,888)	3,03 (9,808)	
LS MW (SE)	-0,98 (1,556)	-0,30 (1,743)	
95 %-KI	[-4,065; 2,099]	[-3,748; 3,152]	
Veränderung zu Woche 20/21			
n/N (%)	27/76 (36)	23/62 (37)	LS MD -0,91 [-5,724; 3,894]
MW (SD)	-2,47 (22,505)	-1,45 (15,822)	
LS MW (SE)	-1,37 (1,608)	-0,45 (1,826)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-4,545; 1,814]	[-4,059; 3,158]	
Veränderung zu Woche 24			
n/N (%)	24/75 (32)	21/60 (35)	LS MD -1,08 [-6,154; 4,002]
MW (SD)	-8,33 (22,522)	-1,59 (16,587)	
LS MW (SE)	-1,63 (1,689)	-0,56 (1,941)	
95 %-KI	[-4,969; 1,703]	[-4,388; 3,273]	
Veränderung zu Woche 36			
n/N (%)	37/67 (55)	25/55 (45)	LS MD -1,63 [-8,269; 5,013]
MW (SD)	-0,90 (26,628)	-1,33 (15,154)	
LS MW (SE)	-2,55 (2,175)	-0,92 (2,582)	
95 %-KI	[-6,831; 1,729]	[-6,000; 4,155]	
Veränderung zu Woche 48			
n/N (%)	5/61 (8)	3/48 (6)	LS MD -2,18 [-10,939; 6,578]
MW (SD)	6,67 (14,907)	0,00 (0,000)	
LS MW (SE)	-3,47 (2,847)	-1,29 (3,428)	
95 %-KI	[-9,064; 2,126]	[-8,026; 5,448]	
<b>Letztes Platin-freies Intervall: ≤ 3 Monate</b>			
Baseline			
n/N (%)	67/83 (81)	62/91 (68)	-
MW (SD)	7,46 (19,950)	12,37 (19,309)	
Absolute Werte zum Studienende			
n/N (%)	3/55 (5)	5/39 (13)	-
MW (SD)	33,33 (33,333)	20,00 (18,257)	
Effekt über Studiendauer			
n	67	62	LS MD -4,89 [-10,660; 0,887] 0,0963
LS MW (SE)	-0,23 (1,958)	4,66 (2,152)	
95 %-KI	[-4,107; 3,656]	[0,401; 8,921]	Hedges' g -0,29 [-0,642; 0,052]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	49/82 (60)	46/86 (53)	LS MD -3,48 [-10,254; 3,295]
MW (SD)	4,08 (22,187)	3,62 (22,474)	
LS MW (SE)	1,96 (2,348)	5,44 (2,496)	
95 %-KI	[-2,665; 6,589]	[0,525; 10,358]	
Veränderung zu Woche 8/9			
n/N (%)	51/81 (63)	46/80 (57)	LS MD -4,13 [-10,120; 1,867]
MW (SD)	1,96 (20,452)	3,62 (30,815)	
LS MW (SE)	0,96 (2,066)	5,08 (2,207)	
95 %-KI	[-3,128; 5,041]	[0,722; 9,444]	
Veränderung zu Woche 12			
n/N (%)	32/78 (41)	25/78 (32)	LS MD -4,58 [-10,342; 1,183]
MW (SD)	2,08 (20,631)	8,00 (29,313)	
LS MW (SE)	0,25 (1,968)	4,83 (2,134)	
95 %-KI	[-3,648; 4,153]	[0,609; 9,054]	
Veränderung zu Woche 15/16			
n/N (%)	34/76 (45)	14/75 (19)	LS MD -5,03 [-10,858; 0,794]
MW (SD)	1,96 (29,520)	11,90 (30,959)	
LS MW (SE)	-0,45 (1,969)	4,58 (2,180)	
95 %-KI	[-4,355; 3,452]	[0,266; 8,894]	
Veränderung zu Woche 20/21			
n/N (%)	21/72 (29)	14/67 (21)	LS MD -5,68 [-12,082; 0,724]
MW (SD)	-9,52 (30,079)	-2,38 (33,242)	
LS MW (SE)	-1,46 (2,136)	4,22 (2,436)	
95 %-KI	[-5,683; 2,769]	[-0,590; 9,033]	
Veränderung zu Woche 24			
n/N (%)	15/72 (21)	12/62 (19)	LS MD -6,13 [-13,215; 0,952]
MW (SD)	-6,67 (28,730)	0,00 (28,427)	
LS MW (SE)	-2,16 (2,350)	3,97 (2,718)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,800; 2,478]	[-1,390; 9,331]	
Veränderung zu Woche 36			
n/N (%)	28/63 (44)	17/50 (34)	LS MD -7,68 [-18,096; 2,729]
MW (SD)	-5,95 (25,746)	-5,88 (13,098)	
LS MW (SE)	-4,57 (3,436)	3,11 (4,040)	
95 %-KI	[-11,332; 2,183]	[-4,836; 11,055]	
Veränderung zu Woche 48			
n/N (%)	2/55 (4)	4/39 (10)	LS MD -9,24 [-23,666; 5,194]
MW (SD)	16,67 (23,570)	0,00 (0,000)	
LS MW (SE)	-6,99 (4,767)	2,25 (5,598)	
95 %-KI	[-16,359; 2,383]	[-8,758; 13,254]	
<b>Letztes Platin-freies Intervall: &gt; 3 Monate</b>			
Baseline			
n/N (%)	110/135 (81)	97/116 (84)	-
MW (SD)	10,61 (22,545)	7,90 (17,195)	
Absolute Werte zum Studienende			
n/N (%)	7/85 (8)	1/71 (1)	-
MW (SD)	4,76 (12,599)	0,00 (NA)	
Effekt über Studiendauer			
n	110	97	LS MD -0,15 [-4,780; 4,472] 0,9479
LS MW (SE)	2,96 (1,575)	3,11 (1,740)	
95 %-KI	[-0,150; 6,065]	[-0,319; 6,541]	Hedges' g -0,01 [-0,282; 0,264]
Veränderung zu Woche 3/4			
n/N (%)	72/131 (55)	64/114 (56)	LS MD -0,22 [-5,382; 4,939]
MW (SD)	6,02 (21,902)	4,69 (18,656)	
LS MW (SE)	3,88 (1,764)	4,10 (1,946)	
95 %-KI	[0,404; 7,348]	[0,269; 7,926]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	94/129 (73)	80/108 (74)	LS MD -0,19 [-4,948; 4,564]
MW (SD)	1,06 (26,528)	3,75 (23,715)	
LS MW (SE)	3,48 (1,637)	3,67 (1,776)	
95 %-KI	[0,252; 6,704]	[0,172; 7,168]	
Veränderung zu Woche 12			
n/N (%)	66/127 (52)	47/105 (45)	LS MD -0,17 [-4,798; 4,455]
MW (SD)	-4,55 (21,789)	4,26 (16,473)	
LS MW (SE)	3,20 (1,588)	3,37 (1,728)	
95 %-KI	[0,068; 6,332]	[-0,036; 6,778]	
Veränderung zu Woche 15/16			
n/N (%)	62/123 (50)	40/103 (39)	LS MD -0,15 [-4,786; 4,484]
MW (SD)	2,69 (22,010)	7,50 (19,226)	
LS MW (SE)	2,92 (1,576)	3,07 (1,746)	
95 %-KI	[-0,188; 6,030]	[-0,369; 6,513]	
Veränderung zu Woche 20/21			
n/N (%)	46/118 (39)	37/98 (38)	LS MD -0,12 [-5,005; 4,762]
MW (SD)	1,45 (24,299)	2,70 (14,441)	
LS MW (SE)	2,52 (1,623)	2,64 (1,879)	
95 %-KI	[-0,677; 5,724]	[-1,055; 6,345]	
Veränderung zu Woche 24			
n/N (%)	39/112 (35)	26/93 (28)	LS MD -0,10 [-5,305; 5,103]
MW (SD)	0,00 (24,183)	10,26 (22,646)	
LS MW (SE)	2,24 (1,699)	2,35 (2,037)	
95 %-KI	[-1,102; 5,591]	[-1,660; 6,352]	
Veränderung zu Woche 36			
n/N (%)	55/97 (57)	30/84 (36)	LS MD -0,03 [-6,971; 6,909]
MW (SD)	5,45 (26,265)	3,33 (16,022)	
LS MW (SE)	1,29 (2,157)	1,32 (2,827)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-2,948; 5,528]	[-4,231; 6,872]	
Veränderung zu Woche 48			
n/N (%)	6/85 (7)	1/71 (1)	LS MD 0,04 [-9,166; 9,245]
MW (SD)	5,56 (13,608)	0,00 (NA)	
LS MW (SE)	0,33 (2,796)	0,30 (3,811)	
95 %-KI	[-5,155; 5,825]	[-7,185; 7,776]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Pegyliertes liposomales Doxorubicin</b>			
Baseline			
n/N (%)	62/80 (78)	57/76 (75)	-
MW (SD)	11,83 (25,676)	9,94 (19,885)	
Absolute Werte zum Studienende			
n/N (%)	3/51 (6)	3/41 (7)	-
MW (SD)	11,11 (19,245)	22,22 (19,245)	
Effekt über Studiendauer			
n	62	57	LS MD 0,68 [-5,091; 6,456] 0,8152  Hedges' g 0,04 [-0,317; 0,403]
LS MW (SE)	1,01 (1,961)	0,32 (2,154)	
95 %-KI	[-2,882; 4,896]	[-3,941; 4,589]	
Veränderung zu Woche 3/4			
n/N (%)	41/76 (54)	43/74 (58)	LS MD 1,34 [-5,122; 7,811]
MW (SD)	-2,44 (15,617)	2,33 (18,395)	
LS MW (SE)	2,13 (2,244)	0,78 (2,388)	
95 %-KI	[-2,301; 6,557]	[-3,927; 5,494]	
Veränderung zu Woche 8/9			
n/N (%)	52/76 (68)	43/66 (65)	LS MD 1,06 [-4,873; 6,985]
MW (SD)	2,56 (21,739)	-1,55 (21,765)	
LS MW (SE)	1,64 (2,056)	0,58 (2,179)	
95 %-KI	[-2,430; 5,708]	[-3,727; 4,893]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	33/75 (44)	23/64 (36)	LS MD 0,85 [-4,910; 6,618]
MW (SD)	-3,03 (26,827)	2,90 (22,277)	
LS MW (SE)	1,30 (1,982)	0,44 (2,129)	
95 %-KI	[-2,631; 5,225]	[-3,773; 4,659]	
Veränderung zu Woche 15/16			
n/N (%)	34/74 (46)	18/62 (29)	LS MD 0,65 [-5,138; 6,442]
MW (SD)	-0,00 (30,704)	0,00 (11,433)	
LS MW (SE)	0,95 (1,962)	0,30 (2,165)	
95 %-KI	[-2,935; 4,845]	[-3,983; 4,589]	
Veränderung zu Woche 20/21			
n/N (%)	26/72 (36)	18/59 (31)	LS MD 0,36 [-5,787; 6,514]
MW (SD)	-1,28 (29,030)	3,70 (15,713)	
LS MW (SE)	0,47 (2,028)	0,10 (2,357)	
95 %-KI	[-3,550; 4,482]	[-4,553; 4,758]	
Veränderung zu Woche 24			
n/N (%)	21/69 (30)	16/54 (30)	LS MD 0,16 [-6,440; 6,762]
MW (SD)	-1,59 (28,822)	0,00 (12,172)	
LS MW (SE)	0,12 (2,136)	-0,04 (2,571)	
95 %-KI	[-4,099; 4,347]	[-5,109; 5,034]	
Veränderung zu Woche 36			
n/N (%)	31/60 (52)	16/48 (33)	LS MD -0,53 [-9,509; 8,447]
MW (SD)	0,00 (27,217)	-2,08 (19,124)	
LS MW (SE)	-1,05 (2,786)	-0,52 (3,613)	
95 %-KI	[-6,533; 4,434]	[-7,624; 6,588]	
Veränderung zu Woche 48			
n/N (%)	2/51 (4)	2/41 (5)	LS MD -1,22 [-13,248; 10,800]
MW (SD)	16,67 (23,570)	0,00 (0,000)	
LS MW (SE)	-2,22 (3,679)	-1,00 (4,885)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-9,454; 5,009]	[-10,601; 8,604]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Paclitaxel</b>			
Baseline			
n/N (%)	76/88 (86)	70/82 (85)	-
MW (SD)	10,09 (21,787)	8,10 (16,483)	
Absolute Werte zum Studienende			
n/N (%)	1/56 (2)	1/49 (2)	-
MW (SD)	33,33 (NA)	0,00 (NA)	
Effekt über Studiendauer			
n	76	70	LS MD -3,67 [-9,787; 2,444] 0,2372  Hedges' g -0,20 [-0,522; 0,129]
LS MW (SE)	3,37 (2,097)	7,04 (2,270)	
95 %-KI	[-0,775; 7,522]	[2,557; 11,533]	
Veränderung zu Woche 3/4			
n/N (%)	56/87 (64)	49/81 (60)	LS MD -4,05 [-11,057; 2,963]
MW (SD)	9,52 (25,198)	6,12 (22,229)	
LS MW (SE)	4,36 (2,416)	8,40 (2,614)	
95 %-KI	[-0,403; 9,117]	[3,255; 13,552]	
Veränderung zu Woche 8/9			
n/N (%)	63/86 (73)	56/79 (71)	LS MD -3,88 [-10,201; 2,447]
MW (SD)	0,53 (29,017)	10,71 (30,555)	
LS MW (SE)	3,91 (2,188)	7,79 (2,339)	
95 %-KI	[-0,409; 8,232]	[3,172; 12,405]	
Veränderung zu Woche 12			
n/N (%)	44/84 (52)	37/77 (48)	LS MD -3,76 [-9,871; 2,355]
MW (SD)	-3,79 (20,606)	8,11 (22,778)	
LS MW (SE)	3,60 (2,108)	7,36 (2,260)	
95 %-KI	[-0,569; 7,769]	[2,890; 11,825]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	46/81 (57)	28/76 (37)	LS MD -3,64 [-9,789; 2,511]
MW (SD)	4,35 (23,943)	16,67 (27,962)	
LS MW (SE)	3,29 (2,103)	6,93 (2,289)	
95 %-KI	[-0,873; 7,449]	[2,403; 11,451]	
Veränderung zu Woche 20/21			
n/N (%)	30/77 (39)	26/73 (36)	LS MD -3,47 [-10,087; 3,149]
MW (SD)	-3,33 (28,162)	2,56 (24,807)	
LS MW (SE)	2,84 (2,226)	6,31 (2,506)	
95 %-KI	[-1,555; 7,240]	[1,369; 11,254]	
Veränderung zu Woche 24			
n/N (%)	22/74 (30)	19/72 (26)	LS MD -3,35 [-10,544; 3,844]
MW (SD)	-1,52 (28,129)	14,04 (32,041)	
LS MW (SE)	2,53 (2,392)	5,88 (2,757)	
95 %-KI	[-2,186; 7,248]	[0,451; 11,311]	
Veränderung zu Woche 36			
n/N (%)	37/64 (58)	23/63 (37)	LS MD -2,94 [-13,083; 7,200]
MW (SD)	5,41 (29,932)	2,90 (13,901)	
LS MW (SE)	1,46 (3,286)	4,40 (3,983)	
95 %-KI	[-4,996; 7,922]	[-3,422; 12,231]	
Veränderung zu Woche 48			
n/N (%)	1/56 (2)	1/49 (2)	LS MD -2,53 [-16,351; 11,284]
MW (SD)	33,33 (NA)	0,00 (NA)	
LS MW (SE)	0,39 (4,435)	2,93 (5,468)	
95 %-KI	[-8,319; 9,107]	[-7,814; 13,669]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Topotecan</b>			
Baseline			
n/N (%)	39/50 (78)	32/49 (65)	-
MW (SD)	4,27 (11,290)	12,50 (18,453)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	6/33 (18)	2/20 (10)	-
MW (SD)	11,11 (27,217)	16,67 (23,570)	
Effekt über Studiendauer			
n	39	32	LS MD -2,58 [-9,182; 4,016] 0,4374  Hedges' g -0,19 [-0,656; 0,281]
LS MW (SE)	1,02 (2,098)	3,61 (2,516)	
95 %-KI	[-3,169; 5,217]	[-1,411; 8,625]	
Veränderung zu Woche 3/4			
n/N (%)	24/50 (48)	18/45 (40)	LS MD -0,94 [-8,038; 6,156]
MW (SD)	8,33 (20,264)	3,70 (19,433)	
LS MW (SE)	2,99 (2,266)	3,93 (2,716)	
95 %-KI	[-1,513; 7,494]	[-1,463; 9,325]	
Veränderung zu Woche 8/9			
n/N (%)	30/48 (62)	27/43 (63)	LS MD -1,64 [-8,320; 5,032]
MW (SD)	1,11 (18,535)	-2,47 (20,519)	
LS MW (SE)	2,15 (2,138)	3,79 (2,542)	
95 %-KI	[-2,117; 6,414]	[-1,273; 8,858]	
Veränderung zu Woche 12			
n/N (%)	21/46 (46)	12/42 (29)	LS MD -2,14 [-8,701; 4,427]
MW (SD)	1,59 (12,807)	2,78 (17,164)	
LS MW (SE)	1,56 (2,098)	3,70 (2,498)	
95 %-KI	[-2,632; 5,750]	[-1,288; 8,678]	
Veränderung zu Woche 15/16			
n/N (%)	16/44 (36)	8/40 (20)	LS MD -2,63 [-9,239; 3,981]
MW (SD)	2,08 (8,333)	0,00 (0,000)	
LS MW (SE)	0,97 (2,100)	3,60 (2,521)	
95 %-KI	[-3,228; 5,165]	[-1,429; 8,625]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	11/41 (27)	7/33 (21)	LS MD -3,33 [-10,276; 3,611]
MW (SD)	0,00 (14,907)	-9,52 (16,265)	
LS MW (SE)	0,13 (2,177)	3,46 (2,667)	
95 %-KI	[-4,215; 4,468]	[-1,845; 8,763]	
Veränderung zu Woche 24			
n/N (%)	11/41 (27)	3/29 (10)	LS MD -3,82 [-11,170; 3,521]
MW (SD)	-3,03 (10,050)	0,00 (0,000)	
LS MW (SE)	-0,46 (2,278)	3,36 (2,839)	
95 %-KI	[-4,996; 4,070]	[-2,270; 8,994]	
Veränderung zu Woche 36			
n/N (%)	15/36 (42)	8/23 (35)	LS MD -5,51 [-15,013; 3,986]
MW (SD)	-4,44 (11,729)	-4,17 (11,785)	
LS MW (SE)	-2,48 (2,849)	3,03 (3,728)	
95 %-KI	[-8,115; 3,146]	[-4,328; 10,386]	
Veränderung zu Woche 48			
n/N (%)	5/33 (15)	2/20 (10)	LS MD -7,20 [-19,546; 5,143]
MW (SD)	0,00 (0,000)	0,00 (0,000)	
LS MW (SE)	-4,51 (3,630)	2,70 (4,873)	
95 %-KI	[-11,665; 2,653]	[-6,911; 12,301]	
<p><i>Analysepopulation: ITT</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023</i></p> <p><i>Modell: Veränderung zu Baseline ~ Behandlung + Baseline-Wert * Zeit in Wochen + Behandlung * Zeit in Wochen + zufällige Effekte durch die Patientin</i></p> <p><i>Die Berechnung des LS-MWs erfolgt durch ein MMRM mit dem oben angegebenen Modell. Basierend hierauf werden KI und p-Wert ermittelt. Hedges' g basiert ebenfalls auf den LS-MW und ist somit auf das Modell angepasst.</i></p> <p><i>Es werden ausschließlich gemeinsame Analysezeitpunkte dargestellt.</i></p> <p><i>Ein LS MD und Hedges' g kleiner als Null bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

## 2.4 EORTC QLQ-C30 Dyspnoe

### EORTC QLQ-C30 Dyspnoe: Subgruppenanalyse

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
<b>EORTC QLQ-C30 Dyspnoe</b>			
<b>Alter: &lt; 65 Jahre</b>			
Baseline			
n/N (%)	95/115 (83)	92/119 (77)	-
MW (SD)	22,11 (26,458)	21,01 (26,482)	
Absolute Werte zum Studienende			
n/N (%)	4/73 (5)	4/64 (6)	-
MW (SD)	33,33 (27,217)	25,00 (31,914)	
Effekt über Studiendauer			
n	95	92	LS MD -12,06 [-17,454; -6,659] < 0,0001  Hedges' g -0,64 [-0,936; -0,348]
LS MW (SE)	-2,10 (1,879)	9,96 (1,988)	
95 %-KI	[-5,807; 1,614]	[6,038; 13,883]	
Veränderung zu Woche 3/4			
n/N (%)	60/113 (53)	61/115 (53)	LS MD -10,40 [-16,479; -4,311]
MW (SD)	-3,33 (25,080)	6,01 (21,524)	
LS MW (SE)	-4,05 (2,135)	6,34 (2,234)	
95 %-KI	[-8,256; 0,151]	[1,946; 10,740]	
Veränderung zu Woche 8/9			
n/N (%)	76/112 (68)	72/108 (67)	LS MD -11,13 [-16,687; -5,565]
MW (SD)	-3,95 (26,087)	7,41 (25,158)	
LS MW (SE)	-3,19 (1,957)	7,93 (2,031)	
95 %-KI	[-7,051; 0,668]	[3,931; 11,938]	
Veränderung zu Woche 12			
n/N (%)	48/110 (44)	40/105 (38)	
MW (SD)	-2,08 (28,688)	13,33 (27,006)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-2,59 (1,892)	9,05 (1,975)	LS MD -11,64 [-17,034; -6,242]
95 %-KI	[-6,323; 1,145]	[5,152; 12,945]	
Veränderung zu Woche 15/16			
n/N (%)	55/107 (51)	33/102 (32)	LS MD -12,15 [-17,565; -6,734]
MW (SD)	-4,85 (25,993)	16,16 (29,013)	
LS MW (SE)	-1,99 (1,882)	10,16 (1,999)	
95 %-KI	[-5,702; 1,729]	[6,221; 14,105]	
Veränderung zu Woche 20/21			
n/N (%)	37/101 (37)	30/96 (31)	LS MD -12,88 [-18,634; -7,126]
MW (SD)	-2,70 (32,753)	6,67 (29,556)	
LS MW (SE)	-1,13 (1,964)	11,75 (2,162)	
95 %-KI	[-4,999; 2,747]	[7,495; 16,014]	
Veränderung zu Woche 24			
n/N (%)	24/99 (24)	19/91 (21)	LS MD -13,39 [-19,574; -7,210]
MW (SD)	2,78 (27,657)	3,51 (26,977)	
LS MW (SE)	-0,52 (2,082)	12,87 (2,353)	
95 %-KI	[-4,625; 3,579]	[8,239; 17,499]	
Veränderung zu Woche 36			
n/N (%)	42/86 (49)	28/79 (35)	LS MD -15,15 [-23,586; -6,706]
MW (SD)	-4,76 (28,103)	14,29 (27,857)	
LS MW (SE)	1,54 (2,755)	16,69 (3,299)	
95 %-KI	[-3,872; 6,957]	[10,208; 23,170]	
Veränderung zu Woche 48			
n/N (%)	4/73 (5)	3/64 (5)	LS MD -16,90 [-28,228; -5,573]
MW (SD)	16,67 (19,245)	0,00 (33,333)	
LS MW (SE)	3,61 (3,654)	20,51 (4,467)	
95 %-KI	[-3,568; 10,785]	[11,737; 29,281]	
<b>Alter: ≥ 65 Jahre</b>			
Baseline			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	81/103 (79)	66/88 (75)	-
MW (SD)	22,63 (23,468)	23,23 (28,627)	
Absolute Werte zum Studienende			
n/N (%)	6/67 (9)	2/46 (4)	-
MW (SD)	27,78 (38,968)	0,00 (0,000)	
Effekt über Studiendauer			
n	81	66	LS MD -7,76 [-13,349; -2,180] 0,0068  Hedges' g -0,46 [-0,784; -0,126]
LS MW (SE)	-4,44 (1,853)	3,33 (2,134)	
95 %-KI	[-8,101; -0,772]	[-0,889; 7,545]	
Veränderung zu Woche 3/4			
n/N (%)	60/100 (60)	49/85 (58)	LS MD -9,61 [-15,723; -3,501]
MW (SD)	-3,33 (23,530)	-0,68 (18,621)	
LS MW (SE)	-6,78 (2,051)	2,83 (2,326)	
95 %-KI	[-10,825; -2,736]	[-1,753; 7,415]	
Veränderung zu Woche 8/9			
n/N (%)	69/98 (70)	54/80 (68)	LS MD -8,79 [-14,465; -3,108]
MW (SD)	-5,80 (20,577)	0,62 (26,295)	
LS MW (SE)	-5,73 (1,909)	3,05 (2,152)	
95 %-KI	[-9,504; -1,962]	[-1,196; 7,302]	
Veränderung zu Woche 12			
n/N (%)	50/95 (53)	31/78 (40)	LS MD -8,21 [-13,771; -2,646]
MW (SD)	-4,67 (21,307)	9,68 (24,636)	
LS MW (SE)	-5,00 (1,860)	3,21 (2,113)	
95 %-KI	[-8,677; -1,323]	[-0,968; 7,385]	
Veränderung zu Woche 15/16			
n/N (%)	41/92 (45)	22/76 (29)	
MW (SD)	-4,07 (22,602)	4,55 (21,320)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-4,27 (1,856)	3,36 (2,149)	LS MD -7,63 [-13,241; -2,020]
95 %-KI	[-7,938; -0,596]	[-0,882; 7,609]	
Veränderung zu Woche 20/21			
n/N (%)	30/89 (34)	21/69 (30)	LS MD -6,81 [-12,760; -0,851]
MW (SD)	-5,56 (23,298)	-7,94 (23,345)	
LS MW (SE)	-3,22 (1,929)	3,59 (2,320)	
95 %-KI	[-7,031; 0,592]	[-0,990; 8,162]	
Veränderung zu Woche 24			
n/N (%)	29/85 (34)	19/64 (30)	LS MD -6,23 [-12,592; 0,136]
MW (SD)	-6,90 (22,501)	-10,53 (22,368)	
LS MW (SE)	-2,49 (2,031)	3,74 (2,510)	
95 %-KI	[-6,494; 1,521]	[-1,204; 8,686]	
Veränderung zu Woche 36			
n/N (%)	39/74 (53)	19/55 (35)	LS MD -4,25 [-12,738; 4,245]
MW (SD)	-1,71 (21,560)	5,26 (22,942)	
LS MW (SE)	0,03 (2,609)	4,27 (3,442)	
95 %-KI	[-5,104; 5,158]	[-2,490; 11,038]	
Veränderung zu Woche 48			
n/N (%)	4/67 (6)	2/46 (4)	LS MD -2,27 [-13,488; 8,956]
MW (SD)	16,67 (57,735)	-16,67 (23,570)	
LS MW (SE)	2,54 (3,392)	4,81 (4,594)	
95 %-KI	[-4,125; 9,205]	[-4,218; 13,830]	
<b>Region: USA</b>			
Baseline			
n/N (%)	49/65 (75)	33/51 (65)	-
MW (SD)	25,17 (25,028)	23,23 (28,241)	
Absolute Werte zum Studienende			
n/N (%)	2/39 (5)	3/27 (11)	-
MW (SD)	33,33 (0,000)	22,22 (38,490)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Effekt über Studiendauer			
n	49	33	LS MD -9,46 [-16,476; -2,452] 0,0088  Hedges' g -0,60 [-1,051; -0,148]
LS MW (SE)	-5,67 (2,226)	3,80 (2,738)	
95 %-KI	[-10,100; -1,231]	[-1,652; 9,250]	
Veränderung zu Woche 3/4			
n/N (%)	33/64 (52)	21/49 (43)	LS MD -7,76 [-15,451; -0,060]
MW (SD)	-5,05 (20,618)	3,17 (20,829)	
LS MW (SE)	-5,67 (2,453)	2,09 (3,018)	
95 %-KI	[-10,533; -0,808]	[-3,894; 8,064]	
Veränderung zu Woche 8/9			
n/N (%)	42/62 (68)	30/46 (65)	LS MD -8,54 [-15,701; -1,372]
MW (SD)	-8,73 (18,123)	1,11 (23,947)	
LS MW (SE)	-5,67 (2,284)	2,87 (2,795)	
95 %-KI	[-10,210; -1,126]	[-2,688; 8,424]	
Veränderung zu Woche 12			
n/N (%)	26/59 (44)	16/45 (36)	LS MD -9,08 [-16,091; -2,074]
MW (SD)	-6,41 (18,901)	6,25 (18,130)	
LS MW (SE)	-5,67 (2,230)	3,42 (2,732)	
95 %-KI	[-10,108; -1,226]	[-2,023; 8,855]	
Veränderung zu Woche 15/16			
n/N (%)	21/56 (38)	11/44 (25)	LS MD -9,63 [-16,671; -2,587]
MW (SD)	-9,52 (23,905)	9,09 (21,556)	
LS MW (SE)	-5,67 (2,233)	3,96 (2,753)	
95 %-KI	[-10,113; -1,217]	[-1,516; 9,444]	
Veränderung zu Woche 20/21			
n/N (%)	13/54 (24)	9/40 (22)	
MW (SD)	-2,56 (21,350)	3,70 (26,058)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-5,66 (2,337)	4,75 (2,924)	LS MD -10,41 [-17,823; -2,997]
95 %-KI	[-10,307; -1,019]	[-1,057; 10,551]	
Veränderung zu Woche 24			
n/N (%)	8/53 (15)	6/38 (16)	LS MD -10,96 [-18,831; -3,082]
MW (SD)	-4,17 (21,362)	0,00 (21,082)	
LS MW (SE)	-5,66 (2,471)	5,29 (3,128)	
95 %-KI	[-10,562; -0,761]	[-0,900; 11,490]	
Veränderung zu Woche 36			
n/N (%)	22/43 (51)	9/33 (27)	LS MD -12,83 [-23,195; -2,466]
MW (SD)	-9,09 (21,036)	3,70 (26,058)	
LS MW (SE)	-5,66 (3,211)	7,17 (4,188)	
95 %-KI	[-11,987; 0,674]	[-1,081; 15,429]	
Veränderung zu Woche 48			
n/N (%)	2/39 (5)	3/27 (11)	LS MD -14,70 [-28,338; -1,070]
MW (SD)	0,00 (0,000)	-11,11 (19,245)	
LS MW (SE)	-5,65 (4,192)	9,05 (5,544)	
95 %-KI	[-13,906; 2,603]	[-1,862; 19,969]	
<b>Region: Rest der Welt</b>			
Baseline			
n/N (%)	127/153 (83)	125/156 (80)	-
MW (SD)	21,26 (25,082)	21,60 (27,191)	
Absolute Werte zum Studienende			
n/N (%)	8/101 (8)	3/83 (4)	-
MW (SD)	29,17 (37,533)	11,11 (19,245)	
Effekt über Studiendauer			
n	127	125	LS MD -10,50 [-15,147; -5,853] < 0,0001  Hedges' g
LS MW (SE)	-2,40 (1,620)	8,10 (1,716)	
95 %-KI	[-5,589; 0,794]	[4,724; 11,480]	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
			-0,56 [-0,811; -0,307]
Veränderung zu Woche 3/4			
n/N (%)	87/149 (58)	89/151 (59)	LS MD -10,83 [-16,014; -5,652]
MW (SD)	-2,68 (25,527)	3,00 (20,499)	
LS MW (SE)	-5,24 (1,825)	5,60 (1,899)	
95 %-KI	[-8,825; -1,645]	[1,864; 9,331]	
Veränderung zu Woche 8/9			
n/N (%)	103/148 (70)	96/142 (68)	LS MD -10,69 [-15,449; -5,925]
MW (SD)	-3,24 (25,358)	5,56 (26,343)	
LS MW (SE)	-3,99 (1,683)	6,70 (1,737)	
95 %-KI	[-7,303; -0,675]	[3,279; 10,116]	
Veränderung zu Woche 12			
n/N (%)	72/146 (49)	55/138 (40)	LS MD -10,58 [-15,221; -5,948]
MW (SD)	-2,31 (27,020)	13,33 (27,666)	
LS MW (SE)	-3,12 (1,630)	7,47 (1,698)	
95 %-KI	[-6,329; 0,095]	[4,124; 10,811]	
Veränderung zu Woche 15/16			
n/N (%)	75/143 (52)	44/134 (33)	LS MD -10,48 [-15,145; -5,819]
MW (SD)	-3,11 (24,613)	12,12 (27,927)	
LS MW (SE)	-2,24 (1,621)	8,24 (1,725)	
95 %-KI	[-5,439; 0,950]	[4,840; 11,634]	
Veränderung zu Woche 20/21			
n/N (%)	54/136 (40)	42/125 (34)	LS MD -10,34 [-15,292; -5,380]
MW (SD)	-4,32 (30,404)	0,00 (28,513)	
LS MW (SE)	-1,00 (1,684)	9,34 (1,873)	
95 %-KI	[-4,315; 2,317]	[5,653; 13,021]	
Veränderung zu Woche 24			
n/N (%)	45/131 (34)	32/117 (27)	
MW (SD)	-2,22 (26,015)	-4,17 (26,437)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-0,13 (1,776)	10,11 (2,039)	LS MD -10,23 [-15,551; -4,916]
95 %-KI	[-3,622; 3,369]	[6,099; 14,114]	
Veränderung zu Woche 36			
n/N (%)	59/117 (50)	38/101 (38)	LS MD -9,88 [-17,089; -2,675]
MW (SD)	-1,13 (26,237)	12,28 (26,191)	
LS MW (SE)	2,86 (2,313)	12,75 (2,850)	
95 %-KI	[-1,678; 7,405]	[7,151; 18,340]	
Veränderung zu Woche 48			
n/N (%)	6/101 (6)	2/83 (2)	LS MD -9,53 [-19,153; 0,091]
MW (SD)	22,22 (45,542)	0,00 (47,140)	
LS MW (SE)	5,85 (3,039)	15,38 (3,844)	
95 %-KI	[-0,111; 11,819]	[7,841; 22,929]	
<b>Stadium bei der Diagnose: I-III</b>			
Baseline			
n/N (%)	111/141 (79)	111/144 (77)	-
MW (SD)	21,02 (24,996)	22,52 (28,127)	
Absolute Werte zum Studienende			
n/N (%)	6/91 (7)	4/76 (5)	-
MW (SD)	33,33 (36,515)	25,00 (31,914)	
Effekt über Studiendauer			
n	111	111	LS MD -11,57 [-16,326; -6,807] < 0,0001
LS MW (SE)	-4,48 (1,669)	7,09 (1,746)	
95 %-KI	[-7,767; -1,187]	[3,649; 10,529]	Hedges' g -0,64 [-0,911; -0,371]
Veränderung zu Woche 3/4			
n/N (%)	74/137 (54)	79/138 (57)	LS MD -11,11 [-16,387; -5,823]
MW (SD)	-4,05 (24,645)	1,69 (19,899)	
LS MW (SE)	-7,18 (1,873)	3,93 (1,922)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-10,865; -3,494]	[0,145; 7,705]	
Veränderung zu Woche 8/9			
n/N (%)	93/136 (68)	88/129 (68)	LS MD -11,31 [-16,189; -6,426]
MW (SD)	-5,02 (23,543)	4,92 (27,469)	
LS MW (SE)	-5,99 (1,732)	5,31 (1,772)	
95 %-KI	[-9,406; -2,583]	[1,824; 8,802]	
Veränderung zu Woche 12			
n/N (%)	62/133 (47)	48/128 (38)	LS MD -11,45 [-16,206; -6,692]
MW (SD)	-2,69 (25,819)	6,94 (25,690)	
LS MW (SE)	-5,16 (1,679)	6,28 (1,733)	
95 %-KI	[-8,475; -1,854]	[2,870; 9,699]	
Veränderung zu Woche 15/16			
n/N (%)	63/130 (48)	35/125 (28)	LS MD -11,59 [-16,363; -6,818]
MW (SD)	-3,70 (24,030)	9,52 (25,012)	
LS MW (SE)	-4,33 (1,670)	7,26 (1,753)	
95 %-KI	[-7,628; -1,042]	[3,801; 10,710]	
Veränderung zu Woche 20/21			
n/N (%)	45/123 (37)	34/116 (29)	LS MD -11,79 [-16,827; -6,759]
MW (SD)	-5,19 (28,387)	0,00 (31,782)	
LS MW (SE)	-3,15 (1,732)	8,64 (1,881)	
95 %-KI	[-6,563; 0,264]	[4,942; 12,345]	
Veränderung zu Woche 24			
n/N (%)	34/121 (28)	27/109 (25)	LS MD -11,93 [-17,300; -6,569]
MW (SD)	0,98 (27,810)	-6,17 (27,792)	
LS MW (SE)	-2,32 (1,824)	9,61 (2,028)	
95 %-KI	[-5,911; 1,272]	[5,626; 13,603]	
Veränderung zu Woche 36			
n/N (%)	52/105 (50)	35/92 (38)	
MW (SD)	-3,85 (26,117)	11,43 (27,939)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	0,53 (2,359)	12,95 (2,769)	LS MD -12,42 [-19,562; -5,278]
95 %-KI	[-4,109; 5,159]	[7,509; 18,382]	
Veränderung zu Woche 48			
n/N (%)	5/91 (5)	4/76 (5)	LS MD -12,91 [-22,359; -3,451]
MW (SD)	20,00 (50,553)	0,00 (27,217)	
LS MW (SE)	3,37 (3,088)	16,28 (3,696)	
95 %-KI	[-2,691; 9,432]	[9,021; 23,531]	
<b>Stadium bei der Diagnose: IV</b>			
Baseline			
n/N (%)	60/72 (83)	45/60 (75)	-
MW (SD)	24,44 (25,941)	20,74 (25,907)	
Absolute Werte zum Studienende			
n/N (%)	4/46 (9)	2/33 (6)	-
MW (SD)	25,00 (31,914)	0,00 (0,000)	
Effekt über Studiendauer			
n	60	45	LS MD -10,09 [-17,310; -2,870] 0,0066  Hedges' g -0,55 [-0,939; -0,152]
LS MW (SE)	-1,32 (2,341)	8,77 (2,782)	
95 %-KI	[-5,970; 3,326]	[3,251; 14,285]	
Veränderung zu Woche 3/4			
n/N (%)	41/71 (58)	29/59 (49)	LS MD -10,93 [-18,952; -2,905]
MW (SD)	-1,63 (23,513)	6,90 (22,501)	
LS MW (SE)	-2,50 (2,616)	8,42 (3,107)	
95 %-KI	[-7,674; 2,665]	[2,289; 14,560]	
Veränderung zu Woche 8/9			
n/N (%)	47/69 (68)	36/56 (64)	LS MD -10,55 [-17,902; -3,203]
MW (SD)	-4,96 (24,056)	3,70 (22,222)	
LS MW (SE)	-1,97 (2,417)	8,58 (2,812)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,764; 2,817]	[3,009; 14,148]	
Veränderung zu Woche 12			
n/N (%)	31/67 (46)	22/52 (42)	LS MD -10,29 [-17,464; -3,113]
MW (SD)	-5,38 (24,490)	22,73 (23,874)	
LS MW (SE)	-1,60 (2,349)	8,69 (2,747)	
95 %-KI	[-6,264; 3,061]	[3,239; 14,135]	
Veränderung zu Woche 15/16			
n/N (%)	30/64 (47)	18/50 (36)	LS MD -10,02 [-17,292; -2,757]
MW (SD)	-7,78 (25,795)	18,52 (28,520)	
LS MW (SE)	-1,23 (2,346)	8,79 (2,809)	
95 %-KI	[-5,888; 3,429]	[3,225; 14,364]	
Veränderung zu Woche 20/21			
n/N (%)	19/62 (31)	16/46 (35)	LS MD -9,65 [-17,485; -1,811]
MW (SD)	-1,75 (30,376)	4,17 (16,667)	
LS MW (SE)	-0,70 (2,454)	8,95 (3,102)	
95 %-KI	[-5,564; 4,166]	[2,817; 15,082]	
Veränderung zu Woche 24			
n/N (%)	17/59 (29)	10/44 (23)	LS MD -9,38 [-17,880; -0,889]
MW (SD)	-9,80 (19,596)	6,67 (14,055)	
LS MW (SE)	-0,33 (2,601)	9,06 (3,420)	
95 %-KI	[-5,472; 4,818]	[2,310; 15,805]	
Veränderung zu Woche 36			
n/N (%)	28/52 (54)	11/41 (27)	LS MD -8,48 [-20,278; 3,318]
MW (SD)	-2,38 (23,880)	6,06 (20,101)	
LS MW (SE)	0,95 (3,414)	9,43 (4,920)	
95 %-KI	[-5,774; 7,670]	[-0,251; 19,106]	
Veränderung zu Woche 48			
n/N (%)	3/46 (7)	1/33 (3)	
MW (SD)	11,11 (19,245)	-33,33 (NA)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	2,22 (4,493)	9,80 (6,713)	LS MD -7,58 [-23,480; 8,328]
95 %-KI	[-6,615; 11,060]	[-3,403; 23,000]	
<b>BRCA Status: Positiv</b>			
Baseline			
n/N (%)	25/27 (93)	23/35 (66)	-
MW (SD)	25,33 (25,963)	17,39 (22,178)	
Absolute Werte zum Studienende			
n/N (%)	1/19 (5)	0/15 (0)	-
MW (SD)	66,67 (NA)	NA (NA)	
Effekt über Studiendauer			
n	25	23	LS MD -7,91 [-19,511; 3,694] 0,1765
LS MW (SE)	0,82 (3,840)	8,73 (4,229)	
95 %-KI	[-6,946; 8,583]	[0,227; 17,227]	Hedges' g -0,39 [-0,967; 0,178]
Veränderung zu Woche 3/4			
n/N (%)	16/27 (59)	18/35 (51)	LS MD -4,24 [-17,039; 8,550]
MW (SD)	-6,25 (21,837)	3,70 (22,547)	
LS MW (SE)	-0,47 (4,410)	3,78 (4,626)	
95 %-KI	[-9,266; 8,335]	[-5,436; 12,994]	
Veränderung zu Woche 8/9			
n/N (%)	21/26 (81)	19/30 (63)	LS MD -6,02 [-17,656; 5,615]
MW (SD)	-9,52 (28,172)	7,02 (26,244)	
LS MW (SE)	0,16 (4,008)	6,18 (4,126)	
95 %-KI	[-7,903; 8,217]	[-2,115; 14,470]	
Veränderung zu Woche 12			
n/N (%)	15/26 (58)	11/30 (37)	LS MD -7,26 [-18,734; 4,206]
MW (SD)	-2,22 (23,458)	15,15 (31,140)	
LS MW (SE)	0,59 (3,864)	7,86 (4,117)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-7,212; 8,397]	[-0,433; 16,145]	
Veränderung zu Woche 15/16			
n/N (%)	12/26 (46)	8/29 (28)	LS MD -8,51 [-20,362; 3,348]
MW (SD)	2,78 (22,285)	12,50 (17,252)	
LS MW (SE)	1,03 (3,850)	9,53 (4,398)	
95 %-KI	[-6,756; 8,812]	[0,717; 18,352]	
Veränderung zu Woche 20/21			
n/N (%)	10/25 (40)	4/25 (16)	LS MD -10,28 [-23,550; 2,984]
MW (SD)	-3,33 (29,187)	8,33 (31,914)	
LS MW (SE)	1,65 (4,053)	11,93 (5,199)	
95 %-KI	[-6,508; 9,808]	[1,592; 22,274]	
Veränderung zu Woche 24			
n/N (%)	8/25 (32)	4/24 (17)	LS MD -11,53 [-26,265; 3,213]
MW (SD)	-4,17 (21,362)	-16,67 (19,245)	
LS MW (SE)	2,09 (4,334)	13,61 (5,950)	
95 %-KI	[-6,594; 10,765]	[1,818; 25,405]	
Veränderung zu Woche 36			
n/N (%)	10/21 (48)	5/20 (25)	LS MD -15,79 [-37,313; 5,737]
MW (SD)	-3,33 (18,922)	13,33 (29,814)	
LS MW (SE)	3,58 (5,883)	19,37 (9,100)	
95 %-KI	[-8,069; 15,227]	[1,390; 37,345]	
Veränderung zu Woche 48			
n/N (%)	1/19 (5)	0/15 (0)	LS MD -20,05 [-49,567; 9,466]
MW (SD)	33,33 (NA)	NA (NA)	
LS MW (SE)	5,07 (7,899)	25,12 (12,617)	
95 %-KI	[-10,534; 20,678]	[0,200; 50,046]	
<b>BRCA Status: Negativ/Unbekannt</b>			
Baseline			
n/N (%)	151/191 (79)	135/172 (78)	-

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	21,85 (24,958)	22,72 (28,111)	
Absolute Werte zum Studienende			
n/N (%)	9/121 (7)	6/95 (6)	-
MW (SD)	25,93 (32,394)	16,67 (27,889)	
Effekt über Studiendauer			
n	151	135	LS MD -10,95 [-15,120; -6,771] < 0,0001  Hedges' g -0,61 [-0,849; -0,373]
LS MW (SE)	-3,88 (1,428)	7,07 (1,568)	
95 %-KI	[-6,691; -1,068]	[3,980; 10,152]	
Veränderung zu Woche 3/4			
n/N (%)	104/186 (56)	92/165 (56)	LS MD -11,11 [-15,747; -6,481]
MW (SD)	-2,88 (24,627)	2,90 (20,165)	
LS MW (SE)	-6,12 (1,594)	5,00 (1,736)	
95 %-KI	[-9,248; -2,982]	[1,587; 8,411]	
Veränderung zu Woche 8/9			
n/N (%)	124/184 (67)	107/158 (68)	LS MD -11,04 [-15,321; -6,761]
MW (SD)	-4,03 (22,728)	4,05 (25,783)	
LS MW (SE)	-5,14 (1,477)	5,90 (1,597)	
95 %-KI	[-8,044; -2,233]	[2,760; 9,045]	
Veränderung zu Woche 12			
n/N (%)	83/179 (46)	60/153 (39)	LS MD -10,99 [-15,160; -6,819]
MW (SD)	-3,61 (25,509)	11,11 (25,055)	
LS MW (SE)	-4,45 (1,435)	6,53 (1,559)	
95 %-KI	[-7,279; -1,630]	[3,466; 9,604]	
Veränderung zu Woche 15/16			
n/N (%)	84/173 (49)	47/149 (32)	LS MD -10,94 [-15,123; -6,752]
MW (SD)	-5,56 (24,725)	11,35 (28,041)	
LS MW (SE)	-3,77 (1,429)	7,17 (1,574)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,585; -0,955]	[4,069; 10,265]	
Veränderung zu Woche 20/21			
n/N (%)	57/165 (35)	47/140 (34)	LS MD -10,86 [-15,281; -6,447]
MW (SD)	-4,09 (28,916)	0,00 (27,802)	
LS MW (SE)	-2,79 (1,486)	8,07 (1,684)	
95 %-KI	[-5,718; 0,131]	[4,760; 11,382]	
Veränderung zu Woche 24			
n/N (%)	45/159 (28)	34/131 (26)	LS MD -10,81 [-15,522; -6,103]
MW (SD)	-2,22 (26,015)	-1,96 (25,874)	
LS MW (SE)	-2,11 (1,566)	8,70 (1,813)	
95 %-KI	[-5,190; 0,971]	[5,140; 12,267]	
Veränderung zu Woche 36			
n/N (%)	71/139 (51)	42/114 (37)	LS MD -10,64 [-16,911; -4,360]
MW (SD)	-3,29 (25,915)	10,32 (26,017)	
LS MW (SE)	0,24 (2,027)	10,87 (2,472)	
95 %-KI	[-3,744; 4,215]	[6,020; 15,723]	
Veränderung zu Woche 48			
n/N (%)	7/121 (6)	5/95 (5)	LS MD -10,46 [-18,768; -2,150]
MW (SD)	14,29 (42,414)	-6,67 (27,889)	
LS MW (SE)	2,58 (2,650)	13,04 (3,301)	
95 %-KI	[-2,620; 7,781]	[6,562; 19,518]	
<b>Baseline ECOG PS: 0</b>			
Baseline			
n/N (%)	101/128 (79)	96/113 (85)	-
MW (SD)	18,81 (22,811)	17,01 (23,192)	
Absolute Werte zum Studienende			
n/N (%)	7/87 (8)	3/72 (4)	-
MW (SD)	28,57 (23,002)	22,22 (38,490)	
Effekt über Studiendauer			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n	101	96	LS MD -8,47 [-13,547; -3,400] 0,0012  Hedges' g -0,47 [-0,751; -0,185]
LS MW (SE)	-1,29 (1,765)	7,18 (1,871)	
95 %-KI	[-4,775; 2,191]	[3,492; 10,870]	
Veränderung zu Woche 3/4			
n/N (%)	70/127 (55)	64/111 (58)	LS MD -9,21 [-14,810; -3,604]
MW (SD)	-2,38 (26,205)	4,17 (20,141)	
LS MW (SE)	-3,22 (1,955)	5,99 (2,068)	
95 %-KI	[-7,067; 0,631]	[1,920; 10,058]	
Veränderung zu Woche 8/9			
n/N (%)	85/126 (67)	75/108 (69)	LS MD -8,89 [-14,091; -3,688]
MW (SD)	-2,75 (24,780)	6,22 (24,928)	
LS MW (SE)	-2,39 (1,824)	6,50 (1,906)	
95 %-KI	[-5,980; 1,210]	[2,748; 10,261]	
Veränderung zu Woche 12			
n/N (%)	53/122 (43)	46/108 (43)	LS MD -8,67 [-13,741; -3,594]
MW (SD)	0,63 (24,885)	14,49 (25,965)	
LS MW (SE)	-1,80 (1,775)	6,87 (1,861)	
95 %-KI	[-5,305; 1,700]	[3,196; 10,535]	
Veränderung zu Woche 15/16			
n/N (%)	55/120 (46)	35/105 (33)	LS MD -8,45 [-13,528; -3,363]
MW (SD)	-1,82 (26,773)	12,38 (26,918)	
LS MW (SE)	-1,22 (1,766)	7,23 (1,876)	
95 %-KI	[-4,705; 2,266]	[3,527; 10,926]	
Veränderung zu Woche 20/21			
n/N (%)	40/117 (34)	32/101 (32)	LS MD -8,13 [-13,458; -2,800]
MW (SD)	-2,50 (31,476)	3,13 (27,251)	
LS MW (SE)	-0,39 (1,823)	7,74 (1,999)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,981; 3,207]	[3,804; 11,680]	
Veränderung zu Woche 24			
n/N (%)	27/112 (24)	22/96 (23)	LS MD -7,91 [-13,556; -2,257]
MW (SD)	-1,23 (28,467)	4,55 (23,672)	
LS MW (SE)	0,20 (1,907)	8,10 (2,147)	
95 %-KI	[-3,561; 3,953]	[3,878; 12,328]	
Veränderung zu Woche 36			
n/N (%)	51/99 (52)	34/87 (39)	LS MD -7,15 [-14,549; 0,257]
MW (SD)	-3,92 (27,201)	4,90 (27,380)	
LS MW (SE)	2,19 (2,408)	9,34 (2,906)	
95 %-KI	[-2,537; 6,927]	[3,634; 15,048]	
Veränderung zu Woche 48			
n/N (%)	5/87 (6)	3/72 (4)	LS MD -6,39 [-16,107; 3,336]
MW (SD)	13,33 (18,257)	-11,11 (19,245)	
LS MW (SE)	4,19 (3,104)	10,58 (3,868)	
95 %-KI	[-1,902; 10,288]	[2,984; 18,173]	
<b>Baseline ECOG PS: 1</b>			
Baseline			
n/N (%)	75/90 (83)	61/91 (67)	-
MW (SD)	27,11 (27,231)	28,42 (30,329)	
Absolute Werte zum Studienende			
n/N (%)	3/53 (6)	3/37 (8)	-
MW (SD)	33,33 (57,735)	11,11 (19,245)	
Effekt über Studiendauer			
n	75	61	LS MD -13,49 [-19,589; -7,381] < 0,0001
LS MW (SE)	-5,72 (2,002)	7,76 (2,352)	
95 %-KI	[-9,689; -1,759]	[3,110; 12,411]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	50/86 (58)	45/87 (52)	LS MD -11,17 [-17,990; -4,349]
MW (SD)	-4,67 (21,307)	1,48 (21,267)	
LS MW (SE)	-8,12 (2,291)	3,05 (2,598)	
95 %-KI	[-12,633; -3,599]	[-2,068; 8,174]	
Veränderung zu Woche 8/9			
n/N (%)	60/84 (71)	50/78 (64)	LS MD -12,23 [-18,451; -6,016]
MW (SD)	-7,78 (21,582)	2,67 (26,802)	
LS MW (SE)	-7,02 (2,082)	5,22 (2,364)	
95 %-KI	[-11,133; -2,902]	[0,545; 9,887]	
Veränderung zu Woche 12			
n/N (%)	45/83 (54)	24/74 (32)	LS MD -12,98 [-19,046; -6,911]
MW (SD)	-8,15 (24,777)	9,72 (20,803)	
LS MW (SE)	-6,25 (2,011)	6,73 (2,321)	
95 %-KI	[-10,228; -2,267]	[2,142; 11,320]	
Veränderung zu Woche 15/16			
n/N (%)	41/79 (52)	20/72 (28)	LS MD -13,72 [-19,884; -7,563]
MW (SD)	-8,13 (20,791)	10,00 (26,710)	
LS MW (SE)	-5,48 (2,010)	8,24 (2,384)	
95 %-KI	[-9,458; -1,499]	[3,533; 12,956]	
Veränderung zu Woche 20/21			
n/N (%)	27/73 (37)	18/63 (29)	LS MD -14,79 [-21,478; -8,097]
MW (SD)	-6,17 (24,525)	-0,00 (25,565)	
LS MW (SE)	-4,38 (2,129)	10,41 (2,641)	
95 %-KI	[-8,587; -0,171]	[5,199; 15,617]	
Veränderung zu Woche 24			
n/N (%)	26/72 (36)	15/58 (26)	LS MD -15,53 [-22,827; -8,238]
MW (SD)	-3,85 (21,760)	-13,33 (24,560)	
LS MW (SE)	-3,61 (2,286)	11,92 (2,914)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-8,121; 0,901]	[6,184; 17,661]	
Veränderung zu Woche 36			
n/N (%)	30/61 (49)	13/46 (28)	LS MD -18,09 [-28,349; -7,823]
MW (SD)	-2,22 (21,323)	25,64 (14,618)	
LS MW (SE)	-0,97 (3,127)	17,11 (4,181)	
95 %-KI	[-7,122; 5,178]	[8,895; 25,333]	
Veränderung zu Woche 48			
n/N (%)	3/53 (6)	2/37 (5)	LS MD -20,64 [-34,546; -6,733]
MW (SD)	22,22 (69,389)	0,00 (47,140)	
LS MW (SE)	1,67 (4,208)	22,31 (5,689)	
95 %-KI	[-6,605; 9,936]	[11,125; 33,486]	
<b>Anzahl vorheriger Therapielinien: 1</b>			
Baseline			
n/N (%)	23/31 (74)	23/29 (79)	-
MW (SD)	18,84 (24,259)	21,74 (25,837)	
Absolute Werte zum Studienende			
n/N (%)	1/22 (5)	0/14 (0)	-
MW (SD)	33,33 (NA)	NA (NA)	
Effekt über Studiendauer			
n	23	23	LS MD -11,52 [-21,888; -1,144] 0,0304  Hedges' g -0,65 [-1,245; -0,056]
LS MW (SE)	-6,56 (3,575)	4,96 (3,682)	
95 %-KI	[-13,783; 0,672]	[-2,461; 12,382]	
Veränderung zu Woche 3/4			
n/N (%)	15/31 (48)	15/29 (52)	LS MD -8,87 [-20,504; 2,762]
MW (SD)	-4,44 (35,337)	4,44 (24,774)	
LS MW (SE)	-8,17 (4,066)	0,70 (4,186)	
95 %-KI	[-16,294; -0,054]	[-7,647; 9,040]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	19/31 (61)	18/26 (69)	LS MD -9,98 [-20,694; 0,724]
MW (SD)	-5,26 (22,942)	-3,70 (19,433)	
LS MW (SE)	-7,49 (3,753)	2,49 (3,783)	
95 %-KI	[-15,038; 0,053]	[-5,104; 10,088]	
Veränderung zu Woche 12			
n/N (%)	14/31 (45)	12/24 (50)	LS MD -10,76 [-21,159; -0,370]
MW (SD)	-7,14 (23,310)	5,56 (19,245)	
LS MW (SE)	-7,02 (3,623)	3,75 (3,661)	
95 %-KI	[-14,327; 0,296]	[-3,628; 11,125]	
Veränderung zu Woche 15/16			
n/N (%)	15/31 (48)	11/22 (50)	LS MD -11,54 [-21,921; -1,167]
MW (SD)	-4,44 (27,794)	3,03 (17,979)	
LS MW (SE)	-6,54 (3,575)	5,01 (3,686)	
95 %-KI	[-13,765; 0,688]	[-2,422; 12,434]	
Veränderung zu Woche 20/21			
n/N (%)	11/30 (37)	9/22 (41)	LS MD -12,66 [-23,517; -1,799]
MW (SD)	-9,09 (21,556)	0,00 (23,570)	
LS MW (SE)	-5,86 (3,655)	6,80 (3,969)	
95 %-KI	[-13,227; 1,514]	[-1,155; 14,758]	
Veränderung zu Woche 24			
n/N (%)	9/30 (30)	11/20 (55)	LS MD -13,44 [-24,963; -1,912]
MW (SD)	-7,41 (14,699)	0,00 (21,082)	
LS MW (SE)	-5,38 (3,809)	8,06 (4,313)	
95 %-KI	[-13,030; 2,271]	[-0,547; 16,664]	
Veränderung zu Woche 36			
n/N (%)	14/26 (54)	6/18 (33)	LS MD -16,11 [-31,418; -0,804]
MW (SD)	-2,38 (24,335)	5,56 (32,773)	
LS MW (SE)	-3,74 (4,810)	12,37 (6,058)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-13,282; 5,795]	[0,387; 24,348]	
Veränderung zu Woche 48			
n/N (%)	0/22 (0)	0/14 (0)	LS MD -18,78 [-39,150; 1,582]
MW (SD)	NA (NA)	NA (NA)	
LS MW (SE)	-2,11 (6,246)	16,68 (8,227)	
95 %-KI	[-14,444; 10,228]	[0,434; 32,919]	
<b>Anzahl vorheriger Therapielinien: 2</b>			
Baseline			
n/N (%)	76/89 (85)	64/83 (77)	-
MW (SD)	22,81 (23,229)	22,40 (27,892)	
Absolute Werte zum Studienende			
n/N (%)	4/59 (7)	2/50 (4)	-
MW (SD)	50,00 (43,033)	0,00 (0,000)	
Effekt über Studiendauer			
n	76	64	LS MD -9,61 [-15,981; -3,247] 0,0034  Hedges' g -0,51 [-0,844; -0,168]
LS MW (SE)	-2,76 (2,107)	6,85 (2,437)	
95 %-KI	[-6,932; 1,409]	[2,035; 11,670]	
Veränderung zu Woche 3/4			
n/N (%)	53/86 (62)	46/80 (57)	LS MD -10,33 [-17,393; -3,269]
MW (SD)	-3,14 (21,940)	-0,72 (20,475)	
LS MW (SE)	-5,78 (2,376)	4,55 (2,681)	
95 %-KI	[-10,465; -1,094]	[-0,732; 9,834]	
Veränderung zu Woche 8/9			
n/N (%)	64/85 (75)	52/77 (68)	LS MD -10,01 [-16,481; -3,532]
MW (SD)	-6,77 (23,140)	5,77 (29,314)	
LS MW (SE)	-4,42 (2,186)	5,59 (2,444)	
95 %-KI	[-8,736; -0,095]	[0,764; 10,418]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	40/83 (48)	30/75 (40)	LS MD -9,78 [-16,107; -3,453]
MW (SD)	-4,17 (21,599)	13,33 (28,500)	
LS MW (SE)	-3,46 (2,118)	6,32 (2,400)	
95 %-KI	[-7,652; 0,731]	[1,574; 11,065]	
Veränderung zu Woche 15/16			
n/N (%)	42/80 (52)	20/74 (27)	LS MD -9,55 [-15,967; -3,140]
MW (SD)	-2,38 (22,563)	16,67 (33,333)	
LS MW (SE)	-2,51 (2,111)	7,05 (2,465)	
95 %-KI	[-6,684; 1,672]	[2,177; 11,919]	
Veränderung zu Woche 20/21			
n/N (%)	32/78 (41)	21/68 (31)	LS MD -9,23 [-16,152; -2,307]
MW (SD)	-1,04 (28,692)	0,00 (33,333)	
LS MW (SE)	-1,14 (2,205)	8,09 (2,728)	
95 %-KI	[-5,500; 3,217]	[2,709; 13,467]	
Veränderung zu Woche 24			
n/N (%)	26/74 (35)	13/65 (20)	LS MD -9,00 [-16,510; -1,496]
MW (SD)	1,28 (22,072)	-5,13 (35,606)	
LS MW (SE)	-0,19 (2,337)	8,82 (3,006)	
95 %-KI	[-4,799; 4,426]	[2,897; 14,735]	
Veränderung zu Woche 36			
n/N (%)	34/65 (52)	18/58 (31)	LS MD -8,23 [-18,645; 2,194]
MW (SD)	-4,90 (21,916)	12,96 (28,328)	
LS MW (SE)	3,09 (3,080)	11,31 (4,301)	
95 %-KI	[-2,970; 9,144]	[2,860; 19,766]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	1/50 (2)	LS MD -7,45 [-21,479; 6,582]
MW (SD)	41,67 (41,944)	-33,33 (NA)	
LS MW (SE)	6,36 (4,069)	13,81 (5,844)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-1,635; 14,357]	[2,327; 25,292]	
<b>Anzahl vorheriger Therapielinien: 3</b>			
Baseline			
n/N (%)	77/98 (79)	71/95 (75)	-
MW (SD)	22,94 (27,177)	21,60 (27,659)	
Absolute Werte zum Studienende			
n/N (%)	5/59 (8)	4/46 (9)	-
MW (SD)	13,33 (18,257)	25,00 (31,914)	
Effekt über Studiendauer			
n	77	71	LS MD -10,82 [-16,538; -5,093] 0,0003  Hedges' g -0,61 [-0,942; -0,282]
LS MW (SE)	-2,54 (1,979)	8,28 (2,114)	
95 %-KI	[-6,452; 1,377]	[4,101; 12,456]	
Veränderung zu Woche 3/4			
n/N (%)	52/96 (54)	49/91 (54)	LS MD -10,56 [-16,853; -4,257]
MW (SD)	-3,21 (23,113)	6,12 (18,848)	
LS MW (SE)	-3,96 (2,192)	6,60 (2,326)	
95 %-KI	[-8,280; 0,363]	[2,012; 11,181]	
Veränderung zu Woche 8/9			
n/N (%)	62/94 (66)	56/85 (66)	LS MD -10,67 [-16,521; -4,820]
MW (SD)	-2,69 (24,367)	5,95 (23,874)	
LS MW (SE)	-3,33 (2,036)	7,34 (2,153)	
95 %-KI	[-7,351; 0,692]	[3,089; 11,593]	
Veränderung zu Woche 12			
n/N (%)	44/91 (48)	29/84 (35)	LS MD -10,75 [-16,467; -5,036]
MW (SD)	-1,52 (28,715)	12,64 (25,841)	
LS MW (SE)	-2,89 (1,984)	7,86 (2,105)	
95 %-KI	[-6,811; 1,034]	[3,702; 12,023]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	39/88 (44)	24/82 (29)	LS MD -10,83 [-16,572; -5,091]
MW (SD)	-6,84 (25,569)	11,11 (23,399)	
LS MW (SE)	-2,45 (1,983)	8,38 (2,123)	
95 %-KI	[-6,371; 1,474]	[4,189; 12,578]	
Veränderung zu Woche 20/21			
n/N (%)	24/82 (29)	21/75 (28)	LS MD -10,95 [-16,993; -4,901]
MW (SD)	-5,56 (32,103)	1,59 (24,667)	
LS MW (SE)	-1,82 (2,072)	9,13 (2,257)	
95 %-KI	[-5,912; 2,274]	[4,675; 13,581]	
Veränderung zu Woche 24			
n/N (%)	18/80 (22)	14/70 (20)	LS MD -11,03 [-17,457; -4,599]
MW (SD)	-5,56 (32,839)	-4,76 (17,817)	
LS MW (SE)	-1,38 (2,190)	9,65 (2,417)	
95 %-KI	[-5,700; 2,942]	[4,886; 14,412]	
Veränderung zu Woche 36			
n/N (%)	33/69 (48)	23/58 (40)	LS MD -11,30 [-19,786; -2,822]
MW (SD)	-2,02 (28,795)	10,14 (23,430)	
LS MW (SE)	0,13 (2,847)	11,44 (3,242)	
95 %-KI	[-5,467; 5,730]	[5,062; 17,810]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	4/46 (9)	LS MD -11,58 [-22,748; -0,414]
MW (SD)	-8,33 (16,667)	0,00 (27,217)	
LS MW (SE)	1,64 (3,722)	13,22 (4,295)	
95 %-KI	[-5,673; 8,956]	[4,784; 21,662]	
<b>Vorherige Verabreichung von Bevacizumab: Ja</b>			
Baseline			
n/N (%)	104/134 (78)	100/132 (76)	-
MW (SD)	23,08 (25,047)	25,00 (31,203)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	3/79 (4)	3/62 (5)	-
MW (SD)	55,56 (38,490)	22,22 (38,490)	
Effekt über Studiendauer			
n	104	100	LS MD -9,71 [-14,723; -4,702] 0,0002  Hedges' g -0,53 [-0,813; -0,255]
LS MW (SE)	-2,15 (1,729)	7,56 (1,861)	
95 %-KI	[-5,565; 1,259]	[3,890; 11,229]	
Veränderung zu Woche 3/4			
n/N (%)	67/130 (52)	69/127 (54)	LS MD -7,55 [-13,137; -1,963]
MW (SD)	-1,00 (20,076)	2,90 (21,189)	
LS MW (SE)	-4,24 (1,947)	3,31 (2,060)	
95 %-KI	[-8,069; -0,406]	[-0,740; 7,364]	
Veränderung zu Woche 8/9			
n/N (%)	85/130 (65)	77/119 (65)	LS MD -8,56 [-13,664; -3,457]
MW (SD)	-3,92 (23,238)	2,16 (26,676)	
LS MW (SE)	-3,26 (1,790)	5,30 (1,870)	
95 %-KI	[-6,791; 0,264]	[1,613; 8,982]	
Veränderung zu Woche 12			
n/N (%)	55/126 (44)	37/114 (32)	LS MD -9,27 [-14,252; -4,283]
MW (SD)	-1,82 (25,189)	4,50 (23,782)	
LS MW (SE)	-2,58 (1,736)	6,69 (1,837)	
95 %-KI	[-6,006; 0,844]	[3,065; 10,308]	
Veränderung zu Woche 15/16			
n/N (%)	58/122 (48)	32/112 (29)	LS MD -9,98 [-15,037; -4,913]
MW (SD)	-3,45 (20,414)	12,50 (25,045)	
LS MW (SE)	-1,90 (1,735)	8,08 (1,892)	
95 %-KI	[-5,322; 1,524]	[4,347; 11,805]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	39/114 (34)	28/103 (27)	LS MD -10,99 [-16,479; -5,493]
MW (SD)	-0,85 (27,023)	-2,38 (27,108)	
LS MW (SE)	-0,92 (1,822)	10,06 (2,108)	
95 %-KI	[-4,517; 2,668]	[5,912; 14,210]	
Veränderung zu Woche 24			
n/N (%)	28/109 (26)	17/95 (18)	LS MD -11,69 [-17,675; -5,711]
MW (SD)	3,57 (22,842)	-3,92 (26,040)	
LS MW (SE)	-0,24 (1,940)	11,45 (2,335)	
95 %-KI	[-4,062; 3,577]	[6,860; 16,040]	
Veränderung zu Woche 36			
n/N (%)	44/93 (47)	22/79 (28)	LS MD -14,12 [-22,499; -5,737]
MW (SD)	-4,55 (22,263)	12,12 (21,932)	
LS MW (SE)	2,10 (2,582)	16,21 (3,375)	
95 %-KI	[-2,976; 7,168]	[9,586; 22,842]	
Veränderung zu Woche 48			
n/N (%)	3/79 (4)	2/62 (3)	LS MD -16,54 [-27,872; -5,214]
MW (SD)	44,44 (50,918)	-16,67 (23,570)	
LS MW (SE)	4,43 (3,425)	20,98 (4,604)	
95 %-KI	[-2,290; 11,159]	[11,937; 30,019]	
<b>Vorherige Verabreichung von Bevacizumab: Nein</b>			
Baseline			
n/N (%)	72/84 (86)	58/75 (77)	-
MW (SD)	21,30 (25,210)	16,67 (17,934)	
Absolute Werte zum Studienende			
n/N (%)	7/61 (11)	3/48 (6)	-
MW (SD)	19,05 (26,227)	11,11 (19,245)	
Effekt über Studiendauer			
n	72	58	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-4,33 (2,015)	6,31 (2,289)	LS MD -10,65 [-16,695; -4,599] 0,0007  Hedges' g -0,61 [-0,968; -0,260]
95 %-KI	[-8,322; -0,343]	[1,784; 10,845]	
Veränderung zu Woche 3/4			
n/N (%)	53/83 (64)	41/73 (56)	LS MD -12,45 [-19,225; -5,674]
MW (SD)	-6,29 (28,537)	3,25 (19,443)	
LS MW (SE)	-6,56 (2,273)	5,89 (2,567)	
95 %-KI	[-11,043; -2,076]	[0,828; 10,951]	
Veränderung zu Woche 8/9			
n/N (%)	60/80 (75)	49/69 (71)	LS MD -11,70 [-17,955; -5,448]
MW (SD)	-6,11 (24,156)	8,16 (24,086)	
LS MW (SE)	-5,64 (2,097)	6,07 (2,361)	
95 %-KI	[-9,781; -1,489]	[1,401; 10,731]	
Veränderung zu Woche 12			
n/N (%)	43/79 (54)	34/69 (49)	LS MD -11,18 [-17,246; -5,109]
MW (SD)	-5,43 (25,124)	19,61 (26,102)	
LS MW (SE)	-4,99 (2,030)	6,19 (2,291)	
95 %-KI	[-9,007; -0,970]	[1,657; 10,722]	
Veränderung zu Woche 15/16			
n/N (%)	38/77 (49)	23/66 (35)	LS MD -10,65 [-16,701; -4,607]
MW (SD)	-6,14 (29,870)	10,14 (29,189)	
LS MW (SE)	-4,34 (2,015)	6,31 (2,289)	
95 %-KI	[-8,330; -0,352]	[1,783; 10,842]	
Veränderung zu Woche 20/21			
n/N (%)	28/76 (37)	23/62 (37)	LS MD -9,91 [-16,206; -3,605]
MW (SD)	-8,33 (30,932)	4,35 (28,962)	
LS MW (SE)	-3,42 (2,083)	6,49 (2,404)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-7,537; 0,704]	[1,738; 11,240]	
Veränderung zu Woche 24			
n/N (%)	25/75 (33)	21/60 (35)	LS MD -9,38 [-16,042; -2,722]
MW (SD)	-9,33 (26,387)	-3,17 (25,614)	
LS MW (SE)	-2,77 (2,190)	6,61 (2,557)	
95 %-KI	[-7,095; 1,555]	[1,565; 11,659]	
Veränderung zu Woche 36			
n/N (%)	37/67 (55)	25/55 (45)	LS MD -7,59 [-16,301; 1,128]
MW (SD)	-1,80 (28,269)	9,33 (29,690)	
LS MW (SE)	-0,55 (2,825)	7,04 (3,401)	
95 %-KI	[-6,109; 5,006]	[0,347; 13,723]	
Veränderung zu Woche 48			
n/N (%)	5/61 (8)	3/48 (6)	LS MD -5,79 [-17,275; 5,693]
MW (SD)	0,00 (23,570)	0,00 (33,333)	
LS MW (SE)	1,67 (3,698)	7,46 (4,507)	
95 %-KI	[-5,600; 8,933]	[-1,399; 16,315]	
<b>Letztes Platin-freies Intervall: ≤ 3 Monate</b>			
Baseline			
n/N (%)	68/83 (82)	62/91 (68)	-
MW (SD)	22,55 (26,038)	23,66 (28,558)	
Absolute Werte zum Studienende			
n/N (%)	3/55 (5)	5/39 (13)	-
MW (SD)	11,11 (19,245)	13,33 (29,814)	
Effekt über Studiendauer			
n	68	62	LS MD -14,12 [-20,152; -8,086] < 0,0001
LS MW (SE)	-7,13 (2,054)	6,99 (2,250)	
95 %-KI	[-11,198; -3,059]	[2,540; 11,441]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	49/82 (60)	46/86 (53)	LS MD -15,30 [-21,976; -8,626]
MW (SD)	-7,48 (24,782)	3,62 (20,158)	
LS MW (SE)	-7,95 (2,309)	7,35 (2,473)	
95 %-KI	[-12,503; -3,394]	[2,475; 12,230]	
Veränderung zu Woche 8/9			
n/N (%)	52/81 (64)	45/80 (56)	LS MD -14,76 [-20,908; -8,616]
MW (SD)	-7,69 (23,445)	6,67 (25,226)	
LS MW (SE)	-7,57 (2,115)	7,19 (2,276)	
95 %-KI	[-11,759; -3,390]	[2,690; 11,685]	
Veränderung zu Woche 12			
n/N (%)	33/78 (42)	25/78 (32)	LS MD -14,38 [-20,392; -8,378]
MW (SD)	-5,05 (27,790)	13,33 (30,429)	
LS MW (SE)	-7,31 (2,055)	7,07 (2,231)	
95 %-KI	[-11,384; -3,242]	[2,658; 11,486]	
Veränderung zu Woche 15/16			
n/N (%)	35/76 (46)	14/75 (19)	LS MD -14,01 [-20,082; -7,933]
MW (SD)	-11,43 (27,939)	16,67 (25,318)	
LS MW (SE)	-7,05 (2,064)	6,96 (2,270)	
95 %-KI	[-11,140; -2,962]	[2,467; 11,446]	
Veränderung zu Woche 20/21			
n/N (%)	22/72 (31)	14/67 (21)	LS MD -13,47 [-19,982; -6,955]
MW (SD)	-7,58 (36,993)	-2,38 (27,625)	
LS MW (SE)	-6,68 (2,193)	6,79 (2,460)	
95 %-KI	[-11,013; -2,341]	[1,935; 11,648]	
Veränderung zu Woche 24			
n/N (%)	16/72 (22)	12/62 (19)	LS MD -13,09 [-20,117; -6,066]
MW (SD)	-12,50 (34,157)	-5,56 (19,245)	
LS MW (SE)	-6,42 (2,354)	6,68 (2,671)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-11,061; -1,769]	[1,409; 11,943]	
Veränderung zu Woche 36			
n/N (%)	28/63 (44)	18/50 (36)	LS MD -11,80 [-21,419; -2,176]
MW (SD)	-13,10 (27,725)	7,41 (21,559)	
LS MW (SE)	-5,52 (3,198)	6,28 (3,702)	
95 %-KI	[-11,807; 0,772]	[-1,000; 13,560]	
Veränderung zu Woche 48			
n/N (%)	2/55 (4)	4/39 (10)	LS MD -10,50 [-23,388; 2,380]
MW (SD)	16,67 (23,570)	-16,67 (19,245)	
LS MW (SE)	-4,62 (4,275)	5,88 (4,968)	
95 %-KI	[-13,024; 3,784]	[-3,881; 15,650]	
<b>Letztes Platin-freies Intervall: &gt; 3 Monate</b>			
Baseline			
n/N (%)	108/135 (80)	96/116 (83)	-
MW (SD)	22,22 (24,541)	20,83 (26,601)	
Absolute Werte zum Studienende			
n/N (%)	7/85 (8)	1/71 (1)	-
MW (SD)	38,10 (35,635)	33,33 (NA)	
Effekt über Studiendauer			
n	108	96	LS MD -8,18 [-13,273; -3,092] 0,0018  Hedges' g -0,44 [-0,722; -0,165]
LS MW (SE)	-0,94 (1,737)	7,24 (1,911)	
95 %-KI	[-4,366; 2,488]	[3,476; 11,011]	
Veränderung zu Woche 3/4			
n/N (%)	71/131 (54)	64/114 (56)	LS MD -6,60 [-12,278; -0,925]
MW (SD)	-0,47 (23,565)	2,60 (20,833)	
LS MW (SE)	-3,78 (1,946)	2,82 (2,131)	
95 %-KI	[-7,610; 0,050]	[-1,370; 7,013]	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	93/129 (72)	81/108 (75)	LS MD -7,29 [-12,518; -2,065]
MW (SD)	-3,23 (23,603)	3,29 (26,143)	
LS MW (SE)	-2,54 (1,804)	4,75 (1,946)	
95 %-KI	[-6,097; 1,016]	[0,917; 8,584]	
Veränderung zu Woche 12			
n/N (%)	65/127 (51)	46/105 (44)	LS MD -7,77 [-12,860; -2,689]
MW (SD)	-2,56 (23,796)	10,87 (23,364)	
LS MW (SE)	-1,67 (1,750)	6,10 (1,896)	
95 %-KI	[-5,125; 1,780]	[2,363; 9,840]	
Veränderung zu Woche 15/16			
n/N (%)	61/123 (50)	41/103 (40)	LS MD -8,26 [-13,360; -3,154]
MW (SD)	-0,55 (21,510)	9,76 (27,125)	
LS MW (SE)	-0,80 (1,738)	7,45 (1,919)	
95 %-KI	[-4,233; 2,623]	[3,669; 11,236]	
Veränderung zu Woche 20/21			
n/N (%)	45/118 (38)	37/98 (38)	LS MD -8,95 [-14,344; -3,550]
MW (SD)	-2,22 (23,995)	1,80 (28,269)	
LS MW (SE)	0,43 (1,793)	9,38 (2,072)	
95 %-KI	[-3,100; 3,970]	[5,302; 13,462]	
Veränderung zu Woche 24			
n/N (%)	37/112 (33)	26/93 (28)	LS MD -9,43 [-15,198; -3,662]
MW (SD)	1,80 (19,158)	-2,56 (28,163)	
LS MW (SE)	1,30 (1,879)	10,73 (2,249)	
95 %-KI	[-2,399; 5,004]	[6,309; 15,156]	
Veränderung zu Woche 36			
n/N (%)	53/97 (55)	29/84 (35)	LS MD -11,09 [-18,833; -3,339]
MW (SD)	1,89 (22,087)	12,64 (28,749)	
LS MW (SE)	4,28 (2,396)	15,36 (3,130)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-0,431; 8,986]	[9,218; 21,509]	
Veränderung zu Woche 48			
n/N (%)	6/85 (7)	1/71 (1)	LS MD -12,74 [-23,047; -2,436]
MW (SD)	16,67 (45,947)	33,33 (NA)	
LS MW (SE)	7,25 (3,114)	19,99 (4,220)	
95 %-KI	[1,139; 13,366]	[11,711; 28,278]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Pegyliertes liposomales Doxorubicin</b>			
Baseline			
n/N (%)	62/80 (78)	57/76 (75)	-
MW (SD)	22,04 (25,567)	19,30 (25,933)	
Absolute Werte zum Studienende			
n/N (%)	3/51 (6)	3/41 (7)	-
MW (SD)	33,33 (33,333)	0,00 (0,000)	
Effekt über Studiendauer			
n	62	57	LS MD -8,56 [-14,696; -2,426] 0,0067  Hedges' g -0,51 [-0,871; -0,140]
LS MW (SE)	-5,50 (2,091)	3,06 (2,283)	
95 %-KI	[-9,651; -1,358]	[-1,463; 7,577]	
Veränderung zu Woche 3/4			
n/N (%)	42/76 (55)	43/74 (58)	LS MD -9,00 [-15,775; -2,229]
MW (SD)	-9,52 (25,805)	3,88 (19,531)	
LS MW (SE)	-7,32 (2,351)	1,68 (2,496)	
95 %-KI	[-11,960; -2,676]	[-3,242; 6,610]	
Veränderung zu Woche 8/9			
n/N (%)	52/76 (68)	43/66 (65)	LS MD -8,81 [-15,082; -2,537]
MW (SD)	-5,13 (25,036)	-1,55 (20,514)	
LS MW (SE)	-6,52 (2,176)	2,28 (2,302)	
95 %-KI	[-10,832; -2,218]	[-2,270; 6,839]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	34/75 (45)	23/64 (36)	LS MD -8,67 [-14,797; -2,551]
MW (SD)	-6,86 (30,462)	10,14 (23,430)	
LS MW (SE)	-5,97 (2,109)	2,70 (2,258)	
95 %-KI	[-10,149; -1,790]	[-1,766; 7,176]	
Veränderung zu Woche 15/16			
n/N (%)	35/74 (47)	19/62 (31)	LS MD -8,54 [-14,692; -2,387]
MW (SD)	-4,76 (26,987)	15,79 (25,744)	
LS MW (SE)	-5,41 (2,092)	3,12 (2,295)	
95 %-KI	[-9,562; -1,267]	[-1,417; 7,667]	
Veränderung zu Woche 20/21			
n/N (%)	27/72 (38)	18/59 (31)	LS MD -8,35 [-14,844; -1,850]
MW (SD)	-9,88 (25,844)	7,41 (26,948)	
LS MW (SE)	-4,62 (2,157)	3,73 (2,479)	
95 %-KI	[-8,893; -0,349]	[-1,172; 8,623]	
Veränderung zu Woche 24			
n/N (%)	22/69 (32)	16/54 (30)	LS MD -8,21 [-15,139; -1,285]
MW (SD)	-6,06 (26,500)	0,00 (21,082)	
LS MW (SE)	-4,07 (2,261)	4,15 (2,685)	
95 %-KI	[-8,537; 0,405]	[-1,150; 9,442]	
Veränderung zu Woche 36			
n/N (%)	30/60 (50)	16/48 (33)	LS MD -7,75 [-16,968; 1,469]
MW (SD)	-4,44 (27,310)	6,25 (27,806)	
LS MW (SE)	-2,16 (2,888)	5,59 (3,696)	
95 %-KI	[-7,848; 3,523]	[-1,682; 12,856]	
Veränderung zu Woche 48			
n/N (%)	2/51 (4)	2/41 (5)	LS MD -7,29 [-19,484; 4,910]
MW (SD)	16,67 (23,570)	-16,67 (23,570)	
LS MW (SE)	-0,26 (3,759)	7,03 (4,945)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-7,650; 7,132]	[-2,692; 16,749]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Paclitaxel</b>			
Baseline			
n/N (%)	75/88 (85)	70/82 (85)	-
MW (SD)	24,44 (25,897)	26,19 (29,430)	
Absolute Werte zum Studienende			
n/N (%)	1/56 (2)	1/49 (2)	-
MW (SD)	33,33 (NA)	0,00 (NA)	
Effekt über Studiendauer			
n	75	70	LS MD -10,33 [-16,402; -4,261] 0,0010  Hedges' g -0,56 [-0,889; -0,225]
LS MW (SE)	-2,76 (2,094)	7,57 (2,246)	
95 %-KI	[-6,899; 1,385]	[3,134; 12,015]	
Veränderung zu Woche 3/4			
n/N (%)	55/87 (63)	49/81 (60)	LS MD -10,16 [-17,051; -3,263]
MW (SD)	-0,61 (24,420)	-0,68 (20,960)	
LS MW (SE)	-4,71 (2,378)	5,45 (2,563)	
95 %-KI	[-9,395; -0,022]	[0,399; 10,498]	
Veränderung zu Woche 8/9			
n/N (%)	63/86 (73)	56/79 (71)	LS MD -10,24 [-16,500; -3,972]
MW (SD)	-5,29 (24,101)	5,36 (28,268)	
LS MW (SE)	-3,82 (2,171)	6,41 (2,312)	
95 %-KI	[-8,113; 0,464]	[1,846; 10,976]	
Veränderung zu Woche 12			
n/N (%)	43/84 (51)	36/77 (47)	LS MD -10,29 [-16,361; -4,221]
MW (SD)	-3,10 (22,787)	12,96 (29,035)	
LS MW (SE)	-3,21 (2,101)	7,09 (2,239)	
95 %-KI	[-7,361; 0,950]	[2,659; 11,512]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	45/81 (56)	28/76 (37)	LS MD -10,35 [-16,449; -4,244]
MW (SD)	-2,96 (24,435)	11,90 (28,995)	
LS MW (SE)	-2,59 (2,100)	7,76 (2,262)	
95 %-KI	[-6,742; 1,568]	[3,288; 12,230]	
Veränderung zu Woche 20/21			
n/N (%)	29/77 (38)	26/73 (36)	LS MD -10,43 [-16,955; -3,896]
MW (SD)	1,15 (31,475)	-2,56 (31,160)	
LS MW (SE)	-1,70 (2,219)	8,72 (2,452)	
95 %-KI	[-6,086; 2,680]	[3,884; 13,561]	
Veränderung zu Woche 24			
n/N (%)	20/74 (27)	19/72 (26)	LS MD -10,48 [-17,539; -3,422]
MW (SD)	-1,67 (22,878)	-7,02 (30,589)	
LS MW (SE)	-1,08 (2,375)	9,40 (2,677)	
95 %-KI	[-5,769; 3,600]	[4,122; 14,671]	
Veränderung zu Woche 36			
n/N (%)	36/64 (56)	24/63 (38)	LS MD -10,67 [-20,471; -0,870]
MW (SD)	-2,78 (21,639)	12,50 (25,656)	
LS MW (SE)	1,04 (3,218)	11,71 (3,797)	
95 %-KI	[-5,290; 7,364]	[4,246; 19,169]	
Veränderung zu Woche 48			
n/N (%)	1/56 (2)	1/49 (2)	LS MD -10,86 [-24,118; 2,398]
MW (SD)	33,33 (NA)	-33,33 (NA)	
LS MW (SE)	3,16 (4,309)	14,02 (5,173)	
95 %-KI	[-5,306; 11,623]	[3,857; 24,181]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Topotecan</b>			
Baseline			
n/N (%)	39/50 (78)	31/49 (63)	-
MW (SD)	18,80 (22,679)	17,20 (24,146)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	6/33 (18)	2/20 (10)	-
MW (SD)	27,78 (38,968)	50,00 (23,570)	
Effekt über Studiendauer			
n	39	31	LS MD -13,64 [-22,835; -4,443] 0,0042  Hedges' g -0,71 [-1,192; -0,219]
LS MW (SE)	0,33 (3,014)	13,97 (3,498)	
95 %-KI	[-5,691; 6,358]	[6,996; 20,947]	
Veränderung zu Woche 3/4			
n/N (%)	23/50 (46)	18/45 (40)	LS MD -11,85 [-21,644; -2,059]
MW (SD)	1,45 (18,744)	11,11 (19,803)	
LS MW (SE)	-2,82 (3,241)	9,03 (3,723)	
95 %-KI	[-9,264; 3,627]	[1,638; 16,428]	
Veränderung zu Woche 8/9			
n/N (%)	30/48 (62)	27/43 (63)	LS MD -12,62 [-21,893; -3,353]
MW (SD)	-3,33 (20,248)	12,35 (26,390)	
LS MW (SE)	-1,46 (3,070)	11,16 (3,503)	
95 %-KI	[-7,586; 4,668]	[4,182; 18,145]	
Veränderung zu Woche 12			
n/N (%)	21/46 (46)	12/42 (29)	LS MD -13,16 [-22,303; -4,021]
MW (SD)	1,59 (19,653)	11,11 (21,711)	
LS MW (SE)	-0,51 (3,015)	12,66 (3,459)	
95 %-KI	[-6,533; 5,519]	[5,755; 19,555]	
Veränderung zu Woche 15/16			
n/N (%)	16/44 (36)	8/40 (20)	LS MD -13,70 [-22,917; -4,487]
MW (SD)	-8,33 (19,245)	0,00 (17,817)	
LS MW (SE)	0,44 (3,017)	14,15 (3,509)	
95 %-KI	[-5,586; 6,475]	[7,151; 21,142]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	11/41 (27)	7/33 (21)	LS MD -14,47 [-24,136; -4,810]
MW (SD)	-3,03 (27,707)	-4,76 (12,599)	
LS MW (SE)	1,80 (3,117)	16,28 (3,736)	
95 %-KI	[-4,413; 8,022]	[8,850; 23,704]	
Veränderung zu Woche 24			
n/N (%)	11/41 (27)	3/29 (10)	LS MD -15,01 [-25,206; -4,819]
MW (SD)	3,03 (27,707)	0,00 (0,000)	
LS MW (SE)	2,76 (3,249)	17,77 (3,989)	
95 %-KI	[-3,712; 9,224]	[9,858; 25,678]	
Veränderung zu Woche 36			
n/N (%)	15/36 (42)	7/23 (30)	LS MD -16,86 [-29,889; -3,836]
MW (SD)	-2,22 (29,457)	14,29 (26,227)	
LS MW (SE)	6,02 (4,010)	22,88 (5,256)	
95 %-KI	[-1,907; 13,945]	[12,510; 33,253]	
Veränderung zu Woche 48			
n/N (%)	5/33 (15)	2/20 (10)	LS MD -18,71 [-35,499; -1,926]
MW (SD)	13,33 (50,553)	16,67 (23,570)	
LS MW (SE)	9,28 (5,064)	27,99 (6,863)	
95 %-KI	[-0,705; 19,269]	[14,464; 41,525]	
<p><i>Analysepopulation: ITT</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023</i></p> <p><i>Modell: Veränderung zu Baseline ~ Behandlung + Baseline-Wert * Zeit in Wochen + Behandlung * Zeit in Wochen + zufällige Effekte durch die Patientin</i></p> <p><i>Die Berechnung des LS-MWs erfolgt durch ein MMRM mit dem oben angegebenen Modell. Basierend hierauf werden KI und p-Wert ermittelt. Hedges' g basiert ebenfalls auf den LS-MW und ist somit auf das Modell angepasst.</i></p> <p><i>Es werden ausschließlich gemeinsame Analysezeitpunkte dargestellt.</i></p> <p><i>Ein LS MD und Hedges' g kleiner als Null bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

## 2.5 EORTC QLQ-C30 Fatigue

### EORTC QLQ-C30 Fatigue: Subgruppenanalyse

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
<b>EORTC QLQ-C30 Fatigue</b>			
<b>Alter: &lt; 65 Jahre</b>			
Baseline			
n/N (%)	95/115 (83)	91/119 (76)	-
MW (SD)	34,04 (24,192)	35,04 (25,441)	
Absolute Werte zum Studienende			
n/N (%)	4/73 (5)	4/64 (6)	-
MW (SD)	33,33 (32,710)	33,33 (0,000)	
Effekt über Studiendauer			
n	95	91	LS MD -9,79 [-14,834; -4,741] 0,0002  Hedges' g -0,56 [-0,852; -0,266]
LS MW (SE)	1,41 (1,752)	11,20 (1,865)	
95 %-KI	[-2,046; 4,873]	[7,522; 14,881]	
Veränderung zu Woche 3/4			
n/N (%)	57/113 (50)	60/115 (52)	LS MD -6,47 [-12,096; -0,841]
MW (SD)	2,14 (18,358)	6,11 (20,295)	
LS MW (SE)	1,87 (1,973)	8,34 (2,072)	
95 %-KI	[-2,010; 5,759]	[4,265; 12,421]	
Veränderung zu Woche 8/9			
n/N (%)	76/112 (68)	71/108 (66)	LS MD -7,93 [-13,110; -2,757]
MW (SD)	1,32 (23,655)	12,21 (23,014)	
LS MW (SE)	1,67 (1,820)	9,60 (1,896)	
95 %-KI	[-1,918; 5,260]	[5,868; 13,342]	
Veränderung zu Woche 12			
n/N (%)	48/110 (44)	40/105 (38)	
MW (SD)	-2,55 (24,605)	10,83 (23,400)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	1,53 (1,764)	10,49 (1,850)	LS MD -8,96 [-13,999; -3,919]
95 %-KI	[-1,952; 5,010]	[6,838; 14,138]	
Veränderung zu Woche 15/16			
n/N (%)	55/107 (51)	32/102 (31)	LS MD -9,98 [-15,049; -4,921]
MW (SD)	0,40 (22,828)	8,33 (23,947)	
LS MW (SE)	1,39 (1,754)	11,37 (1,876)	
95 %-KI	[-2,077; 4,849]	[7,671; 15,071]	
Veränderung zu Woche 20/21			
n/N (%)	37/101 (37)	29/96 (30)	LS MD -11,45 [-16,821; -6,078]
MW (SD)	3,60 (24,294)	6,13 (24,232)	
LS MW (SE)	1,18 (1,822)	12,63 (2,027)	
95 %-KI	[-2,412; 4,778]	[8,639; 16,626]	
Veränderung zu Woche 24			
n/N (%)	25/99 (25)	19/91 (21)	LS MD -12,48 [-18,229; -6,721]
MW (SD)	1,78 (22,608)	8,48 (20,817)	
LS MW (SE)	1,04 (1,923)	13,52 (2,201)	
95 %-KI	[-2,748; 4,829]	[9,184; 17,847]	
Veränderung zu Woche 36			
n/N (%)	41/86 (48)	27/79 (34)	LS MD -15,99 [-23,762; -8,220]
MW (SD)	0,27 (19,640)	13,99 (27,836)	
LS MW (SE)	0,55 (2,503)	16,54 (3,060)	
95 %-KI	[-4,366; 5,470]	[10,532; 22,555]	
Veränderung zu Woche 48			
n/N (%)	4/73 (5)	2/64 (3)	LS MD -19,51 [-29,868; -9,146]
MW (SD)	-11,11 (27,217)	5,56 (39,284)	
LS MW (SE)	0,06 (3,288)	19,57 (4,122)	
95 %-KI	[-6,393; 6,521]	[11,477; 27,665]	
<b>Alter: ≥ 65 Jahre</b>			
Baseline			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	81/103 (79)	67/88 (76)	-
MW (SD)	35,80 (23,439)	33,00 (26,659)	
Absolute Werte zum Studienende			
n/N (%)	6/67 (9)	2/46 (4)	-
MW (SD)	27,78 (18,257)	27,78 (7,857)	
Effekt über Studiendauer			
n	81	67	LS MD -8,82 [-14,418; -3,217] 0,0022  Hedges' g -0,51 [-0,842; -0,184]
LS MW (SE)	1,62 (1,869)	10,44 (2,131)	
95 %-KI	[-2,073; 5,319]	[6,230; 14,651]	
Veränderung zu Woche 3/4			
n/N (%)	60/100 (60)	49/85 (58)	LS MD -8,41 [-14,582; -2,230]
MW (SD)	7,78 (21,289)	7,26 (18,222)	
LS MW (SE)	2,11 (2,078)	10,52 (2,346)	
95 %-KI	[-1,986; 6,209]	[5,894; 15,141]	
Veränderung zu Woche 8/9			
n/N (%)	68/98 (69)	54/80 (68)	LS MD -8,59 [-14,307; -2,870]
MW (SD)	-1,31 (17,334)	9,47 (20,295)	
LS MW (SE)	1,90 (1,929)	10,48 (2,159)	
95 %-KI	[-1,916; 5,706]	[6,221; 14,746]	
Veränderung zu Woche 12			
n/N (%)	49/95 (52)	32/78 (41)	LS MD -8,72 [-14,302; -3,130]
MW (SD)	-3,17 (28,419)	14,58 (18,600)	
LS MW (SE)	1,74 (1,877)	10,46 (2,113)	
95 %-KI	[-1,967; 5,455]	[6,285; 14,635]	
Veränderung zu Woche 15/16			
n/N (%)	41/92 (45)	22/76 (29)	
MW (SD)	-2,44 (18,004)	13,13 (27,568)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	1,59 (1,872)	10,44 (2,144)	LS MD -8,84 [-14,465; -3,222]
95 %-KI	[-2,110; 5,294]	[6,201; 14,670]	
Veränderung zu Woche 20/21			
n/N (%)	29/89 (33)	21/69 (30)	LS MD -9,03 [-14,980; -3,072]
MW (SD)	-1,53 (19,859)	6,35 (19,743)	
LS MW (SE)	1,38 (1,947)	10,40 (2,312)	
95 %-KI	[-2,470; 5,222]	[5,842; 14,962]	
Veränderung zu Woche 24			
n/N (%)	30/85 (35)	19/64 (30)	LS MD -9,15 [-15,514; -2,793]
MW (SD)	-3,33 (23,911)	4,09 (18,224)	
LS MW (SE)	1,22 (2,052)	10,38 (2,503)	
95 %-KI	[-2,824; 5,272]	[5,448; 15,308]	
Veränderung zu Woche 36			
n/N (%)	40/74 (54)	20/55 (36)	LS MD -9,59 [-18,092; -1,090]
MW (SD)	-0,28 (26,328)	8,89 (19,860)	
LS MW (SE)	0,70 (2,649)	10,30 (3,448)	
95 %-KI	[-4,505; 5,914]	[3,519; 17,072]	
Veränderung zu Woche 48			
n/N (%)	4/67 (6)	2/46 (4)	LS MD -10,03 [-21,289; 1,232]
MW (SD)	2,78 (22,906)	0,00 (0,000)	
LS MW (SE)	0,19 (3,456)	10,21 (4,619)	
95 %-KI	[-6,606; 6,976]	[1,139; 19,289]	
<b>Region: USA</b>			
Baseline			
n/N (%)	49/65 (75)	34/51 (67)	-
MW (SD)	34,69 (25,823)	35,95 (23,856)	
Absolute Werte zum Studienende			
n/N (%)	2/39 (5)	3/27 (11)	-
MW (SD)	22,22 (15,713)	29,63 (6,415)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Effekt über Studiendauer			
n	49	34	LS MD -7,33 [-13,943; -0,727] 0,0300  Hedges' g -0,49 [-0,934; -0,046]
LS MW (SE)	0,58 (2,099)	7,92 (2,573)	
95 %-KI	[-3,596; 4,766]	[2,800; 13,040]	
Veränderung zu Woche 3/4			
n/N (%)	33/64 (52)	21/49 (43)	LS MD -7,15 [-14,477; 0,172]
MW (SD)	4,04 (15,669)	6,88 (18,418)	
LS MW (SE)	1,99 (2,324)	9,14 (2,878)	
95 %-KI	[-2,617; 6,593]	[3,441; 14,840]	
Veränderung zu Woche 8/9			
n/N (%)	42/62 (68)	30/46 (65)	LS MD -7,23 [-14,020; -0,449]
MW (SD)	-0,26 (19,707)	8,15 (19,341)	
LS MW (SE)	1,36 (2,157)	8,59 (2,651)	
95 %-KI	[-2,934; 5,645]	[3,324; 13,856]	
Veränderung zu Woche 12			
n/N (%)	26/59 (44)	16/45 (36)	LS MD -7,29 [-13,907; -0,677]
MW (SD)	1,71 (23,242)	11,81 (20,873)	
LS MW (SE)	0,91 (2,103)	8,20 (2,577)	
95 %-KI	[-3,275; 5,100]	[3,077; 13,333]	
Veränderung zu Woche 15/16			
n/N (%)	21/56 (38)	11/44 (25)	LS MD -7,35 [-13,979; -0,721]
MW (SD)	-4,23 (18,079)	4,04 (20,652)	
LS MW (SE)	0,47 (2,105)	7,82 (2,582)	
95 %-KI	[-3,723; 4,662]	[2,683; 12,956]	
Veränderung zu Woche 20/21			
n/N (%)	13/54 (24)	9/40 (22)	
MW (SD)	4,27 (11,599)	4,94 (13,734)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-0,16 (2,205)	7,27 (2,721)	LS MD -7,43 [-14,398; -0,467]
95 %-KI	[-4,545; 4,218]	[1,867; 12,671]	
Veränderung zu Woche 24			
n/N (%)	9/53 (17)	6/38 (16)	LS MD -7,49 [-14,891; -0,090]
MW (SD)	3,70 (14,699)	11,11 (19,876)	
LS MW (SE)	-0,61 (2,335)	6,88 (2,901)	
95 %-KI	[-5,236; 4,024]	[1,138; 12,630]	
Veränderung zu Woche 36			
n/N (%)	22/43 (51)	10/33 (30)	LS MD -7,69 [-17,466; 2,089]
MW (SD)	-4,04 (17,331)	0,00 (10,476)	
LS MW (SE)	-2,13 (3,051)	5,56 (3,870)	
95 %-KI	[-8,141; 3,891]	[-2,066; 13,192]	
Veränderung zu Woche 48			
n/N (%)	2/39 (5)	3/27 (11)	LS MD -7,89 [-20,797; 5,025]
MW (SD)	-27,78 (23,570)	-7,41 (12,830)	
LS MW (SE)	-3,64 (3,999)	4,24 (5,131)	
95 %-KI	[-11,518; 4,230]	[-5,861; 14,346]	
<b>Region: Rest der Welt</b>			
Baseline			
n/N (%)	127/153 (83)	124/156 (79)	-
MW (SD)	34,91 (23,076)	33,69 (26,504)	
Absolute Werte zum Studienende			
n/N (%)	8/101 (8)	3/83 (4)	-
MW (SD)	31,94 (25,502)	33,33 (0,000)	
Effekt über Studiendauer			
n	127	124	LS MD -9,75 [-14,229; -5,264] < 0,0001  Hedges' g
LS MW (SE)	1,93 (1,559)	11,68 (1,657)	
95 %-KI	[-1,138; 5,005]	[8,417; 14,943]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
			-0,54 [-0,791; -0,288]
Veränderung zu Woche 3/4			
n/N (%)	84/149 (56)	88/151 (58)	LS MD -7,16 [-12,121; -2,195]
MW (SD)	5,42 (21,577)	6,57 (19,620)	
LS MW (SE)	2,01 (1,750)	9,17 (1,822)	
95 %-KI	[-1,432; 5,449]	[5,585; 12,748]	
Veränderung zu Woche 8/9			
n/N (%)	102/148 (69)	95/142 (67)	LS MD -8,30 [-12,870; -3,721]
MW (SD)	0,22 (21,437)	11,93 (22,588)	
LS MW (SE)	1,98 (1,618)	10,27 (1,668)	
95 %-KI	[-1,211; 5,162]	[6,988; 13,555]	
Veränderung zu Woche 12			
n/N (%)	71/146 (49)	56/138 (41)	LS MD -9,09 [-13,556; -4,628]
MW (SD)	-4,54 (27,512)	12,70 (21,652)	
LS MW (SE)	1,95 (1,570)	11,04 (1,635)	
95 %-KI	[-1,140; 5,045]	[7,825; 14,264]	
Veränderung zu Woche 15/16			
n/N (%)	75/143 (52)	43/134 (32)	LS MD -9,89 [-14,387; -5,389]
MW (SD)	0,15 (21,574)	11,89 (26,382)	
LS MW (SE)	1,93 (1,560)	11,82 (1,668)	
95 %-KI	[-1,145; 5,004]	[8,534; 15,101]	
Veränderung zu Woche 20/21			
n/N (%)	53/136 (39)	41/125 (33)	LS MD -11,03 [-15,817; -6,234]
MW (SD)	0,63 (24,403)	6,50 (23,828)	
LS MW (SE)	1,90 (1,616)	12,92 (1,821)	
95 %-KI	[-1,287; 5,079]	[9,341; 16,503]	
Veränderung zu Woche 24			
n/N (%)	46/131 (35)	32/117 (27)	
MW (SD)	-1,93 (24,602)	5,38 (19,527)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	1,87 (1,700)	13,70 (1,988)	LS MD -11,82 [-16,966; -6,678]
95 %-KI	[-1,472; 5,219]	[9,788; 17,603]	
Veränderung zu Woche 36			
n/N (%)	59/117 (50)	37/101 (37)	LS MD -14,55 [-21,517; -7,587]
MW (SD)	1,51 (24,799)	15,02 (26,445)	
LS MW (SE)	1,79 (2,192)	16,35 (2,793)	
95 %-KI	[-2,511; 6,099]	[10,864; 21,828]	
Veränderung zu Woche 48			
n/N (%)	6/101 (6)	1/83 (1)	LS MD -17,28 [-26,563; -8,000]
MW (SD)	3,70 (20,688)	33,33 (NA)	
LS MW (SE)	1,71 (2,865)	19,00 (3,769)	
95 %-KI	[-3,908; 7,338]	[11,598; 26,395]	
<b>Stadium bei der Diagnose: I-III</b>			
Baseline			
n/N (%)	113/141 (80)	112/144 (78)	-
MW (SD)	33,53 (23,192)	35,42 (27,033)	
Absolute Werte zum Studienende			
n/N (%)	6/91 (7)	4/76 (5)	-
MW (SD)	35,19 (23,744)	30,56 (5,556)	
Effekt über Studiendauer			
n	113	112	LS MD -8,81 [-13,497; -4,116] 0,0003
LS MW (SE)	2,31 (1,647)	11,11 (1,720)	
95 %-KI	[-0,941; 5,552]	[7,723; 14,502]	Hedges' g -0,49 [-0,757; -0,226]
Veränderung zu Woche 3/4			
n/N (%)	74/137 (54)	79/138 (57)	LS MD -6,91 [-12,042; -1,779]
MW (SD)	4,05 (19,513)	5,91 (19,231)	
LS MW (SE)	1,54 (1,818)	8,45 (1,872)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-2,035; 5,120]	[4,770; 12,136]	
Veränderung zu Woche 8/9			
n/N (%)	94/136 (69)	89/129 (69)	LS MD -7,74 [-12,533; -2,946]
MW (SD)	1,77 (20,240)	10,24 (20,869)	
LS MW (SE)	1,88 (1,699)	9,62 (1,744)	
95 %-KI	[-1,471; 5,223]	[6,180; 13,050]	
Veränderung zu Woche 12			
n/N (%)	63/133 (47)	49/128 (38)	LS MD -8,32 [-13,008; -3,631]
MW (SD)	-3,53 (27,639)	11,11 (21,872)	
LS MW (SE)	2,11 (1,655)	10,43 (1,710)	
95 %-KI	[-1,154; 5,372]	[7,058; 13,799]	
Veränderung zu Woche 15/16			
n/N (%)	64/130 (49)	35/125 (28)	LS MD -8,90 [-13,600; -4,199]
MW (SD)	1,74 (20,878)	11,75 (20,689)	
LS MW (SE)	2,34 (1,648)	11,24 (1,726)	
95 %-KI	[-0,907; 5,592]	[7,841; 14,643]	
Veränderung zu Woche 20/21			
n/N (%)	45/123 (37)	34/116 (29)	LS MD -9,73 [-14,644; -4,812]
MW (SD)	1,23 (23,951)	7,84 (24,394)	
LS MW (SE)	2,68 (1,701)	12,40 (1,831)	
95 %-KI	[-0,675; 6,027]	[8,800; 16,008]	
Veränderung zu Woche 24			
n/N (%)	35/121 (29)	27/109 (25)	LS MD -10,31 [-15,502; -5,115]
MW (SD)	2,22 (24,962)	6,79 (22,240)	
LS MW (SE)	2,91 (1,779)	13,22 (1,954)	
95 %-KI	[-0,593; 6,411]	[9,373; 17,062]	
Veränderung zu Woche 36			
n/N (%)	53/105 (50)	36/92 (39)	
MW (SD)	2,94 (25,333)	15,74 (26,577)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	3,71 (2,240)	16,01 (2,592)	LS MD -12,30 [-19,011; -5,584]
95 %-KI	[-0,692; 8,110]	[10,917; 21,096]	
Veränderung zu Woche 48			
n/N (%)	5/91 (5)	4/76 (5)	LS MD -14,29 [-23,025; -5,548]
MW (SD)	6,67 (21,660)	2,78 (22,906)	
LS MW (SE)	4,51 (2,882)	18,80 (3,409)	
95 %-KI	[-1,149; 10,167]	[12,104; 25,487]	
<b>Stadium bei der Diagnose: IV</b>			
Baseline			
n/N (%)	58/72 (81)	44/60 (73)	-
MW (SD)	37,36 (24,775)	31,31 (22,641)	
Absolute Werte zum Studienende			
n/N (%)	4/46 (9)	2/33 (6)	-
MW (SD)	22,22 (24,003)	33,33 (0,000)	
Effekt über Studiendauer			
n	58	44	LS MD -10,26 [-16,094; -4,417] 0,0007  Hedges' g -0,70 [-1,102; -0,295]
LS MW (SE)	-1,67 (1,871)	8,58 (2,258)	
95 %-KI	[-5,394; 2,044]	[4,100; 13,061]	
Veränderung zu Woche 3/4			
n/N (%)	38/71 (54)	28/59 (47)	LS MD -10,86 [-17,688; -4,027]
MW (SD)	4,68 (19,781)	7,14 (19,177)	
LS MW (SE)	1,03 (2,213)	11,89 (2,659)	
95 %-KI	[-3,334; 5,403]	[6,647; 17,136]	
Veränderung zu Woche 8/9			
n/N (%)	45/69 (65)	35/56 (62)	LS MD -10,59 [-16,585; -4,587]
MW (SD)	-4,94 (21,393)	12,70 (24,572)	
LS MW (SE)	-0,19 (1,978)	10,40 (2,288)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-4,106; 3,732]	[5,869; 14,929]	
Veränderung zu Woche 12			
n/N (%)	29/67 (43)	22/52 (42)	LS MD -10,40 [-16,177; -4,615]
MW (SD)	-6,51 (18,902)	15,66 (20,761)	
LS MW (SE)	-1,04 (1,890)	9,35 (2,208)	
95 %-KI	[-4,794; 2,711]	[4,973; 13,736]	
Veränderung zu Woche 15/16			
n/N (%)	29/64 (45)	17/50 (34)	LS MD -10,21 [-16,108; -4,304]
MW (SD)	-5,75 (20,706)	3,92 (24,514)	
LS MW (SE)	-1,90 (1,874)	8,31 (2,298)	
95 %-KI	[-5,623; 1,829]	[3,753; 12,866]	
Veränderung zu Woche 20/21			
n/N (%)	18/62 (29)	15/46 (33)	LS MD -9,93 [-16,551; -3,318]
MW (SD)	0,62 (19,975)	2,96 (17,551)	
LS MW (SE)	-3,12 (1,982)	6,82 (2,680)	
95 %-KI	[-7,050; 0,813]	[1,522; 12,111]	
Veränderung zu Woche 24			
n/N (%)	18/59 (31)	10/44 (23)	LS MD -9,74 [-17,158; -2,332]
MW (SD)	-6,79 (19,485)	2,22 (4,685)	
LS MW (SE)	-3,97 (2,136)	5,77 (3,073)	
95 %-KI	[-8,201; 0,254]	[-0,287; 11,830]	
Veränderung zu Woche 36			
n/N (%)	27/52 (52)	10/41 (24)	LS MD -9,09 [-20,244; 2,057]
MW (SD)	-5,76 (17,260)	-2,22 (8,765)	
LS MW (SE)	-6,90 (2,986)	2,19 (4,794)	
95 %-KI	[-12,784; -1,026]	[-7,243; 11,621]	
Veränderung zu Woche 48			
n/N (%)	3/46 (7)	0/33 (0)	
MW (SD)	-22,22 (19,245)	NA (NA)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-9,84 (4,077)	-1,39 (6,746)	LS MD -8,44 [-23,994; 7,108]
95 %-KI	[-17,856; -1,817]	[-14,662; 11,875]	
<b>BRCA Status: Positiv</b>			
Baseline			
n/N (%)	25/27 (93)	23/35 (66)	-
MW (SD)	37,78 (27,027)	37,68 (28,962)	
Absolute Werte zum Studienende			
n/N (%)	1/19 (5)	0/15 (0)	-
MW (SD)	55,56 (NA)	NA (NA)	
Effekt über Studiendauer			
n	25	23	LS MD -10,74 [-20,770; -0,718] 0,0363  Hedges' g -0,61 [-1,195; -0,034]
LS MW (SE)	1,90 (3,346)	12,65 (3,687)	
95 %-KI	[-4,853; 8,659]	[5,235; 20,058]	
Veränderung zu Woche 3/4			
n/N (%)	15/27 (56)	18/35 (51)	LS MD -5,75 [-16,718; 5,211]
MW (SD)	2,96 (26,047)	5,56 (22,304)	
LS MW (SE)	3,33 (3,791)	9,08 (3,985)	
95 %-KI	[-4,236; 10,898]	[1,136; 17,033]	
Veränderung zu Woche 8/9			
n/N (%)	21/26 (81)	20/30 (67)	LS MD -8,17 [-18,224; 1,894]
MW (SD)	-1,59 (17,315)	10,00 (26,953)	
LS MW (SE)	2,64 (3,478)	10,81 (3,601)	
95 %-KI	[-4,350; 9,631]	[3,564; 18,048]	
Veränderung zu Woche 12			
n/N (%)	15/26 (58)	11/30 (37)	LS MD -9,85 [-19,778; 0,071]
MW (SD)	3,70 (27,108)	18,18 (22,918)	
LS MW (SE)	2,16 (3,365)	12,01 (3,597)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-4,632; 8,948]	[4,768; 19,255]	
Veränderung zu Woche 15/16			
n/N (%)	12/26 (46)	8/29 (28)	LS MD -11,54 [-21,757; -1,326]
MW (SD)	-0,00 (24,618)	5,56 (16,798)	
LS MW (SE)	1,67 (3,351)	13,22 (3,817)	
95 %-KI	[-5,094; 8,444]	[5,561; 20,871]	
Veränderung zu Woche 20/21			
n/N (%)	10/25 (40)	4/25 (16)	LS MD -13,95 [-25,261; -2,644]
MW (SD)	-3,33 (22,253)	-0,00 (20,286)	
LS MW (SE)	0,98 (3,503)	14,94 (4,448)	
95 %-KI	[-6,062; 8,032]	[6,089; 23,787]	
Veränderung zu Woche 24			
n/N (%)	8/25 (32)	4/24 (17)	LS MD -15,64 [-28,103; -3,179]
MW (SD)	-6,94 (20,520)	-5,56 (19,245)	
LS MW (SE)	0,50 (3,717)	16,14 (5,044)	
95 %-KI	[-6,942; 7,946]	[6,143; 26,143]	
Veränderung zu Woche 36			
n/N (%)	10/21 (48)	5/20 (25)	LS MD -21,43 [-39,303; -3,555]
MW (SD)	-4,44 (17,529)	16,67 (12,423)	
LS MW (SE)	-1,15 (4,925)	20,27 (7,580)	
95 %-KI	[-10,909; 8,600]	[5,301; 35,249]	
Veränderung zu Woche 48			
n/N (%)	1/19 (5)	0/15 (0)	LS MD -27,22 [-51,550; -2,883]
MW (SD)	-11,11 (NA)	NA (NA)	
LS MW (SE)	-2,81 (6,529)	24,41 (10,439)	
95 %-KI	[-15,710; 10,090]	[3,785; 45,028]	
<b>BRCA Status: Negativ/Unbekannt</b>			
Baseline			
n/N (%)	151/191 (79)	135/172 (78)	-

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	34,36 (23,284)	33,58 (25,412)	
Absolute Werte zum Studienende			
n/N (%)	9/121 (7)	6/95 (6)	-
MW (SD)	27,16 (22,981)	31,48 (4,536)	
Effekt über Studiendauer			
n	151	135	LS MD -9,10 [-13,140; -5,051] < 0,0001  Hedges' g -0,52 [-0,760; -0,288]
LS MW (SE)	1,48 (1,384)	10,58 (1,520)	
95 %-KI	[-1,240; 4,209]	[7,588; 13,572]	
Veränderung zu Woche 3/4			
n/N (%)	102/186 (55)	91/165 (55)	LS MD -7,42 [-11,917; -2,927]
MW (SD)	5,34 (19,132)	6,84 (18,796)	
LS MW (SE)	1,79 (1,546)	9,21 (1,687)	
95 %-KI	[-1,252; 4,827]	[5,893; 12,526]	
Veränderung zu Woche 8/9			
n/N (%)	123/184 (67)	105/158 (66)	LS MD -8,15 [-12,302; -4,002]
MW (SD)	0,36 (21,478)	11,22 (20,872)	
LS MW (SE)	1,66 (1,432)	9,81 (1,550)	
95 %-KI	[-1,163; 4,474]	[6,758; 12,856]	
Veränderung zu Woche 12			
n/N (%)	82/179 (46)	61/153 (40)	LS MD -8,66 [-12,704; -4,621]
MW (SD)	-4,07 (26,335)	11,48 (21,079)	
LS MW (SE)	1,56 (1,391)	10,23 (1,512)	
95 %-KI	[-1,176; 4,302]	[7,251; 13,201]	
Veränderung zu Woche 15/16			
n/N (%)	84/173 (49)	46/149 (31)	LS MD -9,17 [-13,228; -5,120]
MW (SD)	-0,93 (20,423)	11,11 (26,605)	
LS MW (SE)	1,47 (1,385)	10,64 (1,526)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-1,257; 4,198]	[7,641; 13,647]	
Veränderung zu Woche 20/21			
n/N (%)	56/165 (34)	46/140 (33)	LS MD -9,90 [-14,181; -5,626]
MW (SD)	2,18 (22,565)	6,76 (22,526)	
LS MW (SE)	1,34 (1,438)	11,24 (1,633)	
95 %-KI	[-1,492; 4,168]	[8,030; 14,453]	
Veränderung zu Woche 24			
n/N (%)	47/159 (30)	34/131 (26)	LS MD -10,41 [-14,975; -5,854]
MW (SD)	-0,00 (23,740)	7,68 (19,246)	
LS MW (SE)	1,25 (1,515)	11,66 (1,760)	
95 %-KI	[-1,733; 4,224]	[8,200; 15,120]	
Veränderung zu Woche 36			
n/N (%)	71/139 (51)	42/114 (37)	LS MD -12,17 [-18,245; -6,088]
MW (SD)	0,63 (23,748)	11,24 (25,752)	
LS MW (SE)	0,93 (1,956)	13,09 (2,408)	
95 %-KI	[-2,912; 4,768]	[8,368; 17,820]	
Veränderung zu Woche 48			
n/N (%)	7/121 (6)	4/95 (4)	LS MD -13,92 [-21,970; -5,866]
MW (SD)	-3,17 (26,227)	2,78 (22,906)	
LS MW (SE)	0,61 (2,555)	14,53 (3,221)	
95 %-KI	[-4,404; 5,624]	[8,207; 20,850]	
<b>Baseline ECOG PS: 0</b>			
Baseline			
n/N (%)	101/128 (79)	96/113 (85)	-
MW (SD)	27,39 (19,472)	27,66 (19,876)	
Absolute Werte zum Studienende			
n/N (%)	7/87 (8)	3/72 (4)	-
MW (SD)	34,92 (19,698)	33,33 (0,000)	
Effekt über Studiendauer			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n	101	96	LS MD -7,58 [-12,489; -2,666] 0,0027  Hedges' g -0,43 [-0,715; -0,150]
LS MW (SE)	5,00 (1,708)	12,58 (1,812)	
95 %-KI	[1,627; 8,368]	[9,001; 16,149]	
Veränderung zu Woche 3/4			
n/N (%)	68/127 (54)	63/111 (57)	LS MD -6,73 [-12,167; -1,289]
MW (SD)	6,70 (19,963)	9,35 (17,535)	
LS MW (SE)	4,92 (1,894)	11,65 (2,012)	
95 %-KI	[1,191; 8,651]	[7,689; 15,608]	
Veränderung zu Woche 8/9			
n/N (%)	84/126 (67)	75/108 (69)	LS MD -7,09 [-12,138; -2,052]
MW (SD)	2,91 (18,586)	13,33 (21,224)	
LS MW (SE)	4,95 (1,767)	12,05 (1,851)	
95 %-KI	[1,471; 8,437]	[8,401; 15,697]	
Veränderung zu Woche 12			
n/N (%)	53/122 (43)	46/108 (43)	LS MD -7,35 [-12,266; -2,437]
MW (SD)	2,94 (24,668)	13,53 (23,763)	
LS MW (SE)	4,98 (1,719)	12,33 (1,804)	
95 %-KI	[1,586; 8,368]	[8,771; 15,887]	
Veränderung zu Woche 15/16			
n/N (%)	56/120 (47)	34/105 (32)	LS MD -7,61 [-12,528; -2,689]
MW (SD)	2,18 (20,697)	16,01 (26,547)	
LS MW (SE)	5,00 (1,709)	12,61 (1,817)	
95 %-KI	[1,629; 8,372]	[9,026; 16,192]	
Veränderung zu Woche 20/21			
n/N (%)	40/117 (34)	31/101 (31)	LS MD -7,98 [-13,131; -2,820]
MW (SD)	4,17 (20,701)	12,90 (22,240)	
LS MW (SE)	5,03 (1,761)	13,01 (1,935)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[1,561; 8,506]	[9,198; 16,820]	
Veränderung zu Woche 24			
n/N (%)	28/112 (25)	22/96 (23)	LS MD -8,23 [-13,697; -2,768]
MW (SD)	3,97 (21,215)	8,84 (19,895)	
LS MW (SE)	5,06 (1,840)	13,29 (2,078)	
95 %-KI	[1,431; 8,683]	[9,201; 17,378]	
Veränderung zu Woche 36			
n/N (%)	51/99 (52)	34/87 (39)	LS MD -9,11 [-16,279; -1,948]
MW (SD)	3,92 (21,178)	11,27 (27,233)	
LS MW (SE)	5,14 (2,318)	14,25 (2,816)	
95 %-KI	[0,580; 9,692]	[8,719; 19,780]	
Veränderung zu Woche 48			
n/N (%)	5/87 (6)	2/72 (3)	LS MD -9,99 [-19,414; -0,575]
MW (SD)	-4,44 (27,889)	-11,11 (15,713)	
LS MW (SE)	5,22 (2,986)	15,21 (3,754)	
95 %-KI	[-0,648; 11,078]	[7,839; 22,580]	
<b>Baseline ECOG PS: 1</b>			
Baseline			
n/N (%)	75/90 (83)	61/91 (67)	-
MW (SD)	44,89 (25,471)	43,35 (30,069)	
Absolute Werte zum Studienende			
n/N (%)	3/53 (6)	3/37 (8)	-
MW (SD)	18,52 (32,075)	29,63 (6,415)	
Effekt über Studiendauer			
n	75	61	LS MD -11,98 [-17,833; -6,135] 0,0001
LS MW (SE)	-3,21 (1,927)	8,78 (2,247)	
95 %-KI	[-7,024; 0,607]	[4,333; 13,219]	Hedges' g -0,70 [-1,046; -0,349]



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	49/86 (57)	45/87 (52)	LS MD -7,42 [-13,906; -0,940]
MW (SD)	2,72 (20,099)	2,96 (21,373)	
LS MW (SE)	-1,88 (2,184)	5,55 (2,462)	
95 %-KI	[-6,184; 2,431]	[0,692; 10,400]	
Veränderung zu Woche 8/9			
n/N (%)	60/84 (71)	49/78 (63)	LS MD -9,51 [-15,454; -3,567]
MW (SD)	-3,89 (23,309)	7,71 (22,704)	
LS MW (SE)	-2,49 (1,999)	7,02 (2,251)	
95 %-KI	[-6,437; 1,465]	[2,575; 11,473]	
Veränderung zu Woche 12			
n/N (%)	44/83 (53)	25/74 (34)	LS MD -10,97 [-16,783; -5,159]
MW (SD)	-9,85 (27,134)	11,56 (16,191)	
LS MW (SE)	-2,91 (1,935)	8,06 (2,215)	
95 %-KI	[-6,744; 0,918]	[3,678; 12,438]	
Veränderung zu Woche 15/16			
n/N (%)	40/79 (51)	20/72 (28)	LS MD -12,43 [-18,331; -6,534]
MW (SD)	-5,00 (20,588)	0,56 (20,225)	
LS MW (SE)	-3,34 (1,933)	9,09 (2,276)	
95 %-KI	[-7,167; 0,488]	[4,594; 13,592]	
Veränderung zu Woche 20/21			
n/N (%)	26/73 (36)	18/63 (29)	LS MD -14,52 [-20,899; -8,140]
MW (SD)	-2,99 (24,657)	-1,85 (13,339)	
LS MW (SE)	-3,95 (2,036)	10,57 (2,517)	
95 %-KI	[-7,974; 0,076]	[5,605; 15,535]	
Veränderung zu Woche 24			
n/N (%)	27/72 (38)	15/58 (26)	LS MD -15,98 [-22,908; -9,053]
MW (SD)	-6,17 (24,525)	3,70 (19,092)	
LS MW (SE)	-4,38 (2,173)	11,60 (2,771)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-8,665; -0,086]	[6,147; 17,063]	
Veränderung zu Woche 36			
n/N (%)	30/61 (49)	13/46 (28)	LS MD -20,99 [-30,627; -11,352]
MW (SD)	-6,67 (24,862)	13,25 (16,902)	
LS MW (SE)	-5,84 (2,923)	15,15 (3,951)	
95 %-KI	[-11,587; -0,091]	[7,385; 22,918]	
Veränderung zu Woche 48			
n/N (%)	3/53 (6)	2/37 (5)	LS MD -26,00 [-38,986; -13,012]
MW (SD)	-3,70 (23,130)	16,67 (23,570)	
LS MW (SE)	-7,30 (3,899)	18,70 (5,358)	
95 %-KI	[-14,964; 0,361]	[8,169; 29,226]	
<b>Anzahl vorheriger Therapielinien: 1</b>			
Baseline			
n/N (%)	24/31 (77)	23/29 (79)	-
MW (SD)	40,28 (24,035)	27,05 (23,884)	
Absolute Werte zum Studienende			
n/N (%)	1/22 (5)	0/14 (0)	-
MW (SD)	33,33 (NA)	NA (NA)	
Effekt über Studiendauer			
n	24	23	LS MD -8,36 [-19,591; 2,868] 0,1404  Hedges' g -0,44 [-1,017; 0,142]
LS MW (SE)	1,26 (3,780)	9,62 (3,980)	
95 %-KI	[-6,373; 8,897]	[1,608; 17,640]	
Veränderung zu Woche 3/4			
n/N (%)	16/31 (52)	15/29 (52)	LS MD -6,58 [-18,876; 5,710]
MW (SD)	0,69 (17,436)	1,48 (17,247)	
LS MW (SE)	-2,78 (4,196)	3,81 (4,388)	
95 %-KI	[-11,169; 5,612]	[-4,952; 12,563]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	20/31 (65)	18/26 (69)	LS MD -7,33 [-18,838; 4,175]
MW (SD)	-2,78 (17,614)	12,35 (28,997)	
LS MW (SE)	-1,08 (3,933)	6,25 (4,042)	
95 %-KI	[-8,987; 6,830]	[-1,867; 14,374]	
Veränderung zu Woche 12			
n/N (%)	14/31 (45)	12/24 (50)	LS MD -7,86 [-19,099; 3,388]
MW (SD)	-16,67 (20,787)	3,70 (19,148)	
LS MW (SE)	0,11 (3,823)	7,97 (3,947)	
95 %-KI	[-7,599; 7,822]	[0,016; 15,918]	
Veränderung zu Woche 15/16			
n/N (%)	15/31 (48)	11/22 (50)	LS MD -8,38 [-19,612; 2,854]
MW (SD)	-4,44 (20,914)	8,08 (34,099)	
LS MW (SE)	1,30 (3,780)	9,68 (3,984)	
95 %-KI	[-6,333; 8,936]	[1,659; 17,703]	
Veränderung zu Woche 20/21			
n/N (%)	11/30 (37)	9/22 (41)	LS MD -9,13 [-20,779; 2,524]
MW (SD)	3,03 (17,979)	3,70 (12,423)	
LS MW (SE)	3,00 (3,839)	12,13 (4,256)	
95 %-KI	[-4,740; 10,742]	[3,602; 20,656]	
Veränderung zu Woche 24			
n/N (%)	9/30 (30)	11/20 (55)	LS MD -9,65 [-21,880; 2,577]
MW (SD)	3,70 (16,667)	2,02 (12,975)	
LS MW (SE)	4,19 (3,962)	13,84 (4,578)	
95 %-KI	[-3,772; 12,154]	[4,710; 22,975]	
Veränderung zu Woche 36			
n/N (%)	15/26 (58)	6/18 (33)	LS MD -11,45 [-27,038; 4,142]
MW (SD)	8,15 (24,655)	15,74 (31,114)	
LS MW (SE)	8,27 (4,796)	19,72 (6,221)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-1,253; 17,794]	[7,417; 32,020]	
Veränderung zu Woche 48			
n/N (%)	0/22 (0)	0/14 (0)	LS MD -13,24 [-33,479; 6,991]
MW (SD)	NA (NA)	NA (NA)	
LS MW (SE)	12,35 (6,043)	25,59 (8,295)	
95 %-KI	[0,411; 24,290]	[9,221; 41,967]	
<b>Anzahl vorheriger Therapielinien: 2</b>			
Baseline			
n/N (%)	75/89 (84)	65/83 (78)	-
MW (SD)	34,07 (23,202)	35,21 (26,829)	
Absolute Werte zum Studienende			
n/N (%)	4/59 (7)	2/50 (4)	-
MW (SD)	50,00 (19,245)	27,78 (7,857)	
Effekt über Studiendauer			
n	75	65	LS MD -9,10 [-14,865; -3,327] 0,0022  Hedges' g -0,53 [-0,865; -0,189]
LS MW (SE)	1,61 (1,930)	10,70 (2,188)	
95 %-KI	[-2,212; 5,429]	[6,379; 15,030]	
Veränderung zu Woche 3/4			
n/N (%)	52/86 (60)	46/80 (57)	LS MD -6,60 [-12,974; -0,230]
MW (SD)	4,91 (20,689)	3,38 (21,580)	
LS MW (SE)	2,10 (2,156)	8,71 (2,409)	
95 %-KI	[-2,148; 6,356]	[3,958; 13,454]	
Veränderung zu Woche 8/9			
n/N (%)	63/85 (74)	52/77 (68)	LS MD -7,72 [-13,601; -1,845]
MW (SD)	-1,59 (20,337)	10,90 (21,947)	
LS MW (SE)	1,88 (1,996)	9,60 (2,206)	
95 %-KI	[-2,064; 5,827]	[5,246; 13,963]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	39/83 (47)	31/75 (41)	LS MD -8,51 [-14,253; -2,763]
MW (SD)	2,85 (21,131)	16,85 (23,284)	
LS MW (SE)	1,73 (1,940)	10,23 (2,163)	
95 %-KI	[-2,113; 5,563]	[5,957; 14,509]	
Veränderung zu Woche 15/16			
n/N (%)	41/80 (51)	20/74 (27)	LS MD -9,29 [-15,094; -3,491]
MW (SD)	0,54 (24,210)	10,56 (26,607)	
LS MW (SE)	1,57 (1,934)	10,86 (2,208)	
95 %-KI	[-2,258; 5,396]	[6,500; 15,224]	
Veränderung zu Woche 20/21			
n/N (%)	31/78 (40)	21/68 (31)	LS MD -10,41 [-16,611; -4,216]
MW (SD)	3,58 (22,841)	8,99 (26,204)	
LS MW (SE)	1,35 (2,013)	11,76 (2,411)	
95 %-KI	[-2,632; 5,325]	[7,004; 16,516]	
Veränderung zu Woche 24			
n/N (%)	27/74 (36)	13/65 (20)	LS MD -11,20 [-17,864; -4,533]
MW (SD)	-3,70 (22,222)	7,26 (26,194)	
LS MW (SE)	1,19 (2,124)	12,39 (2,634)	
95 %-KI	[-3,002; 5,383]	[7,201; 17,577]	
Veränderung zu Woche 36			
n/N (%)	33/65 (51)	19/58 (33)	LS MD -13,89 [-22,952; -4,826]
MW (SD)	0,00 (18,634)	12,87 (27,781)	
LS MW (SE)	0,66 (2,757)	14,55 (3,701)	
95 %-KI	[-4,767; 6,078]	[7,271; 21,819]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	1/50 (2)	LS MD -16,58 [-28,676; -4,484]
MW (SD)	13,89 (16,667)	0,00 (NA)	
LS MW (SE)	0,12 (3,610)	16,70 (4,995)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,972; 7,214]	[6,886; 26,516]	
<b>Anzahl vorheriger Therapielinien: 3</b>			
Baseline			
n/N (%)	77/98 (79)	70/95 (74)	-
MW (SD)	33,91 (24,376)	35,56 (25,632)	
Absolute Werte zum Studienende			
n/N (%)	5/59 (8)	4/46 (9)	-
MW (SD)	13,33 (14,487)	33,33 (0,000)	
Effekt über Studiendauer			
n	77	70	LS MD -9,89 [-15,517; -4,268] 0,0007  Hedges' g -0,57 [-0,902; -0,241]
LS MW (SE)	1,50 (1,933)	11,39 (2,093)	
95 %-KI	[-2,324; 5,321]	[7,254; 15,528]	
Veränderung zu Woche 3/4			
n/N (%)	49/96 (51)	48/91 (53)	LS MD -7,72 [-13,956; -1,477]
MW (SD)	6,58 (20,276)	11,34 (16,763)	
LS MW (SE)	3,58 (2,165)	11,30 (2,316)	
95 %-KI	[-0,690; 7,848]	[6,732; 15,859]	
Veränderung zu Woche 8/9			
n/N (%)	61/94 (65)	55/85 (65)	LS MD -8,68 [-14,442; -2,919]
MW (SD)	2,73 (22,375)	10,71 (19,359)	
LS MW (SE)	2,66 (1,998)	11,34 (2,131)	
95 %-KI	[-1,290; 6,605]	[7,130; 15,546]	
Veränderung zu Woche 12			
n/N (%)	44/91 (48)	29/84 (35)	LS MD -9,36 [-14,973; -3,738]
MW (SD)	-3,54 (30,760)	11,49 (19,355)	
LS MW (SE)	2,01 (1,940)	11,37 (2,081)	
95 %-KI	[-1,825; 5,849]	[7,254; 15,481]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	40/88 (45)	23/82 (28)	LS MD -10,03 [-15,675; -4,387]
MW (SD)	-0,83 (17,137)	11,11 (20,101)	
LS MW (SE)	1,37 (1,936)	11,40 (2,104)	
95 %-KI	[-2,463; 5,196]	[7,240; 15,554]	
Veränderung zu Woche 20/21			
n/N (%)	24/82 (29)	20/75 (27)	LS MD -11,00 [-16,967; -5,023]
MW (SD)	-2,31 (24,073)	4,44 (21,749)	
LS MW (SE)	0,44 (2,023)	11,44 (2,254)	
95 %-KI	[-3,553; 4,442]	[6,991; 15,888]	
Veränderung zu Woche 24			
n/N (%)	19/80 (24)	14/70 (20)	LS MD -11,67 [-18,050; -5,290]
MW (SD)	0,58 (27,585)	8,73 (16,979)	
LS MW (SE)	-0,20 (2,143)	11,47 (2,431)	
95 %-KI	[-4,430; 4,028]	[6,679; 16,259]	
Veränderung zu Woche 36			
n/N (%)	33/69 (48)	22/58 (38)	LS MD -13,98 [-22,530; -5,439]
MW (SD)	-3,70 (25,860)	9,85 (20,711)	
LS MW (SE)	-2,41 (2,814)	11,57 (3,322)	
95 %-KI	[-7,949; 3,120]	[5,041; 18,100]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	3/46 (7)	LS MD -16,30 [-27,645; -4,954]
MW (SD)	-22,22 (15,713)	3,70 (27,962)	
LS MW (SE)	-4,63 (3,707)	11,67 (4,439)	
95 %-KI	[-11,912; 2,658]	[2,949; 20,395]	
<b>Vorherige Verabreichung von Bevacizumab: Ja</b>			
Baseline			
n/N (%)	105/134 (78)	100/132 (76)	-
MW (SD)	33,33 (22,222)	36,78 (27,340)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	3/79 (4)	3/62 (5)	-
MW (SD)	51,85 (16,973)	29,63 (6,415)	
Effekt über Studiendauer			
n	105	100	LS MD -8,32 [-12,973; -3,677] 0,0005  Hedges' g -0,49 [-0,771; -0,215]
LS MW (SE)	2,62 (1,598)	10,94 (1,731)	
95 %-KI	[-0,532; 5,772]	[7,532; 14,358]	
Veränderung zu Woche 3/4			
n/N (%)	67/130 (52)	69/127 (54)	LS MD -6,23 [-11,437; -1,019]
MW (SD)	7,79 (18,654)	7,09 (19,336)	
LS MW (SE)	3,89 (1,812)	10,12 (1,926)	
95 %-KI	[0,327; 7,459]	[6,332; 13,910]	
Veränderung zu Woche 8/9			
n/N (%)	85/130 (65)	76/119 (64)	LS MD -7,21 [-11,951; -2,463]
MW (SD)	1,57 (19,635)	11,26 (21,430)	
LS MW (SE)	3,30 (1,658)	10,51 (1,743)	
95 %-KI	[0,031; 6,567]	[7,071; 13,940]	
Veränderung zu Woche 12			
n/N (%)	55/126 (44)	38/114 (33)	LS MD -7,89 [-12,518; -3,266]
MW (SD)	2,63 (27,213)	8,77 (18,112)	
LS MW (SE)	2,88 (1,605)	10,77 (1,709)	
95 %-KI	[-0,283; 6,049]	[7,405; 14,145]	
Veränderung zu Woche 15/16			
n/N (%)	58/122 (48)	32/112 (29)	LS MD -8,58 [-13,271; -3,882]
MW (SD)	-0,19 (20,760)	11,11 (27,508)	
LS MW (SE)	2,47 (1,603)	11,04 (1,760)	
95 %-KI	[-0,695; 5,629]	[7,576; 14,512]	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	38/114 (33)	28/103 (27)	LS MD -9,56 [-14,654; -4,457]
MW (SD)	2,34 (23,839)	-0,00 (18,144)	
LS MW (SE)	1,87 (1,687)	11,43 (1,962)	
95 %-KI	[-1,452; 5,198]	[7,567; 15,290]	
Veränderung zu Woche 24			
n/N (%)	30/109 (28)	17/95 (18)	LS MD -10,24 [-15,799; -4,682]
MW (SD)	1,11 (15,536)	7,19 (18,401)	
LS MW (SE)	1,46 (1,800)	11,70 (2,175)	
95 %-KI	[-2,087; 5,002]	[7,421; 15,974]	
Veränderung zu Woche 36			
n/N (%)	44/93 (47)	22/79 (28)	LS MD -12,59 [-20,411; -4,767]
MW (SD)	-0,51 (18,084)	10,61 (23,627)	
LS MW (SE)	0,03 (2,419)	12,62 (3,156)	
95 %-KI	[-4,720; 4,783]	[6,422; 18,819]	
Veränderung zu Woche 48			
n/N (%)	3/79 (4)	2/62 (3)	LS MD -14,94 [-25,536; -4,338]
MW (SD)	11,11 (19,245)	-11,11 (15,713)	
LS MW (SE)	-1,39 (3,226)	13,54 (4,315)	
95 %-KI	[-7,729; 4,940]	[5,071; 22,015]	
<b>Vorherige Verabreichung von Bevacizumab: Nein</b>			
Baseline			
n/N (%)	71/84 (85)	58/75 (77)	-
MW (SD)	37,09 (25,952)	29,69 (22,741)	
Absolute Werte zum Studienende			
n/N (%)	7/61 (11)	3/48 (6)	-
MW (SD)	20,63 (19,698)	33,33 (0,000)	
Effekt über Studiendauer			
n	71	58	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	0,19 (2,103)	10,09 (2,365)	LS MD -9,90 [-16,188; -3,612] 0,0023
95 %-KI	[-3,980; 4,350]	[5,406; 14,765]	
Veränderung zu Woche 3/4			
n/N (%)	50/83 (60)	40/73 (55)	LS MD -8,06 [-14,986; -1,140]
MW (SD)	1,33 (21,371)	5,83 (19,488)	
LS MW (SE)	-0,45 (2,327)	7,61 (2,612)	
95 %-KI	[-5,043; 4,143]	[2,461; 12,765]	
Veränderung zu Woche 8/9			
n/N (%)	59/80 (74)	49/69 (71)	LS MD -8,82 [-15,284; -2,360]
MW (SD)	-2,07 (22,553)	10,66 (22,676)	
LS MW (SE)	-0,19 (2,177)	8,63 (2,423)	
95 %-KI	[-4,492; 4,117]	[3,845; 13,424]	
Veränderung zu Woche 12			
n/N (%)	42/79 (53)	34/69 (49)	LS MD -9,35 [-15,655; -3,052]
MW (SD)	-10,05 (23,895)	16,67 (24,042)	
LS MW (SE)	-0,00 (2,119)	9,35 (2,361)	
95 %-KI	[-4,198; 4,190]	[4,677; 14,022]	
Veränderung zu Woche 15/16			
n/N (%)	38/77 (49)	22/66 (33)	LS MD -9,88 [-16,171; -3,599]
MW (SD)	-1,75 (21,228)	9,09 (22,390)	
LS MW (SE)	0,18 (2,103)	10,06 (2,364)	
95 %-KI	[-3,985; 4,344]	[5,387; 14,742]	
Veränderung zu Woche 20/21			
n/N (%)	28/76 (37)	22/62 (35)	LS MD -10,64 [-17,160; -4,128]
MW (SD)	0,00 (20,732)	14,14 (24,770)	
LS MW (SE)	0,44 (2,156)	11,09 (2,477)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,824; 4,708]	[6,191; 15,981]	
Veränderung zu Woche 24			
n/N (%)	25/75 (33)	21/60 (35)	LS MD -11,18 [-18,015; -4,335]
MW (SD)	-3,56 (30,212)	5,56 (20,638)	
LS MW (SE)	0,63 (2,243)	11,80 (2,625)	
95 %-KI	[-3,806; 5,058]	[6,620; 16,981]	
Veränderung zu Woche 36			
n/N (%)	37/67 (55)	25/55 (45)	LS MD -13,00 [-21,712; -4,281]
MW (SD)	0,60 (28,078)	12,89 (25,945)	
LS MW (SE)	1,26 (2,781)	14,25 (3,436)	
95 %-KI	[-4,220; 6,730]	[7,495; 21,009]	
Veränderung zu Woche 48			
n/N (%)	5/61 (8)	2/48 (4)	LS MD -14,82 [-26,111; -3,527]
MW (SD)	-13,33 (24,088)	16,67 (23,570)	
LS MW (SE)	1,88 (3,551)	16,70 (4,507)	
95 %-KI	[-5,094; 8,864]	[7,847; 25,560]	
<b>Letztes Platin-freies Intervall: ≤ 3 Monate</b>			
Baseline			
n/N (%)	68/83 (82)	61/91 (67)	-
MW (SD)	30,07 (20,139)	38,07 (25,536)	
Absolute Werte zum Studienende			
n/N (%)	3/55 (5)	5/39 (13)	-
MW (SD)	29,63 (33,945)	31,11 (4,969)	
Effekt über Studiendauer			
n	68	61	LS MD -11,00 [-16,838; -5,165] 0,0003
LS MW (SE)	2,79 (1,957)	13,79 (2,187)	
95 %-KI	[-1,085; 6,671]	[9,467; 18,122]	Hedges' g -0,66 [-1,014; -0,304]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	49/82 (60)	45/86 (52)	LS MD -9,52 [-16,048; -2,994]
MW (SD)	7,26 (21,100)	11,11 (21,188)	
LS MW (SE)	5,01 (2,218)	14,53 (2,428)	
95 %-KI	[0,636; 9,386]	[9,744; 19,321]	
Veränderung zu Woche 8/9			
n/N (%)	52/81 (64)	45/80 (56)	LS MD -10,20 [-16,169; -4,239]
MW (SD)	3,63 (18,373)	11,11 (21,840)	
LS MW (SE)	3,99 (2,021)	14,19 (2,216)	
95 %-KI	[-0,010; 7,985]	[9,811; 18,572]	
Veränderung zu Woche 12			
n/N (%)	33/78 (42)	25/78 (32)	LS MD -10,68 [-16,498; -4,868]
MW (SD)	0,34 (21,603)	16,00 (23,147)	
LS MW (SE)	3,27 (1,959)	13,95 (2,169)	
95 %-KI	[-0,611; 7,152]	[9,662; 18,244]	
Veränderung zu Woche 15/16			
n/N (%)	35/76 (46)	13/75 (17)	LS MD -11,16 [-17,044; -5,278]
MW (SD)	-0,63 (23,484)	13,68 (23,198)	
LS MW (SE)	2,55 (1,968)	13,71 (2,211)	
95 %-KI	[-1,345; 6,453]	[9,340; 18,089]	
Veränderung zu Woche 20/21			
n/N (%)	22/72 (31)	13/67 (19)	LS MD -11,84 [-18,185; -5,504]
MW (SD)	6,06 (18,696)	5,13 (28,188)	
LS MW (SE)	1,53 (2,100)	13,37 (2,417)	
95 %-KI	[-2,622; 5,681]	[8,601; 18,148]	
Veränderung zu Woche 24			
n/N (%)	16/72 (22)	12/62 (19)	LS MD -12,32 [-19,198; -5,448]
MW (SD)	3,47 (23,906)	4,63 (19,221)	
LS MW (SE)	0,81 (2,263)	13,14 (2,644)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,654; 5,280]	[7,922; 18,350]	
Veränderung zu Woche 36			
n/N (%)	28/63 (44)	17/50 (34)	LS MD -13,96 [-23,523; -4,404]
MW (SD)	-0,79 (20,494)	10,78 (19,883)	
LS MW (SE)	-1,64 (3,113)	12,32 (3,733)	
95 %-KI	[-7,767; 4,478]	[4,976; 19,661]	
Veränderung zu Woche 48			
n/N (%)	2/55 (4)	3/39 (8)	LS MD -15,60 [-28,504; -2,704]
MW (SD)	5,56 (23,570)	-7,41 (12,830)	
LS MW (SE)	-4,10 (4,188)	11,50 (5,054)	
95 %-KI	[-12,336; 4,131]	[1,566; 21,436]	
<b>Letztes Platin-freies Intervall: &gt; 3 Monate</b>			
Baseline			
n/N (%)	108/135 (80)	97/116 (84)	-
MW (SD)	37,86 (25,466)	31,73 (25,958)	
Absolute Werte zum Studienende			
n/N (%)	7/85 (8)	1/71 (1)	-
MW (SD)	30,16 (20,998)	33,33 (NA)	
Effekt über Studiendauer			
n	108	97	LS MD -8,02 [-12,899; -3,135] 0,0014  Hedges' g -0,45 [-0,731; -0,175]
LS MW (SE)	0,81 (1,673)	8,83 (1,816)	
95 %-KI	[-2,485; 4,114]	[5,251; 12,411]	
Veränderung zu Woche 3/4			
n/N (%)	68/131 (52)	64/114 (56)	LS MD -5,69 [-11,100; -0,282]
MW (SD)	3,43 (19,222)	3,47 (17,358)	
LS MW (SE)	0,01 (1,860)	5,70 (2,016)	
95 %-KI	[-3,649; 3,675]	[1,738; 9,669]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	92/129 (71)	80/108 (74)	LS MD -6,70 [-11,706; -1,686]
MW (SD)	-1,93 (22,014)	10,97 (21,974)	
LS MW (SE)	0,36 (1,734)	7,06 (1,851)	
95 %-KI	[-3,059; 3,778]	[3,409; 10,701]	
Veränderung zu Woche 12			
n/N (%)	64/127 (50)	47/105 (45)	LS MD -7,40 [-12,282; -2,518]
MW (SD)	-4,51 (28,670)	10,64 (20,324)	
LS MW (SE)	0,60 (1,686)	8,00 (1,805)	
95 %-KI	[-2,723; 3,927]	[4,444; 11,559]	
Veränderung zu Woche 15/16			
n/N (%)	61/123 (50)	41/103 (40)	LS MD -8,10 [-12,994; -3,213]
MW (SD)	-0,91 (19,383)	9,21 (26,165)	
LS MW (SE)	0,84 (1,673)	8,95 (1,822)	
95 %-KI	[-2,456; 4,145]	[5,357; 12,539]	
Veränderung zu Woche 20/21			
n/N (%)	44/118 (37)	37/98 (38)	LS MD -9,11 [-14,244; -3,973]
MW (SD)	-1,01 (23,941)	6,61 (20,194)	
LS MW (SE)	1,19 (1,719)	10,30 (1,951)	
95 %-KI	[-2,198; 4,580]	[6,459; 14,141]	
Veränderung zu Woche 24			
n/N (%)	39/112 (35)	26/93 (28)	LS MD -9,81 [-15,266; -4,359]
MW (SD)	-2,85 (23,043)	7,05 (19,849)	
LS MW (SE)	1,43 (1,792)	11,25 (2,104)	
95 %-KI	[-2,097; 4,965]	[7,108; 15,385]	
Veränderung zu Woche 36			
n/N (%)	53/97 (55)	30/84 (36)	LS MD -12,23 [-19,411; -5,039]
MW (SD)	0,42 (24,456)	12,41 (27,282)	
LS MW (SE)	2,27 (2,245)	14,49 (2,881)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-2,146; 6,677]	[8,834; 20,147]	
Veränderung zu Woche 48			
n/N (%)	6/85 (7)	1/71 (1)	LS MD -14,64 [-24,106; -5,170]
MW (SD)	-7,41 (25,979)	33,33 (NA)	
LS MW (SE)	3,10 (2,885)	17,74 (3,856)	
95 %-KI	[-2,567; 8,762]	[10,164; 25,306]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Pegyliertes liposomales Doxorubicin</b>			
Baseline			
n/N (%)	61/80 (76)	57/76 (75)	-
MW (SD)	36,25 (23,210)	30,02 (23,846)	
Absolute Werte zum Studienende			
n/N (%)	3/51 (6)	3/41 (7)	-
MW (SD)	37,04 (16,973)	29,63 (6,415)	
Effekt über Studiendauer			
n	61	57	LS MD -9,98 [-15,887; -4,063] 0,0011  Hedges' g -0,62 [-0,985; -0,245]
LS MW (SE)	1,01 (2,017)	10,99 (2,182)	
95 %-KI	[-2,986; 5,014]	[6,668; 15,310]	
Veränderung zu Woche 3/4			
n/N (%)	39/76 (51)	43/74 (58)	LS MD -11,20 [-17,789; -4,601]
MW (SD)	-2,85 (17,236)	7,75 (16,717)	
LS MW (SE)	-1,97 (2,302)	9,22 (2,406)	
95 %-KI	[-6,517; 2,572]	[4,476; 13,970]	
Veränderung zu Woche 8/9			
n/N (%)	51/76 (67)	44/66 (67)	LS MD -10,67 [-16,733; -4,599]
MW (SD)	-0,87 (19,480)	11,87 (21,883)	
LS MW (SE)	-0,68 (2,115)	9,99 (2,203)	
95 %-KI	[-4,861; 3,509]	[5,631; 14,348]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	32/75 (43)	23/64 (36)	LS MD -10,29 [-16,199; -4,391]
MW (SD)	-4,86 (21,482)	13,04 (17,617)	
LS MW (SE)	0,23 (2,040)	10,53 (2,156)	
95 %-KI	[-3,812; 4,274]	[6,257; 14,795]	
Veränderung zu Woche 15/16			
n/N (%)	34/74 (46)	19/62 (31)	LS MD -9,92 [-15,850; -3,998]
MW (SD)	-0,65 (25,061)	12,28 (27,690)	
LS MW (SE)	1,14 (2,018)	11,06 (2,192)	
95 %-KI	[-2,862; 5,139]	[6,723; 15,403]	
Veränderung zu Woche 20/21			
n/N (%)	26/72 (36)	18/59 (31)	LS MD -9,39 [-15,667; -3,122]
MW (SD)	3,42 (20,066)	5,56 (15,829)	
LS MW (SE)	2,43 (2,079)	11,83 (2,382)	
95 %-KI	[-1,683; 6,552]	[7,124; 16,534]	
Veränderung zu Woche 24			
n/N (%)	22/69 (32)	16/54 (30)	LS MD -9,02 [-15,733; -2,315]
MW (SD)	-0,00 (19,994)	4,86 (11,453)	
LS MW (SE)	3,34 (2,183)	12,37 (2,593)	
95 %-KI	[-0,974; 7,659]	[7,252; 17,480]	
Veränderung zu Woche 36			
n/N (%)	30/60 (50)	16/48 (33)	LS MD -7,75 [-16,790; 1,284]
MW (SD)	4,81 (23,828)	15,62 (25,597)	
LS MW (SE)	6,45 (2,821)	14,21 (3,622)	
95 %-KI	[0,901; 12,005]	[7,082; 21,330]	
Veränderung zu Woche 48			
n/N (%)	2/51 (4)	2/41 (5)	LS MD -6,48 [-18,527; 5,563]
MW (SD)	5,56 (23,570)	0,00 (0,000)	
LS MW (SE)	9,56 (3,706)	16,05 (4,882)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[2,278; 16,850]	[6,449; 25,643]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Paclitaxel</b>			
Baseline			
n/N (%)	76/88 (86)	69/82 (84)	-
MW (SD)	36,55 (24,667)	38,65 (26,922)	
Absolute Werte zum Studienende			
n/N (%)	1/56 (2)	1/49 (2)	-
MW (SD)	66,67 (NA)	33,33 (NA)	
Effekt über Studiendauer			
n	76	69	LS MD -9,03 [-14,899; -3,165] 0,0028  Hedges' g -0,50 [-0,835; -0,173]
LS MW (SE)	2,17 (2,010)	11,20 (2,187)	
95 %-KI	[-1,810; 6,142]	[6,875; 15,521]	
Veränderung zu Woche 3/4			
n/N (%)	55/87 (63)	48/81 (59)	LS MD -5,37 [-11,930; 1,196]
MW (SD)	9,29 (22,505)	4,86 (22,329)	
LS MW (SE)	4,55 (2,249)	9,92 (2,458)	
95 %-KI	[0,117; 8,985]	[5,074; 14,761]	
Veränderung zu Woche 8/9			
n/N (%)	63/86 (73)	54/79 (68)	LS MD -7,04 [-13,057; -1,018]
MW (SD)	-0,18 (22,533)	10,70 (23,641)	
LS MW (SE)	3,46 (2,074)	10,50 (2,236)	
95 %-KI	[-0,634; 7,562]	[6,086; 14,916]	
Veränderung zu Woche 12			
n/N (%)	44/84 (52)	37/77 (48)	LS MD -8,21 [-14,067; -2,347]
MW (SD)	-0,51 (27,941)	15,02 (25,285)	
LS MW (SE)	2,70 (2,016)	10,91 (2,176)	
95 %-KI	[-1,284; 6,690]	[6,608; 15,211]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	46/81 (57)	27/76 (36)	LS MD -9,38 [-15,276; -3,477]
MW (SD)	-0,00 (19,738)	11,11 (27,217)	
LS MW (SE)	1,94 (2,016)	11,32 (2,204)	
95 %-KI	[-2,046; 5,930]	[6,962; 15,675]	
Veränderung zu Woche 20/21			
n/N (%)	29/77 (38)	25/73 (34)	LS MD -11,05 [-17,336; -4,758]
MW (SD)	4,21 (23,081)	8,00 (28,241)	
LS MW (SE)	0,86 (2,117)	11,90 (2,389)	
95 %-KI	[-3,326; 5,037]	[7,190; 16,614]	
Veränderung zu Woche 24			
n/N (%)	22/74 (30)	19/72 (26)	LS MD -12,22 [-18,982; -5,451]
MW (SD)	3,03 (23,302)	8,48 (25,551)	
LS MW (SE)	0,09 (2,250)	12,31 (2,601)	
95 %-KI	[-4,344; 4,533]	[7,187; 17,435]	
Veränderung zu Woche 36			
n/N (%)	36/64 (56)	23/63 (37)	LS MD -16,23 [-25,465; -6,986]
MW (SD)	0,31 (20,138)	9,42 (26,135)	
LS MW (SE)	-2,51 (2,979)	13,71 (3,652)	
95 %-KI	[-8,371; 3,343]	[6,536; 20,888]	
Veränderung zu Woche 48			
n/N (%)	1/56 (2)	0/49 (0)	LS MD -20,24 [-32,618; -7,852]
MW (SD)	22,22 (NA)	NA (NA)	
LS MW (SE)	-5,12 (3,937)	15,11 (4,944)	
95 %-KI	[-12,857; 2,613]	[5,401; 24,825]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Topotecan</b>			
Baseline			
n/N (%)	39/50 (78)	32/49 (65)	-
MW (SD)	29,34 (22,726)	31,94 (26,437)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	6/33 (18)	2/20 (10)	-
MW (SD)	20,37 (21,564)	33,33 (0,000)	
Effekt über Studiendauer			
n	39	32	LS MD -8,20 [-16,401; 0,010] 0,0503  Hedges' g -0,47 [-0,945; 0,003]
LS MW (SE)	1,51 (2,702)	9,70 (3,114)	
95 %-KI	[-3,890; 6,908]	[3,496; 15,913]	
Veränderung zu Woche 3/4			
n/N (%)	23/50 (46)	18/45 (40)	LS MD -5,29 [-14,124; 3,541]
MW (SD)	8,21 (13,901)	8,64 (16,853)	
LS MW (SE)	3,07 (2,920)	8,36 (3,380)	
95 %-KI	[-2,735; 8,874]	[1,650; 15,072]	
Veränderung zu Woche 8/9			
n/N (%)	30/48 (62)	27/43 (63)	LS MD -6,53 [-14,831; 1,773]
MW (SD)	2,22 (20,089)	10,29 (18,471)	
LS MW (SE)	2,40 (2,756)	8,93 (3,151)	
95 %-KI	[-3,093; 7,901]	[2,657; 15,210]	
Veränderung zu Woche 12			
n/N (%)	21/46 (46)	12/42 (29)	LS MD -7,40 [-15,556; 0,764]
MW (SD)	-4,76 (30,746)	3,70 (10,941)	
LS MW (SE)	1,94 (2,702)	9,33 (3,090)	
95 %-KI	[-3,461; 7,338]	[3,171; 15,499]	
Veränderung zu Woche 15/16			
n/N (%)	16/44 (36)	8/40 (20)	LS MD -8,26 [-16,479; -0,046]
MW (SD)	-3,47 (13,889)	2,78 (7,857)	
LS MW (SE)	1,47 (2,704)	9,74 (3,119)	
95 %-KI	[-3,930; 6,876]	[3,517; 15,955]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	11/41 (27)	7/33 (21)	LS MD -9,50 [-18,134; -0,868]
MW (SD)	-11,11 (23,831)	1,59 (9,997)	
LS MW (SE)	0,81 (2,799)	10,31 (3,308)	
95 %-KI	[-4,776; 6,391]	[3,731; 16,886]	
Veränderung zu Woche 24			
n/N (%)	11/41 (27)	3/29 (10)	LS MD -10,37 [-19,505; -1,231]
MW (SD)	-11,11 (28,109)	0,00 (0,000)	
LS MW (SE)	0,34 (2,927)	10,71 (3,530)	
95 %-KI	[-5,482; 6,166]	[3,707; 17,712]	
Veränderung zu Woche 36			
n/N (%)	15/36 (42)	8/23 (35)	LS MD -13,34 [-25,171; -1,508]
MW (SD)	-10,37 (26,047)	11,11 (19,698)	
LS MW (SE)	-1,25 (3,652)	12,08 (4,676)	
95 %-KI	[-8,472; 5,962]	[2,853; 21,315]	
Veränderung zu Woche 48			
n/N (%)	5/33 (15)	2/20 (10)	LS MD -16,31 [-31,698; -0,924]
MW (SD)	-13,33 (24,088)	5,56 (39,284)	
LS MW (SE)	-2,85 (4,648)	13,46 (6,146)	
95 %-KI	[-12,018; 6,315]	[1,341; 25,577]	
<p><i>Analysepopulation: ITT</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023</i></p> <p><i>Modell: Veränderung zu Baseline ~ Behandlung + Baseline-Wert * Zeit in Wochen + Behandlung * Zeit in Wochen + zufällige Effekte durch die Patientin</i></p> <p><i>Die Berechnung des LS-MWs erfolgt durch ein MMRM mit dem oben angegebenen Modell. Basierend hierauf werden KI und p-Wert ermittelt. Hedges' g basiert ebenfalls auf den LS-MW und ist somit auf das Modell angepasst.</i></p> <p><i>Es werden ausschließlich gemeinsame Analysezeitpunkte dargestellt.</i></p> <p><i>Ein LS MD und Hedges' g kleiner als Null bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

## 2.6 EORTC QLQ-C30 Schlaflosigkeit

### EORTC QLQ-C30 Schlaflosigkeit: Subgruppenanalyse

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
<b>EORTC QLQ-C30 Schlaflosigkeit</b>			
<b>Alter: &lt; 65 Jahre</b>			
Baseline			
n/N (%)	95/115 (83)	91/119 (76)	-
MW (SD)	32,28 (29,756)	32,60 (32,195)	
Absolute Werte zum Studienende			
n/N (%)	4/73 (5)	4/64 (6)	-
MW (SD)	50,00 (43,033)	25,00 (16,667)	
Effekt über Studiendauer			
n	95	91	LS MD -0,59 [-7,037; 5,864] 0,8579
LS MW (SE)	1,25 (2,238)	1,83 (2,383)	
95 %-KI	[-3,172; 5,663]	[-2,869; 6,532]	Hedges' g -0,03 [-0,314; 0,261]
Veränderung zu Woche 3/4			
n/N (%)	57/113 (50)	60/115 (52)	LS MD 0,43 [-6,814; 7,676]
MW (SD)	-5,85 (29,629)	-0,56 (29,106)	
LS MW (SE)	0,87 (2,539)	0,44 (2,666)	
95 %-KI	[-4,132; 5,864]	[-4,812; 5,682]	
Veränderung zu Woche 8/9			
n/N (%)	76/112 (68)	71/108 (66)	LS MD -0,02 [-6,649; 6,612]
MW (SD)	3,51 (34,675)	2,82 (26,872)	
LS MW (SE)	1,03 (2,330)	1,05 (2,426)	
95 %-KI	[-3,561; 5,628]	[-3,731; 5,834]	
Veränderung zu Woche 12			
n/N (%)	48/110 (44)	40/105 (38)	
MW (SD)	2,78 (36,923)	-1,67 (30,147)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	1,15 (2,253)	1,48 (2,364)	LS MD -0,33 [-6,775; 6,110]
95 %-KI	[-3,296; 5,597]	[-3,179; 6,146]	
Veränderung zu Woche 15/16			
n/N (%)	55/107 (51)	32/102 (31)	LS MD -0,65 [-7,121; 5,827]
MW (SD)	2,42 (36,206)	-1,04 (26,075)	
LS MW (SE)	1,27 (2,240)	1,91 (2,396)	
95 %-KI	[-3,155; 5,691]	[-2,812; 6,641]	
Veränderung zu Woche 20/21			
n/N (%)	37/101 (37)	29/96 (30)	LS MD -1,10 [-7,985; 5,794]
MW (SD)	-3,60 (34,946)	3,45 (18,570)	
LS MW (SE)	1,44 (2,334)	2,53 (2,600)	
95 %-KI	[-3,169; 6,040]	[-2,590; 7,652]	
Veränderung zu Woche 24			
n/N (%)	25/99 (25)	19/91 (21)	LS MD -1,41 [-8,817; 5,997]
MW (SD)	2,67 (42,947)	3,51 (18,904)	
LS MW (SE)	1,55 (2,472)	2,96 (2,833)	
95 %-KI	[-3,318; 6,422]	[-2,612; 8,537]	
Veränderung zu Woche 36			
n/N (%)	41/86 (48)	27/79 (34)	LS MD -2,49 [-12,603; 7,629]
MW (SD)	1,63 (34,117)	6,17 (30,714)	
LS MW (SE)	1,95 (3,258)	4,44 (3,979)	
95 %-KI	[-4,448; 8,356]	[-3,375; 12,258]	
Veränderung zu Woche 48			
n/N (%)	4/73 (5)	2/64 (3)	LS MD -3,56 [-17,134; 10,004]
MW (SD)	8,33 (16,667)	16,67 (23,570)	
LS MW (SE)	2,36 (4,311)	5,92 (5,386)	
95 %-KI	[-6,111; 10,823]	[-4,657; 16,498]	
<b>Alter: ≥ 65 Jahre</b>			
Baseline			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	81/103 (79)	67/88 (76)	-
MW (SD)	29,22 (26,553)	29,85 (30,226)	
Absolute Werte zum Studienende			
n/N (%)	6/67 (9)	2/46 (4)	-
MW (SD)	16,67 (27,889)	0,00 (0,000)	
Effekt über Studiendauer			
n	81	67	LS MD -1,14 [-7,831; 5,558] 0,7376  Hedges' g -0,06 [-0,379; 0,268]
LS MW (SE)	0,72 (2,218)	1,86 (2,569)	
95 %-KI	[-3,669; 5,106]	[-3,221; 6,932]	
Veränderung zu Woche 3/4			
n/N (%)	60/100 (60)	49/85 (58)	LS MD -0,70 [-8,280; 6,883]
MW (SD)	-1,67 (22,487)	-1,36 (23,530)	
LS MW (SE)	0,88 (2,539)	1,57 (2,904)	
95 %-KI	[-4,128; 5,879]	[-4,147; 7,294]	
Veränderung zu Woche 8/9			
n/N (%)	68/98 (69)	53/80 (66)	LS MD -0,89 [-7,780; 5,995]
MW (SD)	1,96 (32,005)	1,26 (33,945)	
LS MW (SE)	0,81 (2,314)	1,70 (2,621)	
95 %-KI	[-3,766; 5,377]	[-3,477; 6,874]	
Veränderung zu Woche 12			
n/N (%)	49/95 (52)	32/78 (41)	LS MD -1,03 [-7,708; 5,651]
MW (SD)	0,68 (28,455)	6,25 (23,090)	
LS MW (SE)	0,76 (2,233)	1,79 (2,547)	
95 %-KI	[-3,658; 5,173]	[-3,248; 6,820]	
Veränderung zu Woche 15/16			
n/N (%)	41/92 (45)	22/76 (29)	
MW (SD)	5,69 (27,791)	-6,06 (35,091)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	0,71 (2,221)	1,87 (2,586)	LS MD -1,16 [-7,889; 5,560]
95 %-KI	[-3,685; 5,103]	[-3,236; 6,983]	
Veränderung zu Woche 20/21			
n/N (%)	28/89 (31)	21/69 (30)	LS MD -1,36 [-8,572; 5,855]
MW (SD)	3,57 (18,898)	6,35 (41,659)	
LS MW (SE)	0,64 (2,328)	2,00 (2,826)	
95 %-KI	[-3,960; 5,239]	[-3,575; 7,572]	
Veränderung zu Woche 24			
n/N (%)	30/85 (35)	19/64 (30)	LS MD -1,49 [-9,306; 6,316]
MW (SD)	6,67 (25,371)	-0,00 (31,427)	
LS MW (SE)	0,59 (2,479)	2,09 (3,099)	
95 %-KI	[-4,300; 5,483]	[-4,017; 8,189]	
Veränderung zu Woche 36			
n/N (%)	40/74 (54)	20/55 (36)	LS MD -1,96 [-12,837; 8,915]
MW (SD)	-4,17 (29,417)	1,67 (25,305)	
LS MW (SE)	0,42 (3,329)	2,39 (4,425)	
95 %-KI	[-6,121; 6,971]	[-6,309; 11,082]	
Veränderung zu Woche 48			
n/N (%)	4/67 (6)	2/46 (4)	LS MD -2,43 [-17,149; 12,294]
MW (SD)	8,33 (16,667)	-16,67 (23,570)	
LS MW (SE)	0,26 (4,449)	2,69 (6,035)	
95 %-KI	[-8,482; 9,000]	[-9,169; 14,541]	
<b>Region: USA</b>			
Baseline			
n/N (%)	49/65 (75)	34/51 (67)	-
MW (SD)	32,65 (29,258)	32,35 (33,318)	
Absolute Werte zum Studienende			
n/N (%)	2/39 (5)	3/27 (11)	-
MW (SD)	66,67 (47,140)	0,00 (0,000)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Effekt über Studiendauer			
n	49	34	LS MD -3,65 [-11,745; 4,452] 0,3726  Hedges' g -0,20 [-0,638; 0,240]
LS MW (SE)	-2,75 (2,568)	0,90 (3,155)	
95 %-KI	[-7,868; 2,369]	[-5,385; 7,179]	
Veränderung zu Woche 3/4			
n/N (%)	33/64 (52)	21/49 (43)	LS MD -5,66 [-15,147; 3,830]
MW (SD)	-3,03 (21,022)	-0,00 (29,814)	
LS MW (SE)	-3,97 (3,019)	1,69 (3,729)	
95 %-KI	[-9,940; 2,004]	[-5,684; 9,065]	
Veränderung zu Woche 8/9			
n/N (%)	42/62 (68)	30/46 (65)	LS MD -4,75 [-13,228; 3,726]
MW (SD)	-4,76 (28,103)	2,22 (21,323)	
LS MW (SE)	-3,42 (2,691)	1,33 (3,313)	
95 %-KI	[-8,765; 1,928]	[-5,245; 7,911]	
Veränderung zu Woche 12			
n/N (%)	26/59 (44)	16/45 (36)	LS MD -4,12 [-12,250; 4,017]
MW (SD)	-2,56 (28,163)	-4,17 (26,874)	
LS MW (SE)	-3,03 (2,579)	1,08 (3,170)	
95 %-KI	[-8,171; 2,103]	[-5,226; 7,390]	
Veränderung zu Woche 15/16			
n/N (%)	21/56 (38)	11/44 (25)	LS MD -3,48 [-11,613; 4,650]
MW (SD)	-3,17 (25,614)	-12,12 (22,473)	
LS MW (SE)	-2,65 (2,579)	0,83 (3,169)	
95 %-KI	[-7,790; 2,490]	[-5,477; 7,141]	
Veränderung zu Woche 20/21			
n/N (%)	13/54 (24)	9/40 (22)	
MW (SD)	-2,56 (16,452)	14,81 (41,201)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-2,10 (2,772)	0,47 (3,412)	LS MD -2,57 [-11,287; 6,139]
95 %-KI	[-7,607; 3,406]	[-6,298; 7,246]	
Veränderung zu Woche 24			
n/N (%)	9/53 (17)	6/38 (16)	LS MD -1,94 [-11,413; 7,535]
MW (SD)	7,41 (22,222)	5,56 (32,773)	
LS MW (SE)	-1,72 (3,021)	0,22 (3,725)	
95 %-KI	[-7,700; 4,268]	[-7,152; 7,598]	
Veränderung zu Woche 36			
n/N (%)	22/43 (51)	10/33 (30)	LS MD 0,24 [-13,243; 13,719]
MW (SD)	-10,61 (31,516)	-0,00 (47,140)	
LS MW (SE)	-0,40 (4,311)	-0,64 (5,345)	
95 %-KI	[-8,891; 8,096]	[-11,168; 9,896]	
Veränderung zu Woche 48			
n/N (%)	2/39 (5)	3/27 (11)	LS MD 2,42 [-16,101; 20,931]
MW (SD)	0,00 (0,000)	-11,11 (19,245)	
LS MW (SE)	0,92 (5,918)	-1,49 (7,356)	
95 %-KI	[-10,731; 12,572]	[-15,979; 12,989]	
<b>Region: Rest der Welt</b>			
Baseline			
n/N (%)	127/153 (83)	124/156 (79)	-
MW (SD)	30,18 (27,994)	31,18 (30,869)	
Absolute Werte zum Studienende			
n/N (%)	8/101 (8)	3/83 (4)	-
MW (SD)	20,83 (30,538)	33,33 (0,000)	
Effekt über Studiendauer			
n	127	124	LS MD -0,12 [-5,671; 5,436] 0,9667 Hedges' g
LS MW (SE)	2,24 (1,928)	2,36 (2,061)	
95 %-KI	[-1,559; 6,039]	[-1,701; 6,417]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
			-0,01 [-0,253; 0,242]
Veränderung zu Woche 3/4			
n/N (%)	84/149 (56)	88/151 (58)	LS MD 1,64 [-4,573; 7,846]
MW (SD)	-3,97 (28,058)	-1,14 (25,992)	
LS MW (SE)	2,51 (2,184)	0,87 (2,288)	
95 %-KI	[-1,787; 6,802]	[-3,627; 5,368]	
Veränderung zu Woche 8/9			
n/N (%)	102/148 (69)	94/142 (66)	LS MD 0,87 [-4,823; 6,555]
MW (SD)	5,88 (34,917)	2,13 (32,354)	
LS MW (SE)	2,39 (2,008)	1,52 (2,083)	
95 %-KI	[-1,564; 6,344]	[-2,576; 5,625]	
Veränderung zu Woche 12			
n/N (%)	71/146 (49)	56/138 (41)	LS MD 0,33 [-5,210; 5,862]
MW (SD)	3,29 (34,344)	3,57 (27,472)	
LS MW (SE)	2,31 (1,942)	1,98 (2,036)	
95 %-KI	[-1,519; 6,134]	[-2,027; 5,991]	
Veränderung zu Woche 15/16			
n/N (%)	75/143 (52)	43/134 (32)	LS MD -0,21 [-5,789; 5,360]
MW (SD)	5,78 (34,386)	-0,78 (31,277)	
LS MW (SE)	2,23 (1,929)	2,44 (2,074)	
95 %-KI	[-1,577; 6,027]	[-1,645; 6,524]	
Veränderung zu Woche 20/21			
n/N (%)	52/136 (38)	41/125 (33)	LS MD -0,99 [-6,936; 4,965]
MW (SD)	-0,00 (31,657)	2,44 (27,275)	
LS MW (SE)	2,11 (2,004)	3,09 (2,268)	
95 %-KI	[-1,839; 6,054]	[-1,369; 7,555]	
Veränderung zu Woche 24			
n/N (%)	46/131 (35)	32/117 (27)	
MW (SD)	4,35 (36,249)	1,04 (24,662)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	2,03 (2,115)	3,55 (2,483)	LS MD -1,53 [-7,933; 4,882]
95 %-KI	[-2,137; 6,188]	[-1,330; 8,431]	
Veränderung zu Woche 36			
n/N (%)	59/117 (50)	37/101 (37)	LS MD -3,38 [-12,145; 5,392]
MW (SD)	2,26 (31,480)	5,41 (21,536)	
LS MW (SE)	1,74 (2,765)	5,12 (3,515)	
95 %-KI	[-3,687; 7,174]	[-1,780; 12,020]	
Veränderung zu Woche 48			
n/N (%)	6/101 (6)	1/83 (1)	LS MD -5,23 [-16,986; 6,531]
MW (SD)	11,11 (17,213)	33,33 (NA)	
LS MW (SE)	1,46 (3,645)	6,69 (4,766)	
95 %-KI	[-5,693; 8,616]	[-2,665; 16,043]	
<b>Stadium bei der Diagnose: I-III</b>			
Baseline			
n/N (%)	113/141 (80)	112/144 (78)	-
MW (SD)	30,09 (27,805)	31,25 (33,268)	
Absolute Werte zum Studienende			
n/N (%)	6/91 (7)	4/76 (5)	-
MW (SD)	22,22 (27,217)	8,33 (16,667)	
Effekt über Studiendauer			
n	113	112	LS MD 0,83 [-4,917; 6,578] 0,7760
LS MW (SE)	2,77 (2,006)	1,94 (2,121)	
95 %-KI	[-1,182; 6,729]	[-2,236; 6,121]	Hedges' g 0,04 [-0,224; 0,299]
Veränderung zu Woche 3/4			
n/N (%)	74/137 (54)	79/138 (57)	LS MD 2,62 [-3,871; 9,108]
MW (SD)	-0,00 (25,879)	-1,69 (28,193)	
LS MW (SE)	3,86 (2,292)	1,24 (2,379)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-0,654; 8,365]	[-3,441; 5,916]	
Veränderung zu Woche 8/9			
n/N (%)	94/136 (69)	88/129 (68)	LS MD 1,84 [-4,095; 7,769]
MW (SD)	5,67 (34,440)	3,03 (32,217)	
LS MW (SE)	3,38 (2,096)	1,55 (2,169)	
95 %-KI	[-0,746; 7,511]	[-2,725; 5,816]	
Veränderung zu Woche 12			
n/N (%)	63/133 (47)	49/128 (38)	LS MD 1,29 [-4,462; 7,041]
MW (SD)	-0,00 (35,419)	1,36 (24,494)	
LS MW (SE)	3,05 (2,022)	1,76 (2,109)	
95 %-KI	[-0,935; 7,038]	[-2,394; 5,917]	
Veränderung zu Woche 15/16			
n/N (%)	64/130 (49)	35/125 (28)	LS MD 0,74 [-5,020; 6,505]
MW (SD)	5,73 (34,403)	-3,81 (28,892)	
LS MW (SE)	2,72 (2,008)	1,98 (2,129)	
95 %-KI	[-1,239; 6,679]	[-2,218; 6,173]	
Veränderung zu Woche 20/21			
n/N (%)	44/123 (36)	34/116 (29)	LS MD -0,04 [-6,144; 6,066]
MW (SD)	3,79 (31,513)	3,92 (29,319)	
LS MW (SE)	2,25 (2,092)	2,29 (2,291)	
95 %-KI	[-1,875; 6,369]	[-2,223; 6,795]	
Veränderung zu Woche 24			
n/N (%)	35/121 (29)	27/109 (25)	LS MD -0,59 [-7,131; 5,960]
MW (SD)	3,81 (38,579)	3,70 (28,244)	
LS MW (SE)	1,92 (2,218)	2,50 (2,482)	
95 %-KI	[-2,450; 6,281]	[-2,380; 7,383]	
Veränderung zu Woche 36			
n/N (%)	53/105 (50)	36/92 (39)	
MW (SD)	-1,26 (34,568)	6,48 (31,692)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	0,78 (2,940)	3,24 (3,447)	LS MD -2,46 [-11,359; 6,436]
95 %-KI	[-4,995; 6,555]	[-3,527; 10,010]	
Veränderung zu Woche 48			
n/N (%)	5/91 (5)	4/76 (5)	LS MD -4,34 [-16,261; 7,587]
MW (SD)	13,33 (18,257)	0,00 (27,217)	
LS MW (SE)	-0,36 (3,908)	3,98 (4,649)	
95 %-KI	[-8,027; 7,316]	[-5,144; 13,107]	
<b>Stadium bei der Diagnose: IV</b>			
Baseline			
n/N (%)	58/72 (81)	44/60 (73)	-
MW (SD)	32,76 (30,263)	31,82 (26,855)	
Absolute Werte zum Studienende			
n/N (%)	4/46 (9)	2/33 (6)	-
MW (SD)	41,67 (50,000)	33,33 (0,000)	
Effekt über Studiendauer			
n	58	44	LS MD -5,96 [-13,949; 2,033] 0,1422
LS MW (SE)	-3,64 (2,578)	2,32 (3,089)	
95 %-KI	[-8,763; 1,481]	[-3,810; 8,444]	Hedges' g -0,30 [-0,690; 0,098]
Veränderung zu Woche 3/4			
n/N (%)	38/71 (54)	28/59 (47)	LS MD -6,86 [-15,911; 2,183]
MW (SD)	-11,40 (26,024)	2,38 (22,090)	
LS MW (SE)	-6,06 (2,936)	0,80 (3,514)	
95 %-KI	[-11,862; -0,262]	[-6,134; 7,739]	
Veränderung zu Woche 8/9			
n/N (%)	45/69 (65)	35/56 (62)	LS MD -6,46 [-14,594; 1,682]
MW (SD)	-4,44 (30,650)	-0,00 (24,254)	
LS MW (SE)	-4,97 (2,683)	1,49 (3,109)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-10,288; 0,347]	[-4,675; 7,645]	
Veränderung zu Woche 12			
n/N (%)	29/67 (43)	22/52 (42)	LS MD -6,17 [-14,085; 1,746]
MW (SD)	3,45 (25,735)	4,55 (33,007)	
LS MW (SE)	-4,21 (2,593)	1,96 (3,029)	
95 %-KI	[-9,355; 0,942]	[-4,047; 7,973]	
Veränderung zu Woche 15/16			
n/N (%)	29/64 (45)	17/50 (34)	LS MD -5,88 [-13,950; 2,182]
MW (SD)	-1,15 (30,188)	-3,92 (28,583)	
LS MW (SE)	-3,44 (2,584)	2,44 (3,133)	
95 %-KI	[-8,575; 1,690]	[-3,772; 8,654]	
Veränderung zu Woche 20/21			
n/N (%)	18/62 (29)	15/46 (33)	LS MD -5,47 [-14,358; 3,408]
MW (SD)	-11,11 (22,866)	8,89 (32,038)	
LS MW (SE)	-2,35 (2,710)	3,12 (3,566)	
95 %-KI	[-7,725; 3,023]	[-3,922; 10,170]	
Veränderung zu Woche 24			
n/N (%)	18/59 (31)	10/44 (23)	LS MD -5,19 [-14,987; 4,609]
MW (SD)	7,41 (26,948)	0,00 (15,713)	
LS MW (SE)	-1,59 (2,887)	3,60 (4,016)	
95 %-KI	[-7,299; 4,125]	[-4,318; 11,521]	
Veränderung zu Woche 36			
n/N (%)	27/52 (52)	10/41 (24)	LS MD -4,21 [-18,400; 9,984]
MW (SD)	-1,23 (26,924)	0,00 (0,000)	
LS MW (SE)	1,03 (3,867)	5,24 (6,040)	
95 %-KI	[-6,583; 8,647]	[-6,642; 17,123]	
Veränderung zu Woche 48			
n/N (%)	3/46 (7)	0/33 (0)	
MW (SD)	0,00 (0,000)	NA (NA)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	3,65 (5,156)	6,88 (8,380)	LS MD -3,23 [-22,704; 16,249]
95 %-KI	[-6,491; 13,794]	[-9,604; 23,362]	
<b>BRCA Status: Positiv</b>			
Baseline			
n/N (%)	25/27 (93)	23/35 (66)	-
MW (SD)	32,00 (29,627)	36,23 (33,201)	
Absolute Werte zum Studienende			
n/N (%)	1/19 (5)	0/15 (0)	-
MW (SD)	66,67 (NA)	NA (NA)	
Effekt über Studiendauer			
n	25	23	LS MD 3,47 [-9,037; 15,982] 0,5785  Hedges' g 0,16 [-0,407; 0,727]
LS MW (SE)	4,14 (4,111)	0,67 (4,636)	
95 %-KI	[-4,172; 12,459]	[-8,656; 9,998]	
Veränderung zu Woche 3/4			
n/N (%)	15/27 (56)	18/35 (51)	LS MD 7,01 [-7,294; 21,306]
MW (SD)	-2,22 (34,427)	0,00 (22,866)	
LS MW (SE)	7,38 (4,929)	0,37 (5,230)	
95 %-KI	[-2,439; 17,191]	[-10,032; 10,773]	
Veränderung zu Woche 8/9			
n/N (%)	21/26 (81)	20/30 (67)	LS MD 5,30 [-7,323; 17,919]
MW (SD)	9,52 (28,172)	0,00 (28,613)	
LS MW (SE)	5,81 (4,365)	0,52 (4,521)	
95 %-KI	[-2,950; 14,578]	[-8,571; 9,603]	
Veränderung zu Woche 12			
n/N (%)	15/26 (58)	11/30 (37)	LS MD 4,10 [-8,237; 16,443]
MW (SD)	11,11 (27,217)	0,00 (44,721)	
LS MW (SE)	4,72 (4,152)	0,62 (4,488)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,664; 13,105]	[-8,429; 9,663]	
Veränderung zu Woche 15/16			
n/N (%)	12/26 (46)	8/29 (28)	LS MD 2,91 [-9,932; 15,748]
MW (SD)	2,78 (30,011)	-20,83 (39,591)	
LS MW (SE)	3,63 (4,118)	0,72 (4,856)	
95 %-KI	[-4,706; 11,960]	[-9,022; 10,460]	
Veränderung zu Woche 20/21			
n/N (%)	10/25 (40)	4/25 (16)	LS MD 1,20 [-13,547; 15,948]
MW (SD)	3,33 (29,187)	0,00 (0,000)	
LS MW (SE)	2,06 (4,383)	0,86 (5,913)	
95 %-KI	[-6,759; 10,889]	[-10,894; 12,623]	
Veränderung zu Woche 24			
n/N (%)	8/25 (32)	4/24 (17)	LS MD 0,01 [-16,711; 16,722]
MW (SD)	-4,17 (27,817)	0,00 (0,000)	
LS MW (SE)	0,97 (4,760)	0,97 (6,889)	
95 %-KI	[-8,553; 10,496]	[-12,687; 14,619]	
Veränderung zu Woche 36			
n/N (%)	10/21 (48)	5/20 (25)	LS MD -4,09 [-29,617; 21,432]
MW (SD)	-3,33 (24,595)	6,67 (27,889)	
LS MW (SE)	-2,78 (6,788)	1,31 (10,894)	
95 %-KI	[-16,212; 10,656]	[-20,207; 22,837]	
Veränderung zu Woche 48			
n/N (%)	1/19 (5)	0/15 (0)	LS MD -8,19 [-43,826; 27,446]
MW (SD)	0,00 (NA)	NA (NA)	
LS MW (SE)	-6,53 (9,355)	1,66 (15,290)	
95 %-KI	[-25,008; 11,954]	[-28,540; 31,866]	
<b>BRCA Status: Negativ/Unbekannt</b>			
Baseline			
n/N (%)	151/191 (79)	135/172 (78)	-

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	30,68 (28,159)	30,62 (31,028)	
Absolute Werte zum Studienende			
n/N (%)	9/121 (7)	6/95 (6)	-
MW (SD)	25,93 (36,430)	16,67 (18,257)	
Effekt über Studiendauer			
n	151	135	LS MD -1,49 [-6,487; 3,503] 0,5570
LS MW (SE)	0,48 (1,704)	1,98 (1,882)	
95 %-KI	[-2,871; 3,840]	[-1,727; 5,681]	Hedges' g -0,07 [-0,302; 0,163]
Veränderung zu Woche 3/4			
n/N (%)	102/186 (55)	91/165 (55)	LS MD -1,18 [-6,795; 4,440]
MW (SD)	-3,92 (24,951)	-1,10 (27,420)	
LS MW (SE)	-0,17 (1,927)	1,01 (2,114)	
95 %-KI	[-3,960; 3,616]	[-3,148; 5,161]	
Veränderung zu Woche 8/9			
n/N (%)	123/184 (67)	104/158 (66)	LS MD -1,31 [-6,459; 3,830]
MW (SD)	1,63 (34,104)	2,56 (30,349)	
LS MW (SE)	0,11 (1,772)	1,43 (1,926)	
95 %-KI	[-3,371; 3,601]	[-2,360; 5,219]	
Veränderung zu Woche 12			
n/N (%)	82/179 (46)	61/153 (40)	LS MD -1,41 [-6,405; 3,583]
MW (SD)	-0,00 (33,538)	2,19 (23,467)	
LS MW (SE)	0,32 (1,715)	1,73 (1,872)	
95 %-KI	[-3,061; 3,691]	[-1,959; 5,411]	
Veränderung zu Woche 15/16			
n/N (%)	84/173 (49)	46/149 (31)	LS MD -1,51 [-6,515; 3,501]
MW (SD)	3,97 (33,295)	-0,00 (27,217)	
LS MW (SE)	0,52 (1,706)	2,02 (1,889)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-2,844; 3,875]	[-1,696; 5,741]	
Veränderung zu Woche 20/21			
n/N (%)	55/165 (33)	46/140 (33)	LS MD -1,64 [-6,953; 3,665]
MW (SD)	-1,21 (29,372)	5,07 (31,401)	
LS MW (SE)	0,80 (1,777)	2,45 (2,031)	
95 %-KI	[-2,696; 4,300]	[-1,549; 6,441]	
Veränderung zu Woche 24			
n/N (%)	47/159 (30)	34/131 (26)	LS MD -1,74 [-7,431; 3,951]
MW (SD)	6,38 (35,193)	1,96 (27,144)	
LS MW (SE)	1,00 (1,881)	2,74 (2,200)	
95 %-KI	[-2,697; 4,702]	[-1,582; 7,067]	
Veränderung zu Woche 36			
n/N (%)	71/139 (51)	42/114 (37)	LS MD -2,07 [-9,790; 5,652]
MW (SD)	-0,94 (32,840)	3,97 (28,705)	
LS MW (SE)	1,69 (2,473)	3,76 (3,055)	
95 %-KI	[-3,165; 6,545]	[-2,237; 9,755]	
Veränderung zu Woche 48			
n/N (%)	7/121 (6)	4/95 (4)	LS MD -2,40 [-12,728; 7,931]
MW (SD)	9,52 (16,265)	0,00 (27,217)	
LS MW (SE)	2,38 (3,267)	4,78 (4,120)	
95 %-KI	[-4,034; 8,788]	[-3,310; 12,860]	
<b>Baseline ECOG PS: 0</b>			
Baseline			
n/N (%)	101/128 (79)	96/113 (85)	-
MW (SD)	30,03 (29,629)	26,39 (28,167)	
Absolute Werte zum Studienende			
n/N (%)	7/87 (8)	3/72 (4)	-
MW (SD)	33,33 (38,490)	11,11 (19,245)	
Effekt über Studiendauer			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n	101	96	LS MD -1,31 [-7,175; 4,546] 0,6587  Hedges' g -0,06 [-0,342; 0,216]
LS MW (SE)	2,84 (2,027)	4,16 (2,164)	
95 %-KI	[-1,157; 6,845]	[-0,109; 8,425]	
Veränderung zu Woche 3/4			
n/N (%)	68/127 (54)	63/111 (57)	LS MD -2,03 [-8,700; 4,646]
MW (SD)	0,49 (26,071)	2,12 (23,089)	
LS MW (SE)	3,17 (2,317)	5,19 (2,474)	
95 %-KI	[-1,393; 7,726]	[0,327; 10,060]	
Veränderung zu Woche 8/9			
n/N (%)	84/126 (67)	75/108 (69)	LS MD -1,72 [-7,786; 4,348]
MW (SD)	3,57 (32,321)	8,00 (23,786)	
LS MW (SE)	3,03 (2,119)	4,75 (2,229)	
95 %-KI	[-1,150; 7,205]	[0,355; 9,138]	
Veränderung zu Woche 12			
n/N (%)	53/122 (43)	46/108 (43)	LS MD -1,50 [-7,370; 4,362]
MW (SD)	1,89 (34,847)	3,62 (30,003)	
LS MW (SE)	2,93 (2,044)	4,43 (2,154)	
95 %-KI	[-1,103; 6,963]	[0,185; 8,682]	
Veränderung zu Woche 15/16			
n/N (%)	56/120 (47)	34/105 (32)	LS MD -1,29 [-7,160; 4,584]
MW (SD)	5,36 (32,272)	2,94 (26,423)	
LS MW (SE)	2,83 (2,029)	4,12 (2,171)	
95 %-KI	[-1,171; 6,836]	[-0,160; 8,401]	
Veränderung zu Woche 20/21			
n/N (%)	40/117 (34)	31/101 (31)	LS MD -0,98 [-7,214; 5,254]
MW (SD)	2,50 (29,610)	8,60 (27,173)	
LS MW (SE)	2,69 (2,111)	3,67 (2,345)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-1,469; 6,855]	[-0,945; 8,292]	
Veränderung zu Woche 24			
n/N (%)	28/112 (25)	22/96 (23)	LS MD -0,76 [-7,468; 5,939]
MW (SD)	-1,19 (40,043)	6,06 (19,616)	
LS MW (SE)	2,60 (2,235)	3,36 (2,556)	
95 %-KI	[-1,806; 6,997]	[-1,668; 8,388]	
Veränderung zu Woche 36			
n/N (%)	51/99 (52)	34/87 (39)	LS MD -0,03 [-9,231; 9,179]
MW (SD)	-1,31 (31,945)	2,94 (28,859)	
LS MW (SE)	2,26 (2,954)	2,29 (3,616)	
95 %-KI	[-3,542; 8,065]	[-4,814; 9,389]	
Veränderung zu Woche 48			
n/N (%)	5/87 (6)	2/72 (3)	LS MD 0,71 [-11,696; 13,121]
MW (SD)	6,67 (14,907)	-16,67 (23,570)	
LS MW (SE)	1,93 (3,921)	1,21 (4,926)	
95 %-KI	[-5,772; 9,626]	[-8,459; 10,887]	
<b>Baseline ECOG PS: 1</b>			
Baseline			
n/N (%)	75/90 (83)	61/91 (67)	-
MW (SD)	32,00 (26,531)	39,89 (34,329)	
Absolute Werte zum Studienende			
n/N (%)	3/53 (6)	3/37 (8)	-
MW (SD)	22,22 (38,490)	22,22 (19,245)	
Effekt über Studiendauer			
n	75	61	LS MD -1,06 [-8,761; 6,650] 0,7868
LS MW (SE)	-2,06 (2,512)	-1,00 (2,984)	
95 %-KI	[-7,033; 2,913]	[-6,906; 4,897]	Hedges' g -0,05 [-0,385; 0,291]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	49/86 (57)	45/87 (52)	LS MD 2,49 [-6,021; 10,997]
MW (SD)	-9,52 (25,459)	-6,67 (28,955)	
LS MW (SE)	-2,81 (2,836)	-5,30 (3,261)	
95 %-KI	[-8,401; 2,786]	[-11,726; 1,135]	
Veränderung zu Woche 8/9			
n/N (%)	60/84 (71)	48/78 (62)	LS MD 0,87 [-6,965; 8,696]
MW (SD)	1,67 (34,947)	-6,94 (36,358)	
LS MW (SE)	-2,47 (2,599)	-3,33 (2,995)	
95 %-KI	[-7,603; 2,672]	[-9,251; 2,590]	
Veränderung zu Woche 12			
n/N (%)	44/83 (53)	25/74 (34)	LS MD -0,27 [-7,933; 7,392]
MW (SD)	1,52 (30,461)	-1,33 (22,526)	
LS MW (SE)	-2,23 (2,520)	-1,96 (2,947)	
95 %-KI	[-7,213; 2,762]	[-7,784; 3,874]	
Veränderung zu Woche 15/16			
n/N (%)	40/79 (51)	20/72 (28)	LS MD -1,41 [-9,173; 6,361]
MW (SD)	1,67 (33,716)	-13,33 (33,157)	
LS MW (SE)	-1,99 (2,521)	-0,58 (3,019)	
95 %-KI	[-6,977; 3,005]	[-6,548; 5,390]	
Veränderung zu Woche 20/21			
n/N (%)	25/73 (34)	18/63 (29)	LS MD -3,03 [-11,392; 5,334]
MW (SD)	-5,33 (28,350)	-1,85 (35,188)	
LS MW (SE)	-1,64 (2,660)	1,39 (3,313)	
95 %-KI	[-6,902; 3,615]	[-5,152; 7,923]	
Veränderung zu Woche 24			
n/N (%)	27/72 (38)	15/58 (26)	LS MD -4,16 [-13,212; 4,882]
MW (SD)	11,11 (26,149)	-6,67 (31,371)	
LS MW (SE)	-1,40 (2,843)	2,76 (3,627)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-7,013; 4,206]	[-4,385; 9,908]	
Veränderung zu Woche 36			
n/N (%)	30/61 (49)	13/46 (28)	LS MD -8,06 [-20,524; 4,406]
MW (SD)	-1,11 (32,144)	7,69 (27,735)	
LS MW (SE)	-0,58 (3,826)	7,48 (5,108)	
95 %-KI	[-8,107; 6,943]	[-2,564; 17,519]	
Veränderung zu Woche 48			
n/N (%)	3/53 (6)	2/37 (5)	LS MD -11,95 [-28,676; 4,770]
MW (SD)	11,11 (19,245)	16,67 (23,570)	
LS MW (SE)	0,24 (5,102)	12,19 (6,892)	
95 %-KI	[-9,786; 10,266]	[-1,349; 25,736]	
<b>Anzahl vorheriger Therapielinien: 1</b>			
Baseline			
n/N (%)	24/31 (77)	23/29 (79)	-
MW (SD)	33,33 (32,601)	23,19 (23,430)	
Absolute Werte zum Studienende			
n/N (%)	1/22 (5)	0/14 (0)	-
MW (SD)	0,00 (NA)	NA (NA)	
Effekt über Studiendauer			
n	24	23	LS MD -3,01 [-13,894; 7,880] 0,5801  Hedges' g -0,16 [-0,733; 0,412]
LS MW (SE)	2,82 (3,701)	5,83 (3,901)	
95 %-KI	[-4,667; 10,313]	[-2,030; 13,690]	
Veränderung zu Woche 3/4			
n/N (%)	16/31 (52)	15/29 (52)	LS MD -4,61 [-17,468; 8,256]
MW (SD)	-8,33 (19,245)	2,22 (19,787)	
LS MW (SE)	-1,93 (4,437)	2,68 (4,672)	
95 %-KI	[-10,767; 6,911]	[-6,608; 11,965]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	20/31 (65)	18/26 (69)	LS MD -3,93 [-15,400; 7,533]
MW (SD)	6,67 (31,715)	9,26 (25,063)	
LS MW (SE)	0,07 (3,979)	4,00 (4,073)	
95 %-KI	[-7,918; 8,059]	[-4,153; 12,162]	
Veränderung zu Woche 12			
n/N (%)	14/31 (45)	12/24 (50)	LS MD -3,46 [-14,423; 7,498]
MW (SD)	-21,43 (38,358)	8,33 (28,868)	
LS MW (SE)	1,47 (3,780)	4,93 (3,879)	
95 %-KI	[-6,159; 9,099]	[-2,876; 12,741]	
Veränderung zu Woche 15/16			
n/N (%)	15/31 (48)	11/22 (50)	LS MD -2,99 [-13,883; 7,901]
MW (SD)	0,00 (28,172)	3,03 (31,463)	
LS MW (SE)	2,87 (3,701)	5,86 (3,906)	
95 %-KI	[-4,619; 10,358]	[-2,008; 13,730]	
Veränderung zu Woche 20/21			
n/N (%)	11/30 (37)	9/22 (41)	LS MD -2,32 [-13,869; 9,232]
MW (SD)	9,09 (26,208)	7,41 (22,222)	
LS MW (SE)	4,87 (3,807)	7,19 (4,312)	
95 %-KI	[-2,811; 12,547]	[-1,450; 15,823]	
Veränderung zu Woche 24			
n/N (%)	9/30 (30)	11/20 (55)	LS MD -1,85 [-14,334; 10,639]
MW (SD)	11,11 (16,667)	3,03 (17,979)	
LS MW (SE)	6,27 (4,025)	8,11 (4,802)	
95 %-KI	[-1,808; 14,343]	[-1,454; 17,683]	
Veränderung zu Woche 36			
n/N (%)	15/26 (58)	6/18 (33)	LS MD -0,23 [-17,896; 17,431]
MW (SD)	11,11 (29,991)	11,11 (17,213)	
LS MW (SE)	11,06 (5,411)	11,30 (7,188)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[0,355; 21,774]	[-2,913; 25,507]	
Veränderung zu Woche 48			
n/N (%)	0/22 (0)	0/14 (0)	LS MD 1,38 [-22,934; 25,698]
MW (SD)	NA (NA)	NA (NA)	
LS MW (SE)	15,86 (7,315)	14,48 (10,044)	
95 %-KI	[1,423; 30,300]	[-5,348; 34,306]	
<b>Anzahl vorheriger Therapielinien: 2</b>			
Baseline			
n/N (%)	75/89 (84)	65/83 (78)	-
MW (SD)	30,67 (24,968)	32,31 (30,028)	
Absolute Werte zum Studienende			
n/N (%)	4/59 (7)	2/50 (4)	-
MW (SD)	41,67 (31,914)	16,67 (23,570)	
Effekt über Studiendauer			
n	75	65	LS MD -1,61 [-8,398; 5,169] 0,6386  Hedges' g -0,08 [-0,412; 0,253]
LS MW (SE)	-0,36 (2,252)	1,25 (2,587)	
95 %-KI	[-4,819; 4,098]	[-3,860; 6,368]	
Veränderung zu Woche 3/4			
n/N (%)	52/86 (60)	46/80 (57)	LS MD 1,34 [-6,311; 8,988]
MW (SD)	-4,49 (26,428)	-3,62 (23,547)	
LS MW (SE)	0,25 (2,575)	-1,09 (2,907)	
95 %-KI	[-4,829; 5,324]	[-6,819; 4,638]	
Veränderung zu Woche 8/9			
n/N (%)	63/85 (74)	51/77 (66)	LS MD 0,01 [-6,936; 6,960]
MW (SD)	0,53 (30,815)	-0,65 (27,881)	
LS MW (SE)	-0,03 (2,348)	-0,04 (2,620)	
95 %-KI	[-4,666; 4,616]	[-5,214; 5,138]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	39/83 (47)	31/75 (41)	LS MD -0,92 [-7,669; 5,837]
MW (SD)	10,26 (29,769)	5,38 (22,928)	
LS MW (SE)	-0,22 (2,267)	0,70 (2,555)	
95 %-KI	[-4,702; 4,269]	[-4,352; 5,751]	
Veränderung zu Woche 15/16			
n/N (%)	41/80 (51)	20/74 (27)	LS MD -1,84 [-8,672; 4,983]
MW (SD)	5,69 (33,252)	1,67 (22,878)	
LS MW (SE)	-0,41 (2,257)	1,44 (2,613)	
95 %-KI	[-4,875; 4,059]	[-3,727; 6,600]	
Veränderung zu Woche 20/21			
n/N (%)	31/78 (40)	21/68 (31)	LS MD -3,17 [-10,548; 4,207]
MW (SD)	1,08 (27,867)	7,94 (27,698)	
LS MW (SE)	-0,68 (2,367)	2,49 (2,890)	
95 %-KI	[-5,360; 3,998]	[-3,210; 8,190]	
Veränderung zu Woche 24			
n/N (%)	27/74 (36)	13/65 (20)	LS MD -4,10 [-12,125; 3,927]
MW (SD)	-1,23 (26,924)	0,00 (13,608)	
LS MW (SE)	-0,87 (2,522)	3,23 (3,193)	
95 %-KI	[-5,850; 4,107]	[-3,061; 9,515]	
Veränderung zu Woche 36			
n/N (%)	33/65 (51)	19/58 (33)	LS MD -7,28 [-18,558; 3,994]
MW (SD)	-5,05 (31,315)	5,26 (22,942)	
LS MW (SE)	-1,53 (3,389)	5,75 (4,618)	
95 %-KI	[-8,192; 5,138]	[-3,321; 14,830]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	1/50 (2)	LS MD -10,46 [-25,765; 4,835]
MW (SD)	16,67 (19,245)	0,00 (NA)	
LS MW (SE)	-2,18 (4,529)	8,28 (6,319)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-11,081; 6,716]	[-4,133; 20,697]	
<b>Anzahl vorheriger Therapielinien: 3</b>			
Baseline			
n/N (%)	77/98 (79)	70/95 (74)	-
MW (SD)	30,30 (30,195)	33,33 (34,520)	
Absolute Werte zum Studienende			
n/N (%)	5/59 (8)	4/46 (9)	-
MW (SD)	26,67 (43,461)	16,67 (19,245)	
Effekt über Studiendauer			
n	77	70	LS MD 0,23 [-7,540; 8,006] 0,9528  Hedges' g 0,01 [-0,314; 0,333]
LS MW (SE)	1,60 (2,669)	1,37 (2,888)	
95 %-KI	[-3,679; 6,879]	[-4,340; 7,075]	
Veränderung zu Woche 3/4			
n/N (%)	49/96 (51)	48/91 (53)	LS MD 0,10 [-8,515; 8,710]
MW (SD)	-1,36 (28,020)	0,69 (31,125)	
LS MW (SE)	2,09 (2,986)	1,99 (3,191)	
95 %-KI	[-3,800; 7,975]	[-4,300; 8,280]	
Veränderung zu Woche 8/9			
n/N (%)	61/94 (65)	55/85 (65)	LS MD 0,16 [-7,800; 8,116]
MW (SD)	3,83 (36,565)	2,42 (33,243)	
LS MW (SE)	1,87 (2,758)	1,71 (2,940)	
95 %-KI	[-3,577; 7,320]	[-4,092; 7,519]	
Veränderung zu Woche 12			
n/N (%)	44/91 (48)	29/84 (35)	LS MD 0,20 [-7,562; 7,962]
MW (SD)	1,52 (30,461)	-4,60 (30,504)	
LS MW (SE)	1,72 (2,679)	1,52 (2,872)	
95 %-KI	[-3,578; 7,018]	[-4,156; 7,197]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	40/88 (45)	23/82 (28)	LS MD 0,24 [-7,559; 8,043]
MW (SD)	3,33 (34,427)	-10,14 (33,986)	
LS MW (SE)	1,57 (2,674)	1,33 (2,902)	
95 %-KI	[-3,720; 6,858]	[-4,408; 7,062]	
Veränderung zu Woche 20/21			
n/N (%)	23/82 (28)	20/75 (27)	LS MD 0,30 [-7,951; 8,555]
MW (SD)	-7,25 (31,713)	0,00 (35,869)	
LS MW (SE)	1,35 (2,795)	1,05 (3,107)	
95 %-KI	[-4,168; 6,874]	[-5,080; 7,181]	
Veränderung zu Woche 24			
n/N (%)	19/80 (24)	14/70 (20)	LS MD 0,34 [-8,471; 9,159]
MW (SD)	10,53 (47,209)	2,38 (38,038)	
LS MW (SE)	1,20 (2,960)	0,86 (3,347)	
95 %-KI	[-4,638; 7,041]	[-5,738; 7,453]	
Veränderung zu Woche 36			
n/N (%)	33/69 (48)	22/58 (38)	LS MD 0,49 [-11,306; 12,283]
MW (SD)	-3,03 (32,664)	1,52 (34,850)	
LS MW (SE)	0,68 (3,882)	0,19 (4,562)	
95 %-KI	[-6,952; 8,317]	[-8,774; 9,163]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	3/46 (7)	LS MD 0,63 [-15,015; 16,280]
MW (SD)	0,00 (0,000)	0,00 (33,333)	
LS MW (SE)	0,16 (5,110)	-0,47 (6,089)	
95 %-KI	[-9,877; 10,206]	[-12,434; 11,497]	
<b>Vorherige Verabreichung von Bevacizumab: Ja</b>			
Baseline			
n/N (%)	105/134 (78)	100/132 (76)	-
MW (SD)	29,52 (26,277)	31,00 (32,911)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	3/79 (4)	3/62 (5)	-
MW (SD)	44,44 (19,245)	11,11 (19,245)	
Effekt über Studiendauer			
n	105	100	LS MD -0,21 [-6,256; 5,827] 0,9442  Hedges' g -0,01 [-0,284; 0,264]
LS MW (SE)	2,82 (2,075)	3,04 (2,257)	
95 %-KI	[-1,274; 6,916]	[-1,414; 7,486]	
Veränderung zu Woche 3/4			
n/N (%)	67/130 (52)	69/127 (54)	LS MD 1,39 [-5,397; 8,182]
MW (SD)	-1,99 (28,944)	-0,48 (27,112)	
LS MW (SE)	3,18 (2,364)	1,79 (2,520)	
95 %-KI	[-1,467; 7,836]	[-3,166; 6,751]	
Veränderung zu Woche 8/9			
n/N (%)	85/130 (65)	75/119 (63)	LS MD 0,64 [-5,526; 6,810]
MW (SD)	3,14 (31,127)	3,11 (32,035)	
LS MW (SE)	3,02 (2,157)	2,37 (2,274)	
95 %-KI	[-1,236; 7,266]	[-2,107; 6,853]	
Veränderung zu Woche 12			
n/N (%)	55/126 (44)	38/114 (33)	LS MD 0,12 [-5,894; 6,128]
MW (SD)	10,91 (30,802)	-0,88 (27,385)	
LS MW (SE)	2,90 (2,085)	2,78 (2,228)	
95 %-KI	[-1,218; 7,010]	[-1,613; 7,172]	
Veränderung zu Woche 15/16			
n/N (%)	58/122 (48)	32/112 (29)	LS MD -0,41 [-6,514; 5,697]
MW (SD)	5,75 (31,922)	-3,13 (32,083)	
LS MW (SE)	2,78 (2,082)	3,19 (2,295)	
95 %-KI	[-1,331; 6,886]	[-1,337; 7,709]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	37/114 (32)	28/103 (27)	LS MD -1,16 [-7,809; 5,491]
MW (SD)	1,80 (28,269)	1,19 (34,525)	
LS MW (SE)	2,61 (2,195)	3,77 (2,567)	
95 %-KI	[-1,720; 6,934]	[-1,285; 8,818]	
Veränderung zu Woche 24			
n/N (%)	30/109 (28)	17/95 (18)	LS MD -1,68 [-8,953; 5,584]
MW (SD)	11,11 (23,705)	1,96 (34,300)	
LS MW (SE)	2,49 (2,347)	4,17 (2,852)	
95 %-KI	[-2,133; 7,110]	[-1,434; 9,780]	
Veränderung zu Woche 36			
n/N (%)	44/93 (47)	22/79 (28)	LS MD -3,49 [-13,775; 6,804]
MW (SD)	-2,27 (30,835)	9,09 (32,824)	
LS MW (SE)	2,08 (3,174)	5,57 (4,161)	
95 %-KI	[-4,155; 8,317]	[-2,604; 13,737]	
Veränderung zu Woche 48			
n/N (%)	3/79 (4)	2/62 (3)	LS MD -5,29 [-19,265; 8,692]
MW (SD)	22,22 (19,245)	0,00 (0,000)	
LS MW (SE)	1,67 (4,249)	6,96 (5,701)	
95 %-KI	[-6,670; 10,016]	[-4,234; 18,153]	
<b>Vorherige Verabreichung von Bevacizumab: Nein</b>			
Baseline			
n/N (%)	71/84 (85)	58/75 (77)	-
MW (SD)	32,86 (31,113)	32,18 (28,590)	
Absolute Werte zum Studienende			
n/N (%)	7/61 (11)	3/48 (6)	-
MW (SD)	23,81 (41,786)	22,22 (19,245)	
Effekt über Studiendauer			
n	71	58	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-1,62 (2,441)	0,45 (2,768)	LS MD -2,07 [-9,377; 5,230] 0,5752  Hedges' g -0,10 [-0,446; 0,248]
95 %-KI	[-6,457; 3,213]	[-5,026; 5,928]	
Veränderung zu Woche 3/4			
n/N (%)	50/83 (60)	40/73 (55)	LS MD -2,30 [-10,593; 5,985]
MW (SD)	-6,00 (22,018)	-1,67 (26,094)	
LS MW (SE)	-2,45 (2,783)	-0,14 (3,153)	
95 %-KI	[-7,935; 3,043]	[-6,359; 6,074]	
Veränderung zu Woche 8/9			
n/N (%)	59/80 (74)	49/69 (71)	LS MD -2,21 [-9,801; 5,384]
MW (SD)	2,26 (36,549)	0,68 (26,779)	
LS MW (SE)	-2,11 (2,556)	0,10 (2,871)	
95 %-KI	[-7,157; 2,946]	[-5,571; 5,777]	
Veränderung zu Woche 12			
n/N (%)	42/79 (53)	34/69 (49)	LS MD -2,14 [-9,481; 5,197]
MW (SD)	-10,32 (31,655)	4,90 (27,380)	
LS MW (SE)	-1,87 (2,466)	0,27 (2,773)	
95 %-KI	[-6,748; 3,013]	[-5,212; 5,761]	
Veränderung zu Woche 15/16			
n/N (%)	38/77 (49)	22/66 (33)	LS MD -2,08 [-9,377; 5,226]
MW (SD)	0,88 (34,211)	-3,03 (27,039)	
LS MW (SE)	-1,63 (2,441)	0,45 (2,766)	
95 %-KI	[-6,463; 3,205]	[-5,029; 5,921]	
Veränderung zu Woche 20/21			
n/N (%)	28/76 (37)	22/62 (35)	LS MD -1,98 [-9,603; 5,643]
MW (SD)	-3,57 (30,550)	9,09 (23,417)	
LS MW (SE)	-1,29 (2,521)	0,69 (2,916)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,277; 3,700]	[-5,072; 6,455]	
Veränderung zu Woche 24			
n/N (%)	25/75 (33)	21/60 (35)	LS MD -1,91 [-10,001; 6,174]
MW (SD)	-2,67 (42,947)	1,59 (16,587)	
LS MW (SE)	-1,05 (2,653)	0,86 (3,120)	
95 %-KI	[-6,291; 4,190]	[-5,293; 7,019]	
Veränderung zu Woche 36			
n/N (%)	37/67 (55)	25/55 (45)	LS MD -1,68 [-12,427; 9,057]
MW (SD)	-0,00 (33,333)	0,00 (23,570)	
LS MW (SE)	-0,23 (3,444)	1,45 (4,230)	
95 %-KI	[-7,010; 6,544]	[-6,867; 9,770]	
Veränderung zu Woche 48			
n/N (%)	5/61 (8)	2/48 (4)	LS MD -1,46 [-15,747; 12,835]
MW (SD)	0,00 (0,000)	0,00 (47,140)	
LS MW (SE)	0,58 (4,535)	2,04 (5,672)	
95 %-KI	[-8,328; 9,495]	[-9,106; 13,186]	
<b>Letztes Platin-freies Intervall: ≤ 3 Monate</b>			
Baseline			
n/N (%)	68/83 (82)	61/91 (67)	-
MW (SD)	31,37 (28,728)	36,07 (34,585)	
Absolute Werte zum Studienende			
n/N (%)	3/55 (5)	5/39 (13)	-
MW (SD)	11,11 (19,245)	13,33 (18,257)	
Effekt über Studiendauer			
n	68	61	LS MD -8,60 [-16,263; -0,933] 0,0282
LS MW (SE)	-4,42 (2,581)	4,17 (2,885)	
95 %-KI	[-9,539; 0,692]	[-1,535; 9,883]	Hedges' g -0,39 [-0,740; -0,042]



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	49/82 (60)	45/86 (52)	LS MD -7,54 [-16,201; 1,112]
MW (SD)	-2,04 (33,616)	0,74 (32,944)	
LS MW (SE)	-2,23 (2,970)	5,31 (3,233)	
95 %-KI	[-8,091; 3,623]	[-1,064; 11,684]	
Veränderung zu Woche 8/9			
n/N (%)	52/81 (64)	45/80 (56)	LS MD -8,03 [-15,875; -0,188]
MW (SD)	-2,56 (32,903)	4,44 (33,029)	
LS MW (SE)	-3,25 (2,681)	4,78 (2,924)	
95 %-KI	[-8,549; 2,056]	[-0,995; 10,564]	
Veränderung zu Woche 12			
n/N (%)	33/78 (42)	25/78 (32)	LS MD -8,37 [-16,002; -0,743]
MW (SD)	-0,00 (35,355)	4,00 (32,375)	
LS MW (SE)	-3,96 (2,587)	4,42 (2,856)	
95 %-KI	[-9,081; 1,170]	[-1,235; 10,069]	
Veränderung zu Woche 15/16			
n/N (%)	35/76 (46)	13/75 (17)	LS MD -8,71 [-16,451; -0,977]
MW (SD)	-6,67 (33,137)	-2,56 (37,172)	
LS MW (SE)	-4,66 (2,596)	4,05 (2,922)	
95 %-KI	[-9,808; 0,479]	[-1,732; 9,830]	
Veränderung zu Woche 20/21			
n/N (%)	21/72 (29)	13/67 (19)	LS MD -9,20 [-17,616; -0,785]
MW (SD)	-4,76 (30,342)	17,95 (32,247)	
LS MW (SE)	-5,68 (2,780)	3,52 (3,229)	
95 %-KI	[-11,174; -0,179]	[-2,851; 9,899]	
Veränderung zu Woche 24			
n/N (%)	16/72 (22)	12/62 (19)	LS MD -9,54 [-18,738; -0,346]
MW (SD)	-8,33 (39,441)	11,11 (21,711)	
LS MW (SE)	-6,39 (3,012)	3,16 (3,562)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-12,330; -0,441]	[-3,865; 10,178]	
Veränderung zu Woche 36			
n/N (%)	28/63 (44)	17/50 (34)	LS MD -10,71 [-23,757; 2,334]
MW (SD)	-7,14 (33,156)	5,88 (33,820)	
LS MW (SE)	-8,82 (4,212)	1,90 (5,130)	
95 %-KI	[-17,100; -0,531]	[-8,192; 11,983]	
Veränderung zu Woche 48			
n/N (%)	2/55 (4)	3/39 (8)	LS MD -11,88 [-29,642; 5,880]
MW (SD)	16,67 (23,570)	-11,11 (19,245)	
LS MW (SE)	-11,25 (5,718)	0,63 (7,002)	
95 %-KI	[-22,488; -0,004]	[-13,131; 14,401]	
<b>Letztes Platin-freies Intervall: &gt; 3 Monate</b>			
Baseline			
n/N (%)	108/135 (80)	97/116 (84)	-
MW (SD)	30,56 (28,139)	28,52 (28,863)	
Absolute Werte zum Studienende			
n/N (%)	7/85 (8)	1/71 (1)	-
MW (SD)	38,10 (40,500)	33,33 (NA)	
Effekt über Studiendauer			
n	108	97	LS MD 3,35 [-2,422; 9,118] 0,2539
LS MW (SE)	3,93 (1,972)	0,58 (2,164)	
95 %-KI	[0,041; 7,820]	[-3,684; 4,849]	Hedges' g 0,16 [-0,115; 0,434]
Veränderung zu Woche 3/4			
n/N (%)	68/131 (52)	64/114 (56)	LS MD 4,44 [-2,075; 10,960]
MW (SD)	-4,90 (19,329)	-2,08 (21,311)	
LS MW (SE)	2,48 (2,235)	-1,96 (2,446)	
95 %-KI	[-1,919; 6,879]	[-6,774; 2,849]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	92/129 (71)	79/108 (73)	LS MD 3,97 [-1,989; 9,929]
MW (SD)	5,80 (33,373)	0,84 (28,231)	
LS MW (SE)	3,11 (2,059)	-0,86 (2,218)	
95 %-KI	[-0,951; 7,164]	[-5,233; 3,507]	
Veränderung zu Woche 12			
n/N (%)	64/127 (50)	47/105 (45)	LS MD 3,64 [-2,136; 9,414]
MW (SD)	2,60 (31,597)	0,71 (24,563)	
LS MW (SE)	3,55 (1,990)	-0,09 (2,152)	
95 %-KI	[-0,380; 7,470]	[-4,335; 4,148]	
Veränderung zu Woche 15/16			
n/N (%)	61/123 (50)	41/103 (40)	LS MD 3,31 [-2,473; 9,089]
MW (SD)	9,84 (31,236)	-3,25 (27,694)	
LS MW (SE)	3,98 (1,972)	0,68 (2,171)	
95 %-KI	[0,093; 7,875]	[-3,604; 4,956]	
Veränderung zu Woche 20/21			
n/N (%)	44/118 (37)	37/98 (38)	LS MD 2,83 [-3,279; 8,949]
MW (SD)	1,52 (28,715)	0,00 (28,328)	
LS MW (SE)	4,61 (2,037)	1,78 (2,342)	
95 %-KI	[0,595; 8,625]	[-2,835; 6,386]	
Veränderung zu Woche 24			
n/N (%)	39/112 (35)	26/93 (28)	LS MD 2,50 [-4,043; 9,051]
MW (SD)	10,26 (30,735)	-2,56 (26,538)	
LS MW (SE)	5,05 (2,140)	2,55 (2,545)	
95 %-KI	[0,834; 9,264]	[-2,461; 7,551]	
Veränderung zu Woche 36			
n/N (%)	53/97 (55)	30/84 (36)	LS MD 1,37 [-7,508; 10,246]
MW (SD)	1,89 (30,950)	3,33 (25,295)	
LS MW (SE)	6,55 (2,763)	5,18 (3,566)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[1,124; 11,981]	[-1,820; 12,187]	
Veränderung zu Woche 48			
n/N (%)	6/85 (7)	1/71 (1)	LS MD 0,23 [-11,653; 12,122]
MW (SD)	5,56 (13,608)	33,33 (NA)	
LS MW (SE)	8,06 (3,623)	7,82 (4,833)	
95 %-KI	[0,943; 15,169]	[-1,666; 17,310]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Pegyliertes liposomales Doxorubicin</b>			
Baseline			
n/N (%)	61/80 (76)	57/76 (75)	-
MW (SD)	31,69 (27,505)	26,32 (27,986)	
Absolute Werte zum Studienende			
n/N (%)	3/51 (6)	3/41 (7)	-
MW (SD)	22,22 (38,490)	11,11 (19,245)	
Effekt über Studiendauer			
n	61	57	LS MD 3,10 [-4,432; 10,641] 0,4162  Hedges' g 0,15 [-0,212; 0,512]
LS MW (SE)	4,48 (2,572)	1,37 (2,790)	
95 %-KI	[-0,622; 9,581]	[-4,150; 6,900]	
Veränderung zu Woche 3/4			
n/N (%)	39/76 (51)	43/74 (58)	LS MD 3,39 [-5,236; 12,022]
MW (SD)	-3,42 (22,679)	0,00 (25,198)	
LS MW (SE)	3,92 (3,022)	0,53 (3,151)	
95 %-KI	[-2,041; 9,883]	[-5,686; 6,742]	
Veränderung zu Woche 8/9			
n/N (%)	51/76 (67)	44/66 (67)	LS MD 3,27 [-4,528; 11,064]
MW (SD)	7,19 (34,842)	3,03 (30,345)	
LS MW (SE)	4,16 (2,729)	0,90 (2,833)	
95 %-KI	[-1,234; 9,562]	[-4,707; 6,499]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	32/75 (43)	23/64 (36)	LS MD 3,18 [-4,351; 10,710]
MW (SD)	-6,25 (37,328)	1,45 (27,484)	
LS MW (SE)	4,33 (2,609)	1,15 (2,754)	
95 %-KI	[-0,837; 9,504]	[-4,300; 6,607]	
Veränderung zu Woche 15/16			
n/N (%)	34/74 (46)	19/62 (31)	LS MD 3,09 [-4,467; 10,650]
MW (SD)	7,84 (34,872)	1,75 (30,376)	
LS MW (SE)	4,50 (2,572)	1,41 (2,806)	
95 %-KI	[-0,598; 9,605]	[-4,143; 6,966]	
Veränderung zu Woche 20/21			
n/N (%)	25/72 (35)	18/59 (31)	LS MD 2,97 [-5,127; 11,059]
MW (SD)	2,67 (30,307)	11,11 (22,866)	
LS MW (SE)	4,75 (2,668)	1,78 (3,090)	
95 %-KI	[-0,539; 10,031]	[-4,325; 7,884]	
Veränderung zu Woche 24			
n/N (%)	22/69 (32)	16/54 (30)	LS MD 2,88 [-5,888; 11,644]
MW (SD)	1,52 (37,765)	2,08 (14,751)	
LS MW (SE)	4,92 (2,831)	2,04 (3,408)	
95 %-KI	[-0,681; 10,512]	[-4,682; 8,757]	
Veränderung zu Woche 36			
n/N (%)	30/60 (50)	16/48 (33)	LS MD 2,58 [-9,693; 14,847]
MW (SD)	-0,00 (35,015)	4,17 (23,960)	
LS MW (SE)	5,50 (3,805)	2,92 (4,922)	
95 %-KI	[-1,989; 12,984]	[-6,760; 12,601]	
Veränderung zu Woche 48			
n/N (%)	2/51 (4)	2/41 (5)	LS MD 2,28 [-14,407; 18,958]
MW (SD)	0,00 (0,000)	-16,67 (23,570)	
LS MW (SE)	6,08 (5,118)	3,80 (6,741)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,981; 16,141]	[-9,447; 17,055]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Paclitaxel</b>			
Baseline			
n/N (%)	76/88 (86)	69/82 (84)	-
MW (SD)	33,77 (29,056)	33,82 (33,084)	
Absolute Werte zum Studienende			
n/N (%)	1/56 (2)	1/49 (2)	-
MW (SD)	33,33 (NA)	33,33 (NA)	
Effekt über Studiendauer			
n	76	69	LS MD -3,41 [-10,817; 3,992] 0,3638  Hedges' g -0,15 [-0,477; 0,175]
LS MW (SE)	-1,69 (2,534)	1,73 (2,760)	
95 %-KI	[-6,698; 3,327]	[-3,729; 7,182]	
Veränderung zu Woche 3/4			
n/N (%)	55/87 (63)	48/81 (59)	LS MD -3,30 [-11,521; 4,920]
MW (SD)	-5,45 (26,265)	2,78 (29,841)	
LS MW (SE)	-2,28 (2,818)	1,02 (3,080)	
95 %-KI	[-7,837; 3,278]	[-5,048; 7,090]	
Veränderung zu Woche 8/9			
n/N (%)	63/86 (73)	53/79 (67)	LS MD -3,35 [-10,929; 4,226]
MW (SD)	-1,59 (33,025)	-0,00 (30,662)	
LS MW (SE)	-2,01 (2,611)	1,34 (2,815)	
95 %-KI	[-7,167; 3,149]	[-4,217; 6,902]	
Veränderung zu Woche 12			
n/N (%)	44/84 (52)	37/77 (48)	LS MD -3,39 [-10,779; 4,005]
MW (SD)	3,79 (28,042)	3,60 (30,209)	
LS MW (SE)	-1,82 (2,541)	1,57 (2,746)	
95 %-KI	[-6,846; 3,206]	[-3,860; 6,995]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	46/81 (57)	27/76 (36)	LS MD -3,42 [-10,867; 4,022]
MW (SD)	2,17 (34,714)	-6,17 (33,381)	
LS MW (SE)	-1,63 (2,541)	1,79 (2,781)	
95 %-KI	[-6,657; 3,396]	[-3,704; 7,288]	
Veränderung zu Woche 20/21			
n/N (%)	29/77 (38)	25/73 (34)	LS MD -3,47 [-11,391; 4,443]
MW (SD)	-1,15 (28,844)	2,67 (37,168)	
LS MW (SE)	-1,36 (2,659)	2,11 (3,004)	
95 %-KI	[-6,613; 3,893]	[-3,812; 8,039]	
Veränderung zu Woche 24			
n/N (%)	22/74 (30)	19/72 (26)	LS MD -3,51 [-12,002; 4,983]
MW (SD)	10,61 (29,790)	1,75 (34,199)	
LS MW (SE)	-1,17 (2,817)	2,34 (3,260)	
95 %-KI	[-6,727; 4,385]	[-4,084; 8,761]	
Veränderung zu Woche 36			
n/N (%)	36/64 (56)	23/63 (37)	LS MD -3,63 [-15,121; 7,856]
MW (SD)	-2,78 (33,214)	4,35 (25,235)	
LS MW (SE)	-0,52 (3,686)	3,11 (4,534)	
95 %-KI	[-7,770; 6,726]	[-5,799; 12,020]	
Veränderung zu Woche 48			
n/N (%)	1/56 (2)	0/49 (0)	LS MD -3,76 [-19,070; 11,560]
MW (SD)	33,33 (NA)	NA (NA)	
LS MW (SE)	0,13 (4,840)	3,88 (6,109)	
95 %-KI	[-9,383; 9,636]	[-8,118; 15,882]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Topotecan</b>			
Baseline			
n/N (%)	39/50 (78)	32/49 (65)	-
MW (SD)	23,93 (27,518)	35,42 (32,723)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	6/33 (18)	2/20 (10)	-
MW (SD)	33,33 (42,164)	16,67 (23,570)	
Effekt über Studiendauer			
n	39	32	LS MD -0,85 [-10,804; 9,101] 0,8648  Hedges' g -0,04 [-0,508; 0,427]
LS MW (SE)	1,25 (3,185)	2,10 (3,796)	
95 %-KI	[-5,123; 7,628]	[-5,469; 9,676]	
Veränderung zu Woche 3/4			
n/N (%)	23/50 (46)	18/45 (40)	LS MD 2,40 [-8,905; 13,709]
MW (SD)	0,00 (31,782)	-12,96 (16,721)	
LS MW (SE)	2,97 (3,667)	0,57 (4,333)	
95 %-KI	[-4,300; 10,245]	[-8,019; 9,159]	
Veränderung zu Woche 8/9			
n/N (%)	30/48 (62)	27/43 (63)	LS MD 1,01 [-9,254; 11,284]
MW (SD)	4,44 (31,237)	4,94 (28,799)	
LS MW (SE)	2,24 (3,327)	1,22 (3,905)	
95 %-KI	[-4,392; 8,869]	[-6,549; 8,997]	
Veränderung zu Woche 12			
n/N (%)	21/46 (46)	12/42 (29)	LS MD 0,04 [-9,894; 9,983]
MW (SD)	9,52 (33,571)	-2,78 (17,164)	
LS MW (SE)	1,73 (3,203)	1,68 (3,776)	
95 %-KI	[-4,679; 8,130]	[-5,850; 9,212]	
Veränderung zu Woche 15/16			
n/N (%)	16/44 (36)	8/40 (20)	LS MD -0,93 [-10,894; 9,041]
MW (SD)	0,00 (21,082)	-4,17 (11,785)	
LS MW (SE)	1,21 (3,188)	2,14 (3,804)	
95 %-KI	[-5,169; 7,593]	[-5,449; 9,727]	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	11/41 (27)	7/33 (21)	LS MD -2,31 [-12,931; 8,304]
MW (SD)	-6,06 (29,129)	-4,76 (12,599)	
LS MW (SE)	0,48 (3,355)	2,79 (4,109)	
95 %-KI	[-6,219; 7,177]	[-5,378; 10,963]	
Veränderung zu Woche 24			
n/N (%)	11/41 (27)	3/29 (10)	LS MD -3,28 [-14,731; 8,163]
MW (SD)	0,00 (36,515)	0,00 (0,000)	
LS MW (SE)	-0,03 (3,588)	3,25 (4,476)	
95 %-KI	[-7,176; 7,107]	[-5,627; 12,127]	
Veränderung zu Woche 36			
n/N (%)	15/36 (42)	8/23 (35)	LS MD -6,61 [-22,450; 9,224]
MW (SD)	0,00 (21,822)	4,17 (45,207)	
LS MW (SE)	-1,79 (4,879)	4,82 (6,329)	
95 %-KI	[-11,432; 7,844]	[-7,672; 17,309]	
Veränderung zu Woche 48			
n/N (%)	5/33 (15)	2/20 (10)	LS MD -9,94 [-31,375; 11,492]
MW (SD)	6,67 (14,907)	16,67 (23,570)	
LS MW (SE)	-3,55 (6,562)	6,39 (8,621)	
95 %-KI	[-16,493; 9,385]	[-10,609; 23,384]	
<p><i>Analysepopulation: ITT</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023</i></p> <p><i>Modell: Veränderung zu Baseline ~ Behandlung + Baseline-Wert * Zeit in Wochen + Behandlung * Zeit in Wochen + zufällige Effekte durch die Patientin</i></p> <p><i>Die Berechnung des LS-MWs erfolgt durch ein MMRM mit dem oben angegebenen Modell. Basierend hierauf werden KI und p-Wert ermittelt. Hedges' g basiert ebenfalls auf den LS-MW und ist somit auf das Modell angepasst.</i></p> <p><i>Es werden ausschließlich gemeinsame Analysezeitpunkte dargestellt.</i></p> <p><i>Ein LS MD und Hedges' g kleiner als Null bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

## 2.7 EORTC QLQ-C30 Übelkeit und Erbrechen

### EORTC QLQ-C30 Übelkeit und Erbrechen: Subgruppenanalyse

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
<b>EORTC QLQ-C30 Übelkeit und Erbrechen</b>			
<b>Alter: &lt; 65 Jahre</b>			
Baseline			
n/N (%)	92/115 (80)	92/119 (77)	-
MW (SD)	12,68 (19,356)	9,60 (16,246)	
Absolute Werte zum Studienende			
n/N (%)	4/73 (5)	4/64 (6)	-
MW (SD)	8,33 (16,667)	4,17 (8,333)	
Effekt über Studiendauer			
n	92	92	LS MD -8,89 [-13,801; -3,973] 0,0005
LS MW (SE)	-0,89 (1,747)	8,00 (1,769)	
95 %-KI	[-4,334; 2,563]	[4,513; 11,491]	Hedges' g -0,52 [-0,819; -0,231]
Veränderung zu Woche 3/4			
n/N (%)	58/113 (51)	61/115 (53)	LS MD -5,40 [-10,502; -0,294]
MW (SD)	-1,15 (21,372)	6,28 (20,897)	
LS MW (SE)	-1,15 (1,822)	4,25 (1,835)	
95 %-KI	[-4,745; 2,439]	[0,628; 7,863]	
Veränderung zu Woche 8/9			
n/N (%)	73/112 (65)	71/108 (66)	LS MD -6,93 [-11,882; -1,986]
MW (SD)	-3,65 (25,797)	5,87 (20,334)	
LS MW (SE)	-1,03 (1,768)	5,90 (1,774)	
95 %-KI	[-4,523; 2,453]	[2,400; 9,398]	
Veränderung zu Woche 12			
n/N (%)	46/110 (42)	40/105 (38)	
MW (SD)	-5,07 (25,789)	2,92 (17,658)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-0,95 (1,750)	7,06 (1,761)	LS MD -8,01 [-12,915; -3,104]
95 %-KI	[-4,406; 2,501]	[3,583; 10,531]	
Veränderung zu Woche 15/16			
n/N (%)	52/107 (49)	33/102 (32)	LS MD -9,08 [-14,006; -4,164]
MW (SD)	-5,45 (16,075)	6,57 (15,556)	
LS MW (SE)	-0,87 (1,748)	8,21 (1,773)	
95 %-KI	[-4,320; 2,580]	[4,718; 11,712]	
Veränderung zu Woche 20/21			
n/N (%)	36/101 (36)	30/96 (31)	LS MD -10,62 [-15,662; -5,579]
MW (SD)	-2,78 (28,868)	4,44 (20,960)	
LS MW (SE)	-0,75 (1,775)	9,87 (1,832)	
95 %-KI	[-4,254; 2,749]	[6,256; 13,480]	
Veränderung zu Woche 24			
n/N (%)	25/99 (25)	19/91 (21)	LS MD -11,70 [-16,887; -6,505]
MW (SD)	-6,67 (28,464)	6,14 (14,918)	
LS MW (SE)	-0,67 (1,813)	11,03 (1,902)	
95 %-KI	[-4,246; 2,906]	[7,280; 14,772]	
Veränderung zu Woche 36			
n/N (%)	40/86 (47)	27/79 (34)	LS MD -15,38 [-21,426; -9,340]
MW (SD)	-2,50 (21,533)	14,81 (25,875)	
LS MW (SE)	-0,39 (2,051)	15,00 (2,276)	
95 %-KI	[-4,423; 3,648]	[10,523; 19,468]	
Veränderung zu Woche 48			
n/N (%)	4/73 (5)	3/64 (5)	LS MD -19,07 [-26,339; -11,800]
MW (SD)	4,17 (20,972)	-5,56 (9,623)	
LS MW (SE)	-0,11 (2,412)	18,96 (2,791)	
95 %-KI	[-4,844; 4,633]	[13,487; 24,443]	
<b>Alter: ≥ 65 Jahre</b>			
Baseline			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	83/103 (81)	66/88 (75)	-
MW (SD)	7,63 (14,563)	10,10 (17,017)	
Absolute Werte zum Studienende			
n/N (%)	6/67 (9)	2/46 (4)	-
MW (SD)	8,33 (13,944)	8,33 (11,785)	
Effekt über Studiendauer			
n	83	66	LS MD -4,54 [-8,718; -0,371] 0,0331  Hedges' g -0,35 [-0,680; -0,028]
LS MW (SE)	0,33 (1,388)	4,87 (1,592)	
95 %-KI	[-2,419; 3,070]	[1,724; 8,016]	
Veränderung zu Woche 3/4			
n/N (%)	62/100 (62)	49/85 (58)	LS MD -4,04 [-8,411; 0,324]
MW (SD)	1,08 (14,113)	7,14 (20,412)	
LS MW (SE)	-0,70 (1,457)	3,34 (1,667)	
95 %-KI	[-3,579; 2,171]	[0,049; 6,629]	
Veränderung zu Woche 8/9			
n/N (%)	70/98 (71)	53/80 (66)	LS MD -4,27 [-8,476; -0,058]
MW (SD)	-0,24 (12,202)	0,31 (21,556)	
LS MW (SE)	-0,24 (1,406)	4,02 (1,601)	
95 %-KI	[-3,023; 2,534]	[0,860; 7,186]	
Veränderung zu Woche 12			
n/N (%)	49/95 (52)	31/78 (40)	LS MD -4,42 [-8,590; -0,257]
MW (SD)	2,04 (19,434)	6,99 (17,625)	
LS MW (SE)	0,08 (1,390)	4,50 (1,586)	
95 %-KI	[-2,670; 2,825]	[1,367; 7,636]	
Veränderung zu Woche 15/16			
n/N (%)	41/92 (45)	22/76 (29)	
MW (SD)	-2,44 (13,724)	-1,52 (15,352)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	0,40 (1,390)	4,98 (1,597)	LS MD -4,58 [-8,763; -0,398]
95 %-KI	[-2,348; 3,147]	[1,825; 8,135]	
Veränderung zu Woche 20/21			
n/N (%)	31/89 (35)	21/69 (30)	LS MD -4,80 [-9,110; -0,498]
MW (SD)	-2,15 (11,174)	-0,00 (18,257)	
LS MW (SE)	0,86 (1,419)	5,66 (1,657)	
95 %-KI	[-1,943; 3,662]	[2,393; 8,935]	
Veränderung zu Woche 24			
n/N (%)	28/85 (33)	19/64 (30)	LS MD -4,96 [-9,419; -0,503]
MW (SD)	-2,98 (12,047)	4,39 (19,909)	
LS MW (SE)	1,18 (1,457)	6,14 (1,728)	
95 %-KI	[-1,696; 4,059]	[2,735; 9,550]	
Veränderung zu Woche 36			
n/N (%)	39/74 (53)	20/55 (36)	LS MD -5,50 [-10,811; -0,185]
MW (SD)	4,27 (21,192)	2,50 (11,180)	
LS MW (SE)	2,29 (1,690)	7,78 (2,108)	
95 %-KI	[-1,041; 5,612]	[3,639; 11,928]	
Veränderung zu Woche 48			
n/N (%)	4/67 (6)	2/46 (4)	LS MD -6,03 [-12,552; 0,482]
MW (SD)	-4,17 (8,333)	0,00 (0,000)	
LS MW (SE)	3,39 (2,032)	9,42 (2,624)	
95 %-KI	[-0,602; 7,381]	[4,271; 14,577]	
<b>Region: USA</b>			
Baseline			
n/N (%)	49/65 (75)	34/51 (67)	-
MW (SD)	8,84 (14,069)	10,29 (15,899)	
Absolute Werte zum Studienende			
n/N (%)	2/39 (5)	3/27 (11)	-
MW (SD)	0,00 (0,000)	11,11 (9,623)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Effekt über Studiendauer			
n	49	34	LS MD -4,11 [-9,824; 1,604] 0,1562  Hedges' g -0,32 [-0,758; 0,123]
LS MW (SE)	2,18 (1,827)	6,29 (2,212)	
95 %-KI	[-1,461; 5,811]	[1,883; 10,688]	
Veränderung zu Woche 3/4			
n/N (%)	34/64 (53)	21/49 (43)	LS MD -3,29 [-9,279; 2,694]
MW (SD)	4,41 (14,968)	5,56 (16,102)	
LS MW (SE)	1,92 (1,908)	5,22 (2,334)	
95 %-KI	[-1,865; 5,711]	[0,583; 9,848]	
Veränderung zu Woche 8/9			
n/N (%)	42/62 (68)	30/46 (65)	LS MD -3,67 [-9,441; 2,111]
MW (SD)	1,19 (14,904)	2,78 (15,832)	
LS MW (SE)	2,04 (1,845)	5,70 (2,242)	
95 %-KI	[-1,631; 5,708]	[1,246; 10,161]	
Veränderung zu Woche 12			
n/N (%)	26/59 (44)	16/45 (36)	LS MD -3,93 [-9,640; 1,788]
MW (SD)	-0,64 (17,308)	7,29 (19,215)	
LS MW (SE)	2,12 (1,826)	6,04 (2,214)	
95 %-KI	[-1,517; 5,754]	[1,640; 10,449]	
Veränderung zu Woche 15/16			
n/N (%)	21/56 (38)	11/44 (25)	LS MD -4,19 [-9,912; 1,538]
MW (SD)	-2,38 (7,968)	1,52 (13,853)	
LS MW (SE)	2,20 (1,830)	6,39 (2,217)	
95 %-KI	[-1,443; 5,842]	[1,976; 10,796]	
Veränderung zu Woche 20/21			
n/N (%)	13/54 (24)	9/40 (22)	
MW (SD)	-1,28 (4,623)	5,56 (32,275)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	2,31 (1,873)	6,87 (2,275)	LS MD -4,56 [-10,425; 1,306]
95 %-KI	[-1,409; 6,038]	[2,353; 11,395]	
Veränderung zu Woche 24			
n/N (%)	9/53 (17)	6/38 (16)	LS MD -4,82 [-10,868; 1,227]
MW (SD)	0,00 (8,333)	2,78 (16,387)	
LS MW (SE)	2,39 (1,928)	7,22 (2,352)	
95 %-KI	[-1,433; 6,222]	[2,550; 11,881]	
Veränderung zu Woche 36			
n/N (%)	21/43 (49)	10/33 (30)	LS MD -5,72 [-12,822; 1,391]
MW (SD)	2,38 (16,060)	1,67 (24,152)	
LS MW (SE)	2,67 (2,247)	8,39 (2,795)	
95 %-KI	[-1,767; 7,108]	[2,871; 13,901]	
Veränderung zu Woche 48			
n/N (%)	2/39 (5)	3/27 (11)	LS MD -6,61 [-15,249; 2,029]
MW (SD)	-8,33 (11,785)	0,00 (0,000)	
LS MW (SE)	2,95 (2,708)	9,56 (3,426)	
95 %-KI	[-2,384; 8,277]	[2,815; 16,298]	
<b>Region: Rest der Welt</b>			
Baseline			
n/N (%)	126/153 (82)	124/156 (79)	-
MW (SD)	10,85 (18,537)	9,68 (16,747)	
Absolute Werte zum Studienende			
n/N (%)	8/101 (8)	3/83 (4)	-
MW (SD)	10,42 (15,269)	0,00 (0,000)	
Effekt über Studiendauer			
n	126	124	LS MD -8,23 [-12,143; -4,311] < 0,0001  Hedges' g
LS MW (SE)	-1,25 (1,389)	6,97 (1,425)	
95 %-KI	[-3,991; 1,481]	[4,166; 9,778]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
			-0,52 [-0,774; -0,269]
Veränderung zu Woche 3/4			
n/N (%)	86/149 (58)	89/151 (59)	LS MD -5,75 [-9,820; -1,681]
MW (SD)	-1,74 (18,792)	6,93 (21,586)	
LS MW (SE)	-2,07 (1,451)	3,68 (1,477)	
95 %-KI	[-4,927; 0,785]	[0,774; 6,586]	
Veränderung zu Woche 8/9			
n/N (%)	101/148 (68)	94/142 (66)	LS MD -6,84 [-10,778; -2,899]
MW (SD)	-3,30 (22,113)	3,72 (22,421)	
LS MW (SE)	-1,71 (1,406)	5,13 (1,426)	
95 %-KI	[-4,482; 1,058]	[2,319; 7,934]	
Veränderung zu Woche 12			
n/N (%)	69/146 (47)	55/138 (40)	LS MD -7,60 [-11,507; -3,694]
MW (SD)	-1,69 (24,778)	3,94 (17,262)	
LS MW (SE)	-1,46 (1,391)	6,14 (1,416)	
95 %-KI	[-4,201; 1,279]	[3,350; 8,929]	
Veränderung zu Woche 15/16			
n/N (%)	72/143 (50)	44/134 (33)	LS MD -8,36 [-12,285; -4,440]
MW (SD)	-4,63 (16,601)	3,79 (16,418)	
LS MW (SE)	-1,21 (1,390)	7,15 (1,429)	
95 %-KI	[-3,947; 1,527]	[4,339; 9,965]	
Veränderung zu Woche 20/21			
n/N (%)	54/136 (40)	42/125 (34)	LS MD -9,45 [-13,480; -5,420]
MW (SD)	-2,78 (24,816)	1,98 (16,545)	
LS MW (SE)	-0,85 (1,411)	8,60 (1,483)	
95 %-KI	[-3,631; 1,928]	[5,679; 11,518]	
Veränderung zu Woche 24			
n/N (%)	44/131 (34)	32/117 (27)	
MW (SD)	-5,68 (23,000)	5,73 (17,765)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-0,60 (1,442)	9,61 (1,545)	LS MD -10,21 [-14,373; -6,051]
95 %-KI	[-3,440; 2,239]	[6,572; 12,651]	
Veränderung zu Woche 36			
n/N (%)	58/117 (50)	37/101 (37)	LS MD -12,82 [-17,717; -7,931]
MW (SD)	0,29 (23,256)	11,71 (20,737)	
LS MW (SE)	0,26 (1,636)	13,08 (1,873)	
95 %-KI	[-2,955; 3,475]	[9,406; 16,762]	
Veränderung zu Woche 48			
n/N (%)	6/101 (6)	2/83 (2)	LS MD -15,44 [-21,367; -9,504]
MW (SD)	2,78 (16,387)	-8,33 (11,785)	
LS MW (SE)	1,12 (1,929)	16,56 (2,316)	
95 %-KI	[-2,667; 4,908]	[12,011; 21,101]	
<b>Stadium bei der Diagnose: I-III</b>			
Baseline			
n/N (%)	111/141 (79)	111/144 (77)	-
MW (SD)	10,51 (18,658)	9,76 (16,888)	
Absolute Werte zum Studienende			
n/N (%)	6/91 (7)	4/76 (5)	-
MW (SD)	2,78 (6,804)	8,33 (9,623)	
Effekt über Studiendauer			
n	111	111	LS MD -7,79 [-11,792; -3,796] 0,0002
LS MW (SE)	-1,27 (1,424)	6,53 (1,446)	
95 %-KI	[-4,072; 1,541]	[3,679; 9,378]	Hedges' g -0,51 [-0,781; -0,246]
Veränderung zu Woche 3/4			
n/N (%)	74/137 (54)	79/138 (57)	LS MD -6,20 [-10,351; -2,042]
MW (SD)	-1,58 (18,541)	7,81 (20,471)	
LS MW (SE)	-2,13 (1,485)	4,07 (1,501)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-5,051; 0,797]	[1,115; 7,024]	
Veränderung zu Woche 8/9			
n/N (%)	92/136 (68)	86/129 (67)	LS MD -6,90 [-10,926; -2,868]
MW (SD)	-3,08 (20,514)	2,33 (20,318)	
LS MW (SE)	-1,75 (1,441)	5,15 (1,452)	
95 %-KI	[-4,589; 1,090]	[2,286; 8,009]	
Veränderung zu Woche 12			
n/N (%)	59/133 (44)	48/128 (38)	LS MD -7,39 [-11,380; -3,394]
MW (SD)	-2,82 (22,984)	4,51 (18,749)	
LS MW (SE)	-1,48 (1,426)	5,90 (1,441)	
95 %-KI	[-4,296; 1,326]	[3,062; 8,742]	
Veränderung zu Woche 15/16			
n/N (%)	61/130 (47)	35/125 (28)	LS MD -7,88 [-11,880; -3,875]
MW (SD)	-5,19 (17,089)	3,81 (18,116)	
LS MW (SE)	-1,22 (1,424)	6,66 (1,449)	
95 %-KI	[-4,028; 1,587]	[3,802; 9,511]	
Veränderung zu Woche 20/21			
n/N (%)	45/123 (37)	34/116 (29)	LS MD -8,58 [-12,669; -4,486]
MW (SD)	-5,19 (23,789)	3,43 (22,011)	
LS MW (SE)	-0,84 (1,445)	7,73 (1,492)	
95 %-KI	[-3,691; 2,005]	[4,797; 10,673]	
Veränderung zu Woche 24			
n/N (%)	33/121 (27)	27/109 (25)	LS MD -9,07 [-13,272; -4,863]
MW (SD)	-5,05 (22,625)	1,85 (15,562)	
LS MW (SE)	-0,58 (1,476)	8,49 (1,543)	
95 %-KI	[-3,485; 2,328]	[5,452; 11,527]	
Veränderung zu Woche 36			
n/N (%)	51/105 (49)	35/92 (38)	
MW (SD)	1,31 (24,909)	10,00 (21,843)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	0,33 (1,665)	11,08 (1,825)	LS MD -10,75 [-15,609; -5,888]
95 %-KI	[-2,946; 3,603]	[7,491; 14,663]	
Veränderung zu Woche 48			
n/N (%)	5/91 (5)	4/76 (5)	LS MD -12,43 [-18,244; -6,614]
MW (SD)	-3,33 (7,454)	0,00 (0,000)	
LS MW (SE)	1,24 (1,955)	13,66 (2,220)	
95 %-KI	[-2,603; 5,073]	[9,308; 18,021]	
<b>Stadium bei der Diagnose: IV</b>			
Baseline			
n/N (%)	59/72 (82)	45/60 (75)	-
MW (SD)	10,17 (15,167)	10,37 (16,005)	
Absolute Werte zum Studienende			
n/N (%)	4/46 (9)	2/33 (6)	-
MW (SD)	16,67 (19,245)	0,00 (0,000)	
Effekt über Studiendauer			
n	59	45	LS MD -6,52 [-12,555; -0,488] 0,0344  Hedges' g -0,42 [-0,814; -0,029]
LS MW (SE)	0,61 (1,988)	7,13 (2,308)	
95 %-KI	[-3,333; 4,556]	[2,557; 11,710]	
Veränderung zu Woche 3/4			
n/N (%)	41/71 (58)	29/59 (49)	LS MD -2,45 [-8,710; 3,808]
MW (SD)	2,85 (17,441)	1,72 (18,008)	
LS MW (SE)	0,42 (2,067)	2,87 (2,399)	
95 %-KI	[-3,670; 4,516]	[-1,875; 7,623]	
Veränderung zu Woche 8/9			
n/N (%)	46/69 (67)	36/56 (64)	LS MD -4,28 [-10,340; 1,775]
MW (SD)	-0,36 (20,932)	6,02 (22,940)	
LS MW (SE)	0,51 (2,007)	4,79 (2,309)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,472; 4,488]	[0,211; 9,370]	
Veränderung zu Woche 12			
n/N (%)	31/67 (46)	22/52 (42)	LS MD -5,56 [-11,578; 0,448]
MW (SD)	-1,61 (16,304)	5,30 (15,758)	
LS MW (SE)	0,57 (1,988)	6,13 (2,294)	
95 %-KI	[-3,378; 4,513]	[1,583; 10,682]	
Veränderung zu Woche 15/16			
n/N (%)	29/64 (45)	18/50 (36)	LS MD -6,85 [-12,897; -0,797]
MW (SD)	-2,30 (10,657)	1,85 (11,273)	
LS MW (SE)	0,63 (1,990)	7,47 (2,318)	
95 %-KI	[-3,322; 4,576]	[2,879; 12,069]	
Veränderung zu Woche 20/21			
n/N (%)	19/62 (31)	16/46 (35)	LS MD -8,68 [-14,921; -2,437]
MW (SD)	3,51 (19,704)	-0,00 (14,907)	
LS MW (SE)	0,71 (2,027)	9,39 (2,418)	
95 %-KI	[-3,307; 4,730]	[4,604; 14,177]	
Veränderung zu Woche 24			
n/N (%)	18/59 (31)	10/44 (23)	LS MD -9,96 [-16,428; -3,494]
MW (SD)	-4,63 (20,457)	11,67 (19,325)	
LS MW (SE)	0,77 (2,076)	10,73 (2,530)	
95 %-KI	[-3,340; 4,883]	[5,731; 15,734]	
Veränderung zu Woche 36			
n/N (%)	27/52 (52)	11/41 (27)	LS MD -14,36 [-22,057; -6,658]
MW (SD)	-0,00 (13,868)	7,58 (22,808)	
LS MW (SE)	0,98 (2,367)	15,33 (3,114)	
95 %-KI	[-3,694; 5,645]	[9,204; 21,461]	
Veränderung zu Woche 48			
n/N (%)	3/46 (7)	1/33 (3)	
MW (SD)	5,56 (25,459)	-16,67 (NA)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	1,18 (2,799)	19,93 (3,891)	LS MD -18,75 [-28,172; -9,335]
95 %-KI	[-4,328; 6,686]	[12,287; 27,578]	
<b>BRCA Status: Positiv</b>			
Baseline			
n/N (%)	25/27 (93)	23/35 (66)	-
MW (SD)	11,33 (18,459)	17,39 (19,770)	
Absolute Werte zum Studienende			
n/N (%)	1/19 (5)	0/15 (0)	-
MW (SD)	33,33 (NA)	NA (NA)	
Effekt über Studiendauer			
n	25	23	LS MD -3,14 [-12,490; 6,219] 0,5031
LS MW (SE)	-2,13 (3,149)	1,01 (3,395)	
95 %-KI	[-8,474; 4,219]	[-5,821; 7,838]	Hedges' g -0,19 [-0,760; 0,375]
Veränderung zu Woche 3/4			
n/N (%)	16/27 (59)	18/35 (51)	LS MD -0,42 [-10,118; 9,282]
MW (SD)	-3,12 (20,384)	1,85 (22,787)	
LS MW (SE)	-1,87 (3,308)	-1,46 (3,503)	
95 %-KI	[-8,508; 4,760]	[-8,480; 5,567]	
Veränderung zu Woche 8/9			
n/N (%)	20/26 (77)	20/30 (67)	LS MD -1,73 [-11,095; 7,627]
MW (SD)	0,00 (19,497)	-5,00 (18,810)	
LS MW (SE)	-2,00 (3,191)	-0,26 (3,358)	
95 %-KI	[-8,417; 4,424]	[-7,024; 6,499]	
Veränderung zu Woche 12			
n/N (%)	14/26 (54)	10/30 (33)	LS MD -2,66 [-11,971; 6,660]
MW (SD)	4,76 (32,310)	6,67 (19,563)	
LS MW (SE)	-2,08 (3,153)	0,57 (3,360)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-8,436; 4,271]	[-6,193; 7,339]	
Veränderung zu Woche 15/16			
n/N (%)	12/26 (46)	8/29 (28)	LS MD -3,58 [-13,005; 5,851]
MW (SD)	-5,56 (16,412)	6,25 (12,400)	
LS MW (SE)	-2,17 (3,154)	1,41 (3,447)	
95 %-KI	[-8,525; 4,188]	[-5,516; 8,333]	
Veränderung zu Woche 20/21			
n/N (%)	10/25 (40)	4/25 (16)	LS MD -4,89 [-14,750; 4,963]
MW (SD)	-5,00 (17,656)	-4,17 (20,972)	
LS MW (SE)	-2,29 (3,222)	2,60 (3,707)	
95 %-KI	[-8,771; 4,188]	[-4,802; 10,006]	
Veränderung zu Woche 24			
n/N (%)	8/25 (32)	4/24 (17)	LS MD -5,81 [-16,144; 4,515]
MW (SD)	-4,17 (23,146)	-4,17 (20,972)	
LS MW (SE)	-2,38 (3,314)	3,44 (3,968)	
95 %-KI	[-9,025; 4,270]	[-4,456; 11,331]	
Veränderung zu Woche 36			
n/N (%)	10/21 (48)	5/20 (25)	LS MD -8,97 [-21,765; 3,817]
MW (SD)	-3,33 (17,213)	6,67 (19,003)	
LS MW (SE)	-2,67 (3,860)	6,30 (5,200)	
95 %-KI	[-10,340; 4,995]	[-3,959; 16,564]	
Veränderung zu Woche 48			
n/N (%)	1/19 (5)	0/15 (0)	LS MD -12,13 [-28,210; 3,942]
MW (SD)	33,33 (NA)	NA (NA)	
LS MW (SE)	-2,97 (4,657)	9,17 (6,721)	
95 %-KI	[-12,165; 6,231]	[-4,066; 22,400]	
<b>BRCA Status: Negativ/Unbekannt</b>			
Baseline			
n/N (%)	150/191 (79)	135/172 (78)	-

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	10,11 (17,260)	8,52 (15,622)	
Absolute Werte zum Studienende			
n/N (%)	9/121 (7)	6/95 (6)	-
MW (SD)	5,56 (11,785)	5,56 (8,607)	
Effekt über Studiendauer			
n	150	135	LS MD -7,75 [-11,266; -4,230] < 0,0001  Hedges' g -0,51 [-0,750; -0,277]
LS MW (SE)	-0,05 (1,222)	7,69 (1,304)	
95 %-KI	[-2,460; 2,352]	[5,126; 10,261]	
Veränderung zu Woche 3/4			
n/N (%)	104/186 (56)	92/165 (56)	LS MD -5,73 [-9,398; -2,069]
MW (SD)	0,48 (17,604)	7,61 (20,136)	
LS MW (SE)	-0,84 (1,274)	4,90 (1,359)	
95 %-KI	[-3,343; 1,671]	[2,224; 7,571]	
Veränderung zu Woche 8/9			
n/N (%)	123/184 (67)	104/158 (66)	LS MD -6,61 [-10,161; -3,067]
MW (SD)	-2,30 (20,504)	5,13 (21,040)	
LS MW (SE)	-0,49 (1,236)	6,12 (1,312)	
95 %-KI	[-2,927; 1,938]	[3,537; 8,702]	
Veränderung zu Woche 12			
n/N (%)	81/179 (45)	61/153 (40)	LS MD -7,23 [-10,744; -3,717]
MW (SD)	-2,47 (20,935)	4,37 (17,454)	
LS MW (SE)	-0,25 (1,223)	6,98 (1,300)	
95 %-KI	[-2,663; 2,153]	[4,416; 9,535]	
Veränderung zu Woche 15/16			
n/N (%)	81/173 (47)	47/149 (32)	LS MD -7,85 [-11,369; -4,325]
MW (SD)	-3,91 (14,970)	2,84 (16,418)	
LS MW (SE)	-0,02 (1,223)	7,83 (1,307)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-2,423; 2,392]	[5,260; 10,403]	
Veränderung zu Woche 20/21			
n/N (%)	57/165 (35)	47/140 (34)	LS MD -8,73 [-12,334; -5,121]
MW (SD)	-2,05 (23,161)	3,19 (19,854)	
LS MW (SE)	0,33 (1,243)	9,05 (1,346)	
95 %-KI	[-2,120; 2,773]	[6,406; 11,702]	
Veränderung zu Woche 24			
n/N (%)	45/159 (28)	34/131 (26)	LS MD -9,34 [-13,057; -5,632]
MW (SD)	-4,81 (21,208)	6,37 (16,925)	
LS MW (SE)	0,57 (1,272)	9,91 (1,394)	
95 %-KI	[-1,936; 3,068]	[7,169; 12,651]	
Veränderung zu Woche 36			
n/N (%)	69/139 (50)	42/114 (37)	LS MD -11,46 [-15,783; -7,133]
MW (SD)	1,45 (22,092)	9,92 (22,105)	
LS MW (SE)	1,39 (1,446)	12,84 (1,657)	
95 %-KI	[-1,455; 4,228]	[9,590; 16,098]	
Veränderung zu Woche 48			
n/N (%)	7/121 (6)	5/95 (5)	LS MD -13,57 [-18,781; -8,362]
MW (SD)	-4,76 (8,133)	-3,33 (7,454)	
LS MW (SE)	2,21 (1,708)	15,78 (2,026)	
95 %-KI	[-1,146; 5,560]	[11,804; 19,753]	
<b>Baseline ECOG PS: 0</b>			
Baseline			
n/N (%)	99/128 (77)	97/113 (86)	-
MW (SD)	8,08 (15,859)	8,76 (15,607)	
Absolute Werte zum Studienende			
n/N (%)	7/87 (8)	3/72 (4)	-
MW (SD)	9,52 (16,265)	11,11 (9,623)	
Effekt über Studiendauer			



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n	99	97	LS MD -5,48 [-9,137; -1,815] 0,0036  Hedges' g -0,42 [-0,703; -0,137]
LS MW (SE)	-0,73 (1,295)	4,75 (1,330)	
95 %-KI	[-3,286; 1,825]	[2,124; 7,368]	
Veränderung zu Woche 3/4			
n/N (%)	69/127 (54)	64/111 (58)	LS MD -2,97 [-6,803; 0,862]
MW (SD)	-0,00 (18,960)	3,65 (15,844)	
LS MW (SE)	-0,64 (1,356)	2,33 (1,395)	
95 %-KI	[-3,311; 2,034]	[-0,416; 5,080]	
Veränderung zu Woche 8/9			
n/N (%)	82/126 (65)	75/108 (69)	LS MD -4,06 [-7,755; -0,356]
MW (SD)	-1,63 (16,893)	2,22 (18,851)	
LS MW (SE)	-0,68 (1,313)	3,38 (1,341)	
95 %-KI	[-3,267; 1,911]	[0,734; 6,021]	
Veränderung zu Woche 12			
n/N (%)	50/122 (41)	46/108 (43)	LS MD -4,82 [-8,475; -1,156]
MW (SD)	-0,33 (23,447)	3,99 (19,621)	
LS MW (SE)	-0,71 (1,298)	4,11 (1,326)	
95 %-KI	[-3,266; 1,854]	[1,494; 6,725]	
Veränderung zu Woche 15/16			
n/N (%)	53/120 (44)	35/105 (33)	LS MD -5,57 [-9,239; -1,911]
MW (SD)	-4,09 (18,171)	1,90 (13,869)	
LS MW (SE)	-0,73 (1,296)	4,84 (1,332)	
95 %-KI	[-3,290; 1,823]	[2,215; 7,467]	
Veränderung zu Woche 20/21			
n/N (%)	40/117 (34)	32/101 (32)	LS MD -6,66 [-10,409; -2,911]
MW (SD)	-2,50 (19,447)	-0,00 (15,264)	
LS MW (SE)	-0,77 (1,316)	5,89 (1,373)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,368; 1,821]	[3,180; 8,592]	
Veränderung zu Woche 24			
n/N (%)	27/112 (24)	22/96 (23)	LS MD -7,42 [-11,279; -3,560]
MW (SD)	-6,17 (22,715)	4,55 (13,784)	
LS MW (SE)	-0,80 (1,345)	6,62 (1,424)	
95 %-KI	[-3,453; 1,850]	[3,813; 9,423]	
Veränderung zu Woche 36			
n/N (%)	48/99 (48)	34/87 (39)	LS MD -10,02 [-14,532; -5,515]
MW (SD)	-1,04 (21,307)	5,39 (18,221)	
LS MW (SE)	-0,90 (1,529)	9,13 (1,710)	
95 %-KI	[-3,904; 2,111]	[5,767; 12,486]	
Veränderung zu Woche 48			
n/N (%)	5/87 (6)	3/72 (4)	LS MD -12,63 [-18,079; -7,176]
MW (SD)	3,33 (18,257)	-5,56 (9,623)	
LS MW (SE)	-0,99 (1,808)	11,64 (2,108)	
95 %-KI	[-4,543; 2,559]	[7,498; 15,773]	
<b>Baseline ECOG PS: 1</b>			
Baseline			
n/N (%)	76/90 (84)	60/91 (66)	-
MW (SD)	13,16 (18,918)	11,39 (18,022)	
Absolute Werte zum Studienende			
n/N (%)	3/53 (6)	3/37 (8)	-
MW (SD)	5,56 (9,623)	0,00 (0,000)	
Effekt über Studiendauer			
n	76	60	LS MD -10,38 [-16,422; -4,332] 0,0009
LS MW (SE)	0,13 (2,017)	10,51 (2,303)	
95 %-KI	[-3,857; 4,125]	[5,958; 15,064]	Hedges' g -0,58 [-0,929; -0,237]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	51/86 (59)	45/87 (52)	LS MD -8,35 [-14,593; -2,100]
MW (SD)	-0,00 (16,667)	11,48 (25,332)	
LS MW (SE)	-1,53 (2,101)	6,82 (2,371)	
95 %-KI	[-5,683; 2,620]	[2,133; 11,497]	
Veränderung zu Woche 8/9			
n/N (%)	61/84 (73)	48/78 (62)	LS MD -9,28 [-15,337; -3,218]
MW (SD)	-2,46 (24,312)	4,86 (23,809)	
LS MW (SE)	-0,77 (2,038)	8,51 (2,297)	
95 %-KI	[-4,798; 3,261]	[3,967; 13,051]	
Veränderung zu Woche 12			
n/N (%)	45/83 (54)	24/74 (32)	LS MD -9,93 [-15,952; -3,905]
MW (SD)	-2,59 (22,461)	6,94 (12,926)	
LS MW (SE)	-0,23 (2,018)	9,69 (2,288)	
95 %-KI	[-4,226; 3,759]	[5,170; 14,220]	
Veränderung zu Woche 15/16			
n/N (%)	40/79 (51)	20/72 (28)	LS MD -10,58 [-16,647; -4,513]
MW (SD)	-4,17 (9,806)	5,83 (18,945)	
LS MW (SE)	0,30 (2,020)	10,88 (2,315)	
95 %-KI	[-3,696; 4,297]	[6,304; 15,458]	
Veränderung zu Woche 20/21			
n/N (%)	27/73 (37)	18/63 (29)	LS MD -11,51 [-17,775; -5,246]
MW (SD)	-2,47 (26,435)	8,33 (25,725)	
LS MW (SE)	1,06 (2,060)	12,57 (2,413)	
95 %-KI	[-3,009; 5,137]	[7,810; 17,340]	
Veränderung zu Woche 24			
n/N (%)	26/72 (36)	15/58 (26)	LS MD -12,16 [-18,653; -5,671]
MW (SD)	-3,21 (20,011)	5,56 (22,420)	
LS MW (SE)	1,60 (2,113)	13,76 (2,520)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-2,575; 5,772]	[8,791; 18,730]	
Veränderung zu Woche 36			
n/N (%)	31/61 (51)	13/46 (28)	LS MD -14,40 [-22,110; -6,681]
MW (SD)	3,76 (21,820)	20,51 (26,487)	
LS MW (SE)	3,43 (2,425)	17,83 (3,066)	
95 %-KI	[-1,345; 8,206]	[11,797; 23,855]	
Veränderung zu Woche 48			
n/N (%)	3/53 (6)	2/37 (5)	LS MD -16,63 [-26,037; -7,221]
MW (SD)	-5,56 (9,623)	0,00 (0,000)	
LS MW (SE)	5,26 (2,885)	21,89 (3,793)	
95 %-KI	[-0,407; 10,932]	[14,443; 29,341]	
<b>Anzahl vorheriger Therapielinien: 1</b>			
Baseline			
n/N (%)	24/31 (77)	23/29 (79)	-
MW (SD)	10,42 (16,161)	5,80 (10,788)	
Absolute Werte zum Studienende			
n/N (%)	1/22 (5)	0/14 (0)	-
MW (SD)	0,00 (NA)	NA (NA)	
Effekt über Studiendauer			
n	24	23	LS MD -10,20 [-17,360; -3,041] 0,0063  Hedges' g -0,83 [-1,425; -0,229]
LS MW (SE)	-1,75 (2,470)	8,45 (2,536)	
95 %-KI	[-6,741; 3,232]	[3,339; 13,553]	
Veränderung zu Woche 3/4			
n/N (%)	16/31 (52)	15/29 (52)	LS MD -2,35 [-9,946; 5,240]
MW (SD)	1,04 (12,865)	2,22 (21,700)	
LS MW (SE)	-3,40 (2,634)	-1,05 (2,717)	
95 %-KI	[-8,685; 1,877]	[-6,487; 4,385]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	20/31 (65)	18/26 (69)	LS MD -5,68 [-12,937; 1,579]
MW (SD)	-5,00 (10,949)	-0,93 (15,627)	
LS MW (SE)	-2,70 (2,526)	2,97 (2,564)	
95 %-KI	[-7,791; 2,382]	[-2,182; 8,130]	
Veränderung zu Woche 12			
n/N (%)	14/31 (45)	12/24 (50)	LS MD -8,01 [-15,162; -0,852]
MW (SD)	-4,76 (7,813)	5,56 (16,412)	
LS MW (SE)	-2,22 (2,484)	5,79 (2,523)	
95 %-KI	[-7,226; 2,795]	[0,710; 10,873]	
Veränderung zu Woche 15/16			
n/N (%)	15/31 (48)	11/22 (50)	LS MD -10,33 [-17,498; -3,172]
MW (SD)	-2,22 (5,864)	4,55 (16,817)	
LS MW (SE)	-1,73 (2,470)	8,61 (2,538)	
95 %-KI	[-6,712; 3,261]	[3,498; 13,720]	
Veränderung zu Woche 20/21			
n/N (%)	11/30 (37)	9/22 (41)	LS MD -13,66 [-21,027; -6,294]
MW (SD)	0,00 (7,454)	3,70 (7,349)	
LS MW (SE)	-1,03 (2,501)	12,63 (2,658)	
95 %-KI	[-6,069; 4,016]	[7,303; 17,965]	
Veränderung zu Woche 24			
n/N (%)	9/30 (30)	11/20 (55)	LS MD -15,99 [-23,625; -8,352]
MW (SD)	-1,85 (5,556)	10,61 (15,407)	
LS MW (SE)	-0,54 (2,557)	15,45 (2,802)	
95 %-KI	[-5,680; 4,606]	[9,853; 21,050]	
Veränderung zu Woche 36			
n/N (%)	15/26 (58)	5/18 (28)	LS MD -23,97 [-33,195; -14,746]
MW (SD)	3,33 (19,107)	23,33 (25,276)	
LS MW (SE)	1,14 (2,934)	25,11 (3,573)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-4,699; 6,981]	[18,044; 32,179]	
Veränderung zu Woche 48			
n/N (%)	0/22 (0)	0/14 (0)	LS MD -31,95 [-43,450; -20,454]
MW (SD)	NA (NA)	NA (NA)	
LS MW (SE)	2,82 (3,519)	34,77 (4,595)	
95 %-KI	[-4,136; 9,774]	[25,718; 43,825]	
<b>Anzahl vorheriger Therapielinien: 2</b>			
Baseline			
n/N (%)	76/89 (85)	64/83 (77)	-
MW (SD)	9,21 (14,756)	9,38 (17,027)	
Absolute Werte zum Studienende			
n/N (%)	4/59 (7)	2/50 (4)	-
MW (SD)	12,50 (15,957)	0,00 (0,000)	
Effekt über Studiendauer			
n	76	64	LS MD -6,73 [-12,018; -1,450] 0,0129
LS MW (SE)	1,85 (1,782)	8,59 (1,994)	
95 %-KI	[-1,672; 5,380]	[4,647; 12,529]	
Veränderung zu Woche 3/4			
n/N (%)	54/86 (63)	46/80 (57)	LS MD -5,93 [-11,455; -0,415]
MW (SD)	2,78 (18,243)	9,42 (24,255)	
LS MW (SE)	1,02 (1,872)	6,95 (2,081)	
95 %-KI	[-2,681; 4,711]	[2,841; 11,059]	
Veränderung zu Woche 8/9			
n/N (%)	63/85 (74)	51/77 (66)	LS MD -6,29 [-11,610; -0,980]
MW (SD)	-0,53 (18,200)	5,88 (20,227)	
LS MW (SE)	1,39 (1,806)	7,69 (1,996)	
95 %-KI	[-2,178; 4,964]	[3,743; 11,633]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	39/83 (47)	31/75 (41)	LS MD -6,55 [-11,814; -1,280]
MW (SD)	2,99 (21,922)	4,84 (21,600)	
LS MW (SE)	1,66 (1,785)	8,21 (1,981)	
95 %-KI	[-1,872; 5,188]	[4,289; 12,121]	
Veränderung zu Woche 15/16			
n/N (%)	42/80 (52)	20/74 (27)	LS MD -6,80 [-12,099; -1,498]
MW (SD)	-1,59 (13,175)	5,83 (16,468)	
LS MW (SE)	1,92 (1,784)	8,72 (2,003)	
95 %-KI	[-1,607; 5,452]	[4,763; 12,681]	
Veränderung zu Woche 20/21			
n/N (%)	32/78 (41)	21/68 (31)	LS MD -7,16 [-12,646; -1,672]
MW (SD)	1,04 (19,371)	6,35 (20,053)	
LS MW (SE)	2,30 (1,820)	9,46 (2,099)	
95 %-KI	[-1,297; 5,899]	[5,318; 13,602]	
Veränderung zu Woche 24			
n/N (%)	27/74 (36)	13/65 (20)	LS MD -7,41 [-13,117; -1,705]
MW (SD)	-1,85 (22,329)	8,97 (21,099)	
LS MW (SE)	2,57 (1,869)	9,98 (2,205)	
95 %-KI	[-1,127; 6,259]	[5,630; 14,324]	
Veränderung zu Woche 36			
n/N (%)	33/65 (51)	19/58 (33)	LS MD -8,28 [-15,178; -1,373]
MW (SD)	2,53 (24,339)	10,53 (20,943)	
LS MW (SE)	3,47 (2,166)	11,75 (2,752)	
95 %-KI	[-0,792; 7,739]	[6,340; 17,158]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	1/50 (2)	LS MD -9,14 [-17,689; -0,590]
MW (SD)	8,33 (16,667)	0,00 (NA)	
LS MW (SE)	4,38 (2,604)	13,52 (3,472)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-0,735; 9,498]	[6,703; 20,339]	
<b>Anzahl vorheriger Therapielinien: 3</b>			
Baseline			
n/N (%)	75/98 (77)	71/95 (75)	-
MW (SD)	11,33 (20,164)	11,50 (17,501)	
Absolute Werte zum Studienende			
n/N (%)	5/59 (8)	4/46 (9)	-
MW (SD)	6,67 (14,907)	8,33 (9,623)	
Effekt über Studiendauer			
n	75	71	LS MD -7,04 [-12,089; -1,989] 0,0066  Hedges' g -0,45 [-0,782; -0,125]
LS MW (SE)	-2,44 (1,775)	4,60 (1,839)	
95 %-KI	[-5,949; 1,070]	[0,964; 8,234]	
Veränderung zu Woche 3/4			
n/N (%)	50/96 (52)	49/91 (54)	LS MD -4,86 [-10,061; 0,333]
MW (SD)	-3,33 (18,748)	5,44 (16,097)	
LS MW (SE)	-2,38 (1,830)	2,48 (1,893)	
95 %-KI	[-5,997; 1,233]	[-1,255; 6,220]	
Veränderung zu Woche 8/9			
n/N (%)	60/94 (64)	55/85 (65)	LS MD -5,83 [-10,905; -0,751]
MW (SD)	-2,50 (24,515)	2,73 (23,077)	
LS MW (SE)	-2,41 (1,788)	3,42 (1,846)	
95 %-KI	[-5,941; 1,126]	[-0,228; 7,069]	
Veränderung zu Woche 12			
n/N (%)	42/91 (46)	28/84 (33)	LS MD -6,50 [-11,547; -1,458]
MW (SD)	-4,37 (26,560)	4,17 (13,322)	
LS MW (SE)	-2,43 (1,775)	4,08 (1,835)	
95 %-KI	[-5,935; 1,084]	[0,450; 7,705]	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	36/88 (41)	24/82 (29)	LS MD -7,18 [-12,233; -2,121]
MW (SD)	-7,87 (18,892)	0,69 (15,132)	
LS MW (SE)	-2,44 (1,777)	4,73 (1,842)	
95 %-KI	[-5,956; 1,069]	[1,093; 8,375]	
Veränderung zu Woche 20/21			
n/N (%)	24/82 (29)	21/75 (28)	LS MD -8,14 [-13,289; -2,993]
MW (SD)	-8,33 (29,076)	-1,59 (22,916)	
LS MW (SE)	-2,47 (1,804)	5,67 (1,883)	
95 %-KI	[-6,034; 1,095]	[1,953; 9,391]	
Veränderung zu Woche 24			
n/N (%)	17/80 (21)	14/70 (20)	LS MD -8,82 [-14,079; -3,553]
MW (SD)	-10,78 (24,254)	-2,38 (12,839)	
LS MW (SE)	-2,49 (1,840)	6,33 (1,932)	
95 %-KI	[-6,120; 1,145]	[2,515; 10,142]	
Veränderung zu Woche 36			
n/N (%)	31/69 (45)	23/58 (40)	LS MD -11,13 [-17,064; -5,195]
MW (SD)	-2,15 (19,599)	5,80 (21,087)	
LS MW (SE)	-2,55 (2,054)	8,58 (2,209)	
95 %-KI	[-6,595; 1,497]	[4,232; 12,929]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	4/46 (9)	LS MD -13,44 [-20,376; -6,510]
MW (SD)	-8,33 (9,623)	-4,17 (8,333)	
LS MW (SE)	-2,61 (2,379)	10,83 (2,609)	
95 %-KI	[-7,287; 2,066]	[5,705; 15,959]	
<b>Vorherige Verabreichung von Bevacizumab: Ja</b>			
Baseline			
n/N (%)	103/134 (77)	99/132 (75)	-
MW (SD)	9,39 (14,699)	11,11 (17,334)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	3/79 (4)	3/62 (5)	-
MW (SD)	5,56 (9,623)	5,56 (9,623)	
Effekt über Studiendauer			
n	103	99	LS MD -5,78 [-10,186; -1,377] 0,0104  Hedges' g -0,36 [-0,640; -0,084]
LS MW (SE)	1,80 (1,545)	7,58 (1,621)	
95 %-KI	[-1,246; 4,847]	[4,387; 10,777]	
Veränderung zu Woche 3/4			
n/N (%)	67/130 (52)	69/127 (54)	LS MD -4,07 [-8,673; 0,532]
MW (SD)	3,48 (15,499)	6,52 (19,220)	
LS MW (SE)	1,05 (1,622)	5,12 (1,689)	
95 %-KI	[-2,142; 4,249]	[1,797; 8,452]	
Veränderung zu Woche 8/9			
n/N (%)	84/130 (65)	75/119 (63)	LS MD -4,87 [-9,301; -0,445]
MW (SD)	0,20 (19,273)	4,00 (22,233)	
LS MW (SE)	1,40 (1,564)	6,28 (1,619)	
95 %-KI	[-1,679; 4,488]	[3,086; 9,468]	
Veränderung zu Woche 12			
n/N (%)	53/126 (42)	38/114 (33)	LS MD -5,43 [-9,826; -1,043]
MW (SD)	1,57 (26,607)	3,07 (12,767)	
LS MW (SE)	1,65 (1,546)	7,08 (1,609)	
95 %-KI	[-1,400; 4,698]	[3,911; 10,257]	
Veränderung zu Woche 15/16			
n/N (%)	55/122 (45)	32/112 (29)	LS MD -6,00 [-10,423; -1,570]
MW (SD)	-2,73 (11,459)	2,08 (16,258)	
LS MW (SE)	1,89 (1,547)	7,89 (1,634)	
95 %-KI	[-1,157; 4,947]	[4,670; 11,112]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	39/114 (34)	28/103 (27)	LS MD -6,80 [-11,397; -2,200]
MW (SD)	-0,43 (23,096)	2,98 (20,813)	
LS MW (SE)	2,25 (1,583)	9,04 (1,725)	
95 %-KI	[-0,876; 5,366]	[5,646; 12,441]	
Veränderung zu Woche 24			
n/N (%)	28/109 (26)	17/95 (18)	LS MD -7,36 [-12,157; -2,563]
MW (SD)	-1,19 (11,940)	9,80 (20,462)	
LS MW (SE)	2,49 (1,630)	9,85 (1,823)	
95 %-KI	[-0,722; 5,702]	[6,263; 13,438]	
Veränderung zu Woche 36			
n/N (%)	43/93 (46)	21/79 (27)	LS MD -9,29 [-15,143; -3,428]
MW (SD)	4,26 (20,604)	8,73 (18,722)	
LS MW (SE)	3,33 (1,908)	12,62 (2,314)	
95 %-KI	[-0,419; 7,081]	[8,073; 17,161]	
Veränderung zu Woche 48			
n/N (%)	3/79 (4)	2/62 (3)	LS MD -11,21 [-18,507; -3,915]
MW (SD)	0,00 (0,000)	0,00 (0,000)	
LS MW (SE)	4,17 (2,309)	15,38 (2,946)	
95 %-KI	[-0,361; 8,705]	[9,602; 21,164]	
<b>Vorherige Verabreichung von Bevacizumab: Nein</b>			
Baseline			
n/N (%)	72/84 (86)	59/75 (79)	-
MW (SD)	11,57 (20,677)	7,63 (14,946)	
Absolute Werte zum Studienende			
n/N (%)	7/61 (11)	3/48 (6)	-
MW (SD)	9,52 (16,265)	5,56 (9,623)	
Effekt über Studiendauer			
n	72	59	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-3,27 (1,612)	5,12 (1,793)	LS MD -8,39 [-13,177; -3,608] 0,0007  Hedges' g -0,61 [-0,960; -0,256]
95 %-KI	[-6,464; -0,082]	[1,572; 8,667]	
Veränderung zu Woche 3/4			
n/N (%)	53/83 (64)	41/73 (56)	LS MD -5,83 [-10,801; -0,857]
MW (SD)	-4,40 (19,923)	6,91 (22,966)	
LS MW (SE)	-3,98 (1,678)	1,85 (1,867)	
95 %-KI	[-7,299; -0,669]	[-1,844; 5,534]	
Veränderung zu Woche 8/9			
n/N (%)	59/80 (74)	49/69 (71)	LS MD -6,89 [-11,723; -2,056]
MW (SD)	-5,08 (21,499)	2,72 (19,048)	
LS MW (SE)	-3,69 (1,631)	3,20 (1,811)	
95 %-KI	[-6,917; -0,463]	[-0,382; 6,782]	
Veränderung zu Woche 12			
n/N (%)	42/79 (53)	33/69 (48)	LS MD -7,63 [-12,419; -2,845]
MW (SD)	-5,16 (16,662)	6,57 (22,024)	
LS MW (SE)	-3,48 (1,615)	4,15 (1,793)	
95 %-KI	[-6,680; -0,288]	[0,600; 7,696]	
Veränderung zu Woche 15/16			
n/N (%)	38/77 (49)	23/66 (35)	LS MD -8,37 [-13,158; -3,590]
MW (SD)	-6,14 (19,149)	5,07 (15,435)	
LS MW (SE)	-3,28 (1,612)	5,10 (1,793)	
95 %-KI	[-6,469; -0,087]	[1,549; 8,643]	
Veränderung zu Woche 20/21			
n/N (%)	28/76 (37)	23/62 (37)	LS MD -9,43 [-14,289; -4,581]
MW (SD)	-5,36 (21,302)	2,17 (19,006)	
LS MW (SE)	-2,98 (1,632)	6,45 (1,823)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,213; 0,245]	[2,845; 10,056]	
Veränderung zu Woche 24			
n/N (%)	25/75 (33)	21/60 (35)	LS MD -10,18 [-15,131; -5,224]
MW (SD)	-8,67 (28,104)	1,59 (13,849)	
LS MW (SE)	-2,78 (1,663)	7,40 (1,865)	
95 %-KI	[-6,065; 0,508]	[3,713; 11,085]	
Veränderung zu Woche 36			
n/N (%)	36/67 (54)	26/55 (47)	LS MD -12,72 [-18,297; -7,149]
MW (SD)	-3,24 (22,118)	10,26 (24,073)	
LS MW (SE)	-2,07 (1,855)	10,65 (2,121)	
95 %-KI	[-5,730; 1,585]	[6,472; 14,828]	
Veränderung zu Woche 48			
n/N (%)	5/61 (8)	3/48 (6)	LS MD -15,27 [-21,793; -8,743]
MW (SD)	0,00 (20,412)	-5,56 (9,623)	
LS MW (SE)	-1,37 (2,155)	13,90 (2,505)	
95 %-KI	[-5,604; 2,871]	[8,977; 18,825]	
<b>Letztes Platin-freies Intervall: ≤ 3 Monate</b>			
Baseline			
n/N (%)	67/83 (81)	62/91 (68)	-
MW (SD)	7,46 (15,155)	13,44 (19,520)	
Absolute Werte zum Studienende			
n/N (%)	3/55 (5)	5/39 (13)	-
MW (SD)	11,11 (19,245)	6,67 (9,129)	
Effekt über Studiendauer			
n	67	62	LS MD -9,59 [-15,620; -3,556] 0,0021
LS MW (SE)	-2,34 (2,082)	7,24 (2,200)	
95 %-KI	[-6,466; 1,776]	[2,891; 11,597]	Hedges' g -0,55 [-0,907; -0,203]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	49/82 (60)	46/86 (53)	LS MD -8,33 [-14,485; -2,176]
MW (SD)	-2,04 (17,557)	4,71 (22,406)	
LS MW (SE)	-2,10 (2,131)	6,23 (2,241)	
95 %-KI	[-6,311; 2,117]	[1,803; 10,664]	
Veränderung zu Woche 8/9			
n/N (%)	51/81 (63)	46/80 (57)	LS MD -8,91 [-14,957; -2,865]
MW (SD)	-0,00 (21,344)	3,99 (25,138)	
LS MW (SE)	-2,21 (2,091)	6,70 (2,201)	
95 %-KI	[-6,349; 1,926]	[2,346; 11,053]	
Veränderung zu Woche 12			
n/N (%)	33/78 (42)	24/78 (31)	LS MD -9,32 [-15,340; -3,295]
MW (SD)	-0,51 (21,844)	2,78 (17,492)	
LS MW (SE)	-2,29 (2,081)	7,03 (2,194)	
95 %-KI	[-6,409; 1,827]	[2,684; 11,368]	
Veränderung zu Woche 15/16			
n/N (%)	33/76 (43)	14/75 (19)	LS MD -9,72 [-15,768; -3,680]
MW (SD)	-7,07 (19,108)	-0,00 (9,245)	
LS MW (SE)	-2,37 (2,085)	7,35 (2,206)	
95 %-KI	[-6,498; 1,756]	[2,988; 11,717]	
Veränderung zu Woche 20/21			
n/N (%)	22/72 (31)	14/67 (21)	LS MD -10,30 [-16,455; -4,154]
MW (SD)	-5,30 (22,055)	-9,52 (12,599)	
LS MW (SE)	-2,49 (2,118)	7,82 (2,254)	
95 %-KI	[-6,674; 1,703]	[3,364; 12,274]	
Veränderung zu Woche 24			
n/N (%)	15/72 (21)	12/62 (19)	LS MD -10,71 [-16,988; -4,435]
MW (SD)	-8,89 (26,627)	-2,78 (13,914)	
LS MW (SE)	-2,57 (2,157)	8,15 (2,307)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,831; 1,699]	[3,587; 12,704]	
Veränderung zu Woche 36			
n/N (%)	26/63 (41)	18/50 (36)	LS MD -12,10 [-19,096; -5,114]
MW (SD)	-4,49 (18,594)	0,93 (17,594)	
LS MW (SE)	-2,84 (2,390)	9,26 (2,603)	
95 %-KI	[-7,552; 1,871]	[4,137; 14,392]	
Veränderung zu Woche 48			
n/N (%)	2/55 (4)	4/39 (10)	LS MD -13,50 [-21,548; -5,449]
MW (SD)	0,00 (0,000)	-4,17 (8,333)	
LS MW (SE)	-3,11 (2,738)	10,38 (3,027)	
95 %-KI	[-8,502; 2,272]	[4,432; 16,335]	
<b>Letztes Platin-freies Intervall: &gt; 3 Monate</b>			
Baseline			
n/N (%)	108/135 (80)	96/116 (83)	-
MW (SD)	12,04 (18,488)	7,47 (13,864)	
Absolute Werte zum Studienende			
n/N (%)	7/85 (8)	1/71 (1)	-
MW (SD)	7,14 (13,113)	0,00 (NA)	
Effekt über Studiendauer			
n	108	96	LS MD -5,14 [-8,964; -1,313] 0,0087  Hedges' g -0,37 [-0,649; -0,094]
LS MW (SE)	1,15 (1,319)	6,28 (1,414)	
95 %-KI	[-1,456; 3,747]	[3,497; 9,071]	
Veränderung zu Woche 3/4			
n/N (%)	71/131 (54)	64/114 (56)	LS MD -1,73 [-5,804; 2,341]
MW (SD)	1,41 (18,202)	8,07 (19,243)	
LS MW (SE)	0,11 (1,403)	1,84 (1,508)	
95 %-KI	[-2,652; 2,876]	[-1,126; 4,813]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	92/129 (71)	78/108 (72)	LS MD -3,21 [-7,091; 0,672]
MW (SD)	-3,08 (19,756)	3,21 (18,229)	
LS MW (SE)	0,56 (1,345)	3,77 (1,428)	
95 %-KI	[-2,092; 3,213]	[0,954; 6,585]	
Veränderung zu Woche 12			
n/N (%)	62/127 (49)	47/105 (45)	LS MD -4,24 [-8,067; -0,421]
MW (SD)	-1,88 (23,590)	5,67 (17,814)	
LS MW (SE)	0,87 (1,324)	5,12 (1,407)	
95 %-KI	[-1,737; 3,485]	[2,343; 7,892]	
Veränderung zu Woche 15/16			
n/N (%)	60/123 (49)	41/103 (40)	LS MD -5,28 [-9,109; -1,448]
MW (SD)	-2,50 (12,207)	4,47 (17,490)	
LS MW (SE)	1,19 (1,319)	6,47 (1,417)	
95 %-KI	[-1,414; 3,790]	[3,673; 9,259]	
Veränderung zu Woche 20/21			
n/N (%)	45/118 (38)	37/98 (38)	LS MD -6,76 [-10,709; -2,803]
MW (SD)	-1,11 (22,585)	7,21 (20,238)	
LS MW (SE)	1,64 (1,341)	8,39 (1,482)	
95 %-KI	[-1,008; 4,281]	[5,474; 11,310]	
Veränderung zu Woche 24			
n/N (%)	38/112 (34)	26/93 (28)	LS MD -7,79 [-11,903; -3,678]
MW (SD)	-3,07 (18,926)	8,97 (17,783)	
LS MW (SE)	1,95 (1,376)	9,74 (1,559)	
95 %-KI	[-0,762; 4,662]	[6,672; 12,809]	
Veränderung zu Woche 36			
n/N (%)	53/97 (55)	29/84 (35)	LS MD -11,34 [-16,356; -6,319]
MW (SD)	3,46 (22,494)	14,94 (22,425)	
LS MW (SE)	3,03 (1,600)	14,36 (1,974)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-0,119; 6,171]	[10,488; 18,239]	
Veränderung zu Woche 48			
n/N (%)	6/85 (7)	1/71 (1)	LS MD -14,88 [-21,167; -8,601]
MW (SD)	0,00 (18,257)	0,00 (NA)	
LS MW (SE)	4,10 (1,936)	18,99 (2,524)	
95 %-KI	[0,301; 7,903]	[14,033; 23,940]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Pegyliertes liposomales Doxorubicin</b>			
Baseline			
n/N (%)	61/80 (76)	57/76 (75)	-
MW (SD)	12,30 (20,162)	7,89 (15,140)	
Absolute Werte zum Studienende			
n/N (%)	3/51 (6)	3/41 (7)	-
MW (SD)	11,11 (19,245)	5,56 (9,623)	
Effekt über Studiendauer			
n	61	57	LS MD -10,87 [-16,847; -4,889] 0,0005  Hedges' g -0,66 [-1,033; -0,291]
LS MW (SE)	-0,68 (2,071)	10,19 (2,181)	
95 %-KI	[-4,780; 3,428]	[5,874; 14,510]	
Veränderung zu Woche 3/4			
n/N (%)	41/76 (54)	43/74 (58)	LS MD -6,27 [-12,503; -0,044]
MW (SD)	-2,85 (22,330)	10,08 (22,164)	
LS MW (SE)	-1,66 (2,177)	4,62 (2,261)	
95 %-KI	[-5,961; 2,651]	[0,149; 9,089]	
Veränderung zu Woche 8/9			
n/N (%)	50/76 (66)	44/66 (67)	LS MD -8,29 [-14,319; -2,271]
MW (SD)	-2,00 (22,996)	5,68 (21,248)	
LS MW (SE)	-1,22 (2,104)	7,07 (2,182)	
95 %-KI	[-5,391; 2,943]	[2,752; 11,390]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	32/75 (43)	23/64 (36)	LS MD -9,71 [-15,678; -3,741]
MW (SD)	-5,21 (22,175)	8,70 (23,500)	
LS MW (SE)	-0,92 (2,078)	8,79 (2,167)	
95 %-KI	[-5,039; 3,193]	[4,495; 13,078]	
Veränderung zu Woche 15/16			
n/N (%)	32/74 (43)	19/62 (31)	LS MD -11,12 [-17,113; -5,136]
MW (SD)	-6,25 (21,482)	10,53 (20,192)	
LS MW (SE)	-0,62 (2,072)	10,50 (2,187)	
95 %-KI	[-4,726; 3,484]	[6,174; 14,833]	
Veränderung zu Woche 20/21			
n/N (%)	27/72 (38)	18/59 (31)	LS MD -13,15 [-19,290; -7,000]
MW (SD)	-5,56 (22,169)	12,96 (25,280)	
LS MW (SE)	-0,19 (2,100)	12,96 (2,273)	
95 %-KI	[-4,348; 3,968]	[8,461; 17,449]	
Veränderung zu Woche 24			
n/N (%)	21/69 (30)	16/54 (30)	LS MD -14,56 [-20,900; -8,220]
MW (SD)	-5,56 (27,046)	7,29 (16,066)	
LS MW (SE)	0,11 (2,144)	14,67 (2,370)	
95 %-KI	[-4,131; 4,354]	[9,991; 19,352]	
Veränderung zu Woche 36			
n/N (%)	29/60 (48)	15/48 (31)	LS MD -19,41 [-26,861; -11,960]
MW (SD)	1,72 (30,649)	20,00 (30,989)	
LS MW (SE)	1,15 (2,431)	20,56 (2,882)	
95 %-KI	[-3,647; 5,938]	[14,885; 26,227]	
Veränderung zu Woche 48			
n/N (%)	2/51 (4)	2/41 (5)	LS MD -24,26 [-33,300; -15,222]
MW (SD)	16,67 (23,570)	0,00 (0,000)	
LS MW (SE)	2,18 (2,872)	26,44 (3,572)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,469; 7,828]	[19,423; 33,458]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Paclitaxel</b>			
Baseline			
n/N (%)	75/88 (85)	69/82 (84)	-
MW (SD)	11,33 (18,001)	10,63 (18,518)	
Absolute Werte zum Studienende			
n/N (%)	1/56 (2)	1/49 (2)	-
MW (SD)	0,00 (NA)	0,00 (NA)	
Effekt über Studiendauer			
n	75	69	LS MD -2,74 [-7,649; 2,173] 0,2722  Hedges' g -0,18 [-0,510; 0,145]
LS MW (SE)	0,70 (1,712)	3,43 (1,807)	
95 %-KI	[-2,691; 4,081]	[-0,138; 7,005]	
Veränderung zu Woche 3/4			
n/N (%)	55/87 (63)	49/81 (60)	LS MD -1,98 [-7,118; 3,152]
MW (SD)	1,52 (16,441)	2,72 (20,226)	
LS MW (SE)	-0,36 (1,793)	1,62 (1,893)	
95 %-KI	[-3,902; 3,178]	[-2,114; 5,357]	
Veränderung zu Woche 8/9			
n/N (%)	63/86 (73)	54/79 (68)	LS MD -2,33 [-7,278; 2,628]
MW (SD)	-2,91 (21,903)	1,23 (21,440)	
LS MW (SE)	0,12 (1,732)	2,44 (1,819)	
95 %-KI	[-3,306; 3,540]	[-1,153; 6,037]	
Veränderung zu Woche 12			
n/N (%)	42/84 (50)	36/77 (47)	LS MD -2,56 [-7,469; 2,340]
MW (SD)	0,00 (26,798)	3,24 (14,811)	
LS MW (SE)	0,45 (1,713)	3,02 (1,802)	
95 %-KI	[-2,935; 3,839]	[-0,545; 6,578]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	45/81 (56)	28/76 (37)	LS MD -2,80 [-7,726; 2,119]
MW (SD)	-1,85 (10,791)	-0,00 (12,830)	
LS MW (SE)	0,79 (1,715)	3,59 (1,813)	
95 %-KI	[-2,604; 4,178]	[0,008; 7,174]	
Veränderung zu Woche 20/21			
n/N (%)	29/77 (38)	26/73 (36)	LS MD -3,15 [-8,208; 1,917]
MW (SD)	1,15 (25,947)	-3,85 (15,135)	
LS MW (SE)	1,27 (1,753)	4,41 (1,878)	
95 %-KI	[-2,198; 4,729]	[0,704; 8,119]	
Veränderung zu Woche 24			
n/N (%)	21/74 (28)	19/72 (26)	LS MD -3,39 [-8,620; 1,850]
MW (SD)	-3,17 (20,152)	4,39 (19,909)	
LS MW (SE)	1,60 (1,803)	4,99 (1,954)	
95 %-KI	[-1,958; 5,160]	[1,131; 8,841]	
Veränderung zu Woche 36			
n/N (%)	35/64 (55)	24/63 (38)	LS MD -4,21 [-10,417; 2,006]
MW (SD)	1,90 (16,053)	4,86 (14,311)	
LS MW (SE)	2,75 (2,096)	6,96 (2,371)	
95 %-KI	[-1,377; 6,876]	[2,293; 11,618]	
Veränderung zu Woche 48			
n/N (%)	1/56 (2)	1/49 (2)	LS MD -5,03 [-12,619; 2,567]
MW (SD)	0,00 (NA)	-16,67 (NA)	
LS MW (SE)	3,90 (2,524)	8,92 (2,941)	
95 %-KI	[-1,061; 8,857]	[3,149; 14,700]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Topotecan</b>			
Baseline			
n/N (%)	39/50 (78)	32/49 (65)	-
MW (SD)	5,13 (8,680)	11,46 (14,317)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	6/33 (18)	2/20 (10)	-
MW (SD)	8,33 (13,944)	8,33 (11,785)	
Effekt über Studiendauer			
n	39	32	LS MD -8,73 [-15,190; -2,262] 0,0089  Hedges' g -0,64 [-1,125; -0,165]
LS MW (SE)	-1,14 (2,095)	7,59 (2,429)	
95 %-KI	[-5,323; 3,041]	[2,738; 12,432]	
Veränderung zu Woche 3/4			
n/N (%)	24/50 (48)	18/45 (40)	LS MD -7,87 [-14,455; -1,291]
MW (SD)	1,39 (11,955)	9,26 (16,392)	
LS MW (SE)	-0,71 (2,129)	7,17 (2,483)	
95 %-KI	[-4,950; 3,540]	[2,220; 12,116]	
Veränderung zu Woche 8/9			
n/N (%)	30/48 (62)	26/43 (60)	LS MD -8,24 [-14,725; -1,750]
MW (SD)	0,00 (9,787)	4,49 (19,753)	
LS MW (SE)	-0,89 (2,102)	7,35 (2,440)	
95 %-KI	[-5,086; 3,304]	[2,480; 12,213]	
Veränderung zu Woche 12			
n/N (%)	21/46 (46)	12/42 (29)	LS MD -8,49 [-14,953; -2,033]
MW (SD)	1,59 (13,849)	1,39 (11,143)	
LS MW (SE)	-1,02 (2,094)	7,47 (2,427)	
95 %-KI	[-5,202; 3,159]	[2,628; 12,315]	
Veränderung zu Woche 15/16			
n/N (%)	16/44 (36)	8/40 (20)	LS MD -8,75 [-15,214; -2,283]
MW (SD)	-6,25 (8,333)	-2,08 (5,893)	
LS MW (SE)	-1,15 (2,096)	7,60 (2,430)	
95 %-KI	[-5,335; 3,031]	[2,748; 12,445]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	11/41 (27)	7/33 (21)	LS MD -9,11 [-15,642; -2,584]
MW (SD)	-4,55 (7,785)	0,00 (0,000)	
LS MW (SE)	-1,34 (2,113)	7,77 (2,460)	
95 %-KI	[-5,554; 2,877]	[2,870; 12,679]	
Veränderung zu Woche 24			
n/N (%)	11/41 (27)	3/29 (10)	LS MD -9,37 [-15,980; -2,756]
MW (SD)	-6,06 (8,409)	0,00 (0,000)	
LS MW (SE)	-1,47 (2,137)	7,90 (2,499)	
95 %-KI	[-5,728; 2,790]	[2,922; 12,876]	
Veränderung zu Woche 36			
n/N (%)	15/36 (42)	8/23 (35)	LS MD -10,24 [-17,363; -3,122]
MW (SD)	-3,33 (6,901)	4,17 (11,785)	
LS MW (SE)	-1,92 (2,279)	8,33 (2,733)	
95 %-KI	[-6,443; 2,611]	[2,908; 13,746]	
Veränderung zu Woche 48			
n/N (%)	5/33 (15)	2/20 (10)	LS MD -11,12 [-19,042; -3,193]
MW (SD)	-6,67 (9,129)	0,00 (0,000)	
LS MW (SE)	-2,36 (2,505)	8,75 (3,093)	
95 %-KI	[-7,319; 2,594]	[2,647; 14,862]	
<p><i>Analysepopulation: ITT</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023</i></p> <p><i>Modell: Veränderung zu Baseline ~ Behandlung + Baseline-Wert * Zeit in Wochen + Behandlung * Zeit in Wochen + zufällige Effekte durch die Patientin</i></p> <p><i>Die Berechnung des LS-MWs erfolgt durch ein MMRM mit dem oben angegebenen Modell. Basierend hierauf werden KI und p-Wert ermittelt. Hedges' g basiert ebenfalls auf den LS-MW und ist somit auf das Modell angepasst.</i></p> <p><i>Es werden ausschließlich gemeinsame Analysezeitpunkte dargestellt.</i></p> <p><i>Ein LS MD und Hedges' g kleiner als Null bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

## 2.8 EORTC QLQ-C30 Schmerzen

### EORTC QLQ-C30 Schmerzen: Subgruppenanalyse

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
<b>EORTC QLQ-C30 Schmerzen</b>			
<b>Alter: &lt; 65 Jahre</b>			
Baseline			
n/N (%)	95/115 (83)	91/119 (76)	-
MW (SD)	25,96 (28,633)	32,23 (27,756)	
Absolute Werte zum Studienende			
n/N (%)	4/73 (5)	4/64 (6)	-
MW (SD)	37,50 (36,956)	4,17 (8,333)	
Effekt über Studiendauer			
n	95	91	LS MD -4,68 [-11,167; 1,798] 0,1557  Hedges' g -0,21 [-0,497; 0,080]
LS MW (SE)	-0,81 (2,267)	3,87 (2,373)	
95 %-KI	[-5,287; 3,658]	[-0,810; 8,550]	
Veränderung zu Woche 3/4			
n/N (%)	57/113 (50)	60/115 (52)	LS MD -1,04 [-7,763; 5,677]
MW (SD)	-0,58 (24,993)	-6,39 (22,147)	
LS MW (SE)	-1,93 (2,357)	-0,89 (2,455)	
95 %-KI	[-6,576; 2,718]	[-5,726; 3,953]	
Veränderung zu Woche 8/9			
n/N (%)	76/112 (68)	71/108 (66)	LS MD -2,65 [-9,179; 3,877]
MW (SD)	0,66 (33,823)	1,17 (27,935)	
LS MW (SE)	-1,44 (2,292)	1,21 (2,380)	
95 %-KI	[-5,959; 3,085]	[-3,481; 5,908]	
Veränderung zu Woche 12			
n/N (%)	48/110 (44)	40/105 (38)	
MW (SD)	-4,17 (33,245)	0,83 (22,630)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-1,09 (2,270)	2,68 (2,363)	LS MD -3,78 [-10,251; 2,699]
95 %-KI	[-5,572; 3,387]	[-1,979; 7,346]	
Veränderung zu Woche 15/16			
n/N (%)	55/107 (51)	31/102 (30)	LS MD -4,90 [-11,393; 1,590]
MW (SD)	-1,52 (32,596)	-4,84 (23,646)	
LS MW (SE)	-0,75 (2,268)	4,15 (2,378)	
95 %-KI	[-5,223; 3,727]	[-0,537; 8,843]	
Veränderung zu Woche 20/21			
n/N (%)	37/101 (37)	29/96 (30)	LS MD -6,51 [-13,142; 0,124]
MW (SD)	-3,15 (33,063)	-3,45 (26,495)	
LS MW (SE)	-0,26 (2,299)	6,25 (2,450)	
95 %-KI	[-4,791; 4,279]	[1,423; 11,083]	
Veränderung zu Woche 24			
n/N (%)	25/99 (25)	19/91 (21)	LS MD -7,63 [-14,446; -0,823]
MW (SD)	2,67 (29,139)	3,51 (21,928)	
LS MW (SE)	0,09 (2,344)	7,72 (2,535)	
95 %-KI	[-4,533; 4,711]	[2,730; 12,717]	
Veränderung zu Woche 36			
n/N (%)	41/86 (48)	27/79 (34)	LS MD -11,49 [-19,334; -3,651]
MW (SD)	-0,41 (31,066)	9,88 (27,056)	
LS MW (SE)	1,27 (2,628)	12,76 (2,997)	
95 %-KI	[-3,901; 6,441]	[6,872; 18,654]	
Veränderung zu Woche 48			
n/N (%)	4/73 (5)	2/64 (3)	LS MD -15,35 [-24,695; -6,007]
MW (SD)	4,17 (55,067)	-8,33 (35,355)	
LS MW (SE)	2,45 (3,063)	17,80 (3,641)	
95 %-KI	[-3,567; 8,470]	[10,655; 24,950]	
<b>Alter: ≥ 65 Jahre</b>			
Baseline			



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	81/103 (79)	67/88 (76)	-
MW (SD)	25,10 (25,293)	25,62 (27,726)	
Absolute Werte zum Studienende			
n/N (%)	6/67 (9)	2/46 (4)	-
MW (SD)	22,22 (25,092)	16,67 (0,000)	
Effekt über Studiendauer			
n	81	67	LS MD -0,95 [-7,654; 5,750] 0,7793  Hedges' g -0,05 [-0,370; 0,278]
LS MW (SE)	2,56 (2,252)	3,51 (2,540)	
95 %-KI	[-1,892; 7,015]	[-1,505; 8,532]	
Veränderung zu Woche 3/4			
n/N (%)	59/100 (59)	49/85 (58)	LS MD 0,97 [-6,031; 7,966]
MW (SD)	7,91 (26,144)	0,68 (26,123)	
LS MW (SE)	1,91 (2,359)	0,94 (2,653)	
95 %-KI	[-2,748; 6,566]	[-4,293; 6,176]	
Veränderung zu Woche 8/9			
n/N (%)	67/98 (68)	53/80 (66)	LS MD 0,12 [-6,635; 6,872]
MW (SD)	-3,73 (24,243)	-0,63 (30,829)	
LS MW (SE)	2,20 (2,281)	2,08 (2,551)	
95 %-KI	[-2,310; 6,705]	[-2,960; 7,118]	
Veränderung zu Woche 12			
n/N (%)	49/95 (52)	32/78 (41)	LS MD -0,48 [-7,165; 6,212]
MW (SD)	-0,68 (23,560)	5,73 (19,218)	
LS MW (SE)	2,40 (2,255)	2,88 (2,528)	
95 %-KI	[-2,059; 6,858]	[-2,119; 7,872]	
Veränderung zu Woche 15/16			
n/N (%)	41/92 (45)	22/76 (29)	
MW (SD)	0,41 (22,818)	-3,79 (38,121)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	2,60 (2,254)	3,67 (2,547)	LS MD -1,07 [-7,785; 5,643]
95 %-KI	[-1,855; 7,059]	[-1,359; 8,705]	
Veränderung zu Woche 20/21			
n/N (%)	29/89 (33)	21/69 (30)	LS MD -1,92 [-8,827; 4,986]
MW (SD)	-4,02 (20,728)	-4,76 (32,121)	
LS MW (SE)	2,89 (2,296)	4,81 (2,643)	
95 %-KI	[-1,646; 7,428]	[-0,407; 10,029]	
Veränderung zu Woche 24			
n/N (%)	30/85 (35)	19/64 (30)	LS MD -2,51 [-9,658; 4,628]
MW (SD)	-2,22 (23,866)	0,00 (33,333)	
LS MW (SE)	3,09 (2,354)	5,61 (2,756)	
95 %-KI	[-1,555; 7,741]	[0,173; 11,043]	
Veränderung zu Woche 36			
n/N (%)	40/74 (54)	19/55 (35)	LS MD -4,55 [-13,028; 3,921]
MW (SD)	2,08 (19,680)	14,91 (35,090)	
LS MW (SE)	3,79 (2,706)	8,34 (3,358)	
95 %-KI	[-1,541; 9,114]	[1,736; 14,943]	
Veränderung zu Woche 48			
n/N (%)	4/67 (6)	2/46 (4)	LS MD -6,59 [-16,948; 3,764]
MW (SD)	0,00 (0,000)	-16,67 (23,570)	
LS MW (SE)	4,48 (3,229)	11,07 (4,176)	
95 %-KI	[-1,866; 10,825]	[2,871; 19,272]	
<b>Region: USA</b>			
Baseline			
n/N (%)	49/65 (75)	34/51 (67)	-
MW (SD)	24,15 (25,699)	28,92 (25,062)	
Absolute Werte zum Studienende			
n/N (%)	2/39 (5)	3/27 (11)	-
MW (SD)	33,33 (23,570)	11,11 (9,623)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Effekt über Studiendauer			
n	49	34	LS MD -2,90 [-12,265; 6,466] 0,5395  Hedges' g -0,14 [-0,575; 0,301]
LS MW (SE)	0,24 (2,988)	3,14 (3,640)	
95 %-KI	[-5,710; 6,184]	[-4,107; 10,380]	
Veränderung zu Woche 3/4			
n/N (%)	33/64 (52)	21/49 (43)	LS MD -3,08 [-12,835; 6,674]
MW (SD)	8,59 (25,042)	1,59 (24,667)	
LS MW (SE)	0,30 (3,099)	3,38 (3,812)	
95 %-KI	[-5,855; 6,457]	[-4,186; 10,949]	
Veränderung zu Woche 8/9			
n/N (%)	42/62 (68)	30/46 (65)	LS MD -3,00 [-12,461; 6,463]
MW (SD)	-7,54 (22,148)	1,11 (30,617)	
LS MW (SE)	0,27 (3,013)	3,27 (3,683)	
95 %-KI	[-5,723; 6,267]	[-4,052; 10,594]	
Veränderung zu Woche 12			
n/N (%)	26/59 (44)	16/45 (36)	LS MD -2,94 [-12,312; 6,429]
MW (SD)	-3,21 (17,650)	3,12 (18,478)	
LS MW (SE)	0,25 (2,988)	3,19 (3,642)	
95 %-KI	[-5,695; 6,199]	[-4,054; 10,441]	
Veränderung zu Woche 15/16			
n/N (%)	21/56 (38)	11/44 (25)	LS MD -2,88 [-12,260; 6,491]
MW (SD)	-3,97 (21,019)	-7,58 (13,670)	
LS MW (SE)	0,23 (2,992)	3,12 (3,645)	
95 %-KI	[-5,723; 6,186]	[-4,136; 10,369]	
Veränderung zu Woche 20/21			
n/N (%)	13/54 (24)	9/40 (22)	
MW (SD)	-2,56 (13,344)	-9,26 (22,222)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	0,20 (3,047)	3,01 (3,723)	LS MD -2,80 [-12,353; 6,747]
95 %-KI	[-5,857; 6,261]	[-4,394; 10,405]	
Veränderung zu Woche 24			
n/N (%)	9/53 (17)	6/38 (16)	LS MD -2,75 [-12,529; 7,038]
MW (SD)	-1,85 (15,466)	-5,56 (37,515)	
LS MW (SE)	0,18 (3,120)	2,93 (3,827)	
95 %-KI	[-6,014; 6,378]	[-4,668; 10,524]	
Veränderung zu Woche 36			
n/N (%)	22/43 (51)	10/33 (30)	LS MD -2,55 [-13,744; 8,644]
MW (SD)	-4,55 (20,690)	6,67 (41,722)	
LS MW (SE)	0,11 (3,551)	2,66 (4,442)	
95 %-KI	[-6,905; 7,130]	[-6,110; 11,435]	
Veränderung zu Woche 48			
n/N (%)	2/39 (5)	3/27 (11)	LS MD -2,35 [-15,658; 10,951]
MW (SD)	-33,33 (47,140)	-22,22 (19,245)	
LS MW (SE)	0,04 (4,190)	2,40 (5,341)	
95 %-KI	[-8,209; 8,295]	[-8,119; 12,912]	
<b>Region: Rest der Welt</b>			
Baseline			
n/N (%)	127/153 (83)	124/156 (79)	-
MW (SD)	26,12 (27,666)	29,57 (28,659)	
Absolute Werte zum Studienende			
n/N (%)	8/101 (8)	3/83 (4)	-
MW (SD)	27,08 (32,043)	5,56 (9,623)	
Effekt über Studiendauer			
n	127	124	LS MD -3,10 [-8,514; 2,319] 0,2611 Hedges' g
LS MW (SE)	1,14 (1,905)	4,24 (1,985)	
95 %-KI	[-2,611; 4,894]	[0,331; 8,148]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
			-0,14 [-0,390; 0,106]
Veränderung zu Woche 3/4			
n/N (%)	83/149 (56)	88/151 (58)	LS MD 0,93 [-4,698; 6,553]
MW (SD)	1,81 (26,031)	-4,36 (24,039)	
LS MW (SE)	-0,25 (1,989)	-1,18 (2,054)	
95 %-KI	[-4,166; 3,664]	[-5,222; 2,864]	
Veränderung zu Woche 8/9			
n/N (%)	101/148 (68)	94/142 (66)	LS MD -0,84 [-6,290; 4,609]
MW (SD)	1,16 (32,081)	0,18 (28,763)	
LS MW (SE)	0,36 (1,929)	1,20 (1,985)	
95 %-KI	[-3,438; 4,160]	[-2,707; 5,110]	
Veränderung zu Woche 12			
n/N (%)	71/146 (49)	56/138 (41)	LS MD -2,08 [-7,482; 3,326]
MW (SD)	-2,11 (31,864)	2,98 (22,044)	
LS MW (SE)	0,79 (1,908)	2,87 (1,972)	
95 %-KI	[-2,970; 4,548]	[-1,017; 6,752]	
Veränderung zu Woche 15/16			
n/N (%)	75/143 (52)	42/134 (31)	LS MD -3,32 [-8,740; 2,109]
MW (SD)	0,22 (30,572)	-3,57 (33,239)	
LS MW (SE)	1,22 (1,906)	4,53 (1,990)	
95 %-KI	[-2,537; 4,972]	[0,614; 8,452]	
Veränderung zu Woche 20/21			
n/N (%)	53/136 (39)	41/125 (33)	LS MD -5,08 [-10,651; 0,484]
MW (SD)	-3,77 (30,774)	-2,85 (30,024)	
LS MW (SE)	1,83 (1,934)	6,91 (2,067)	
95 %-KI	[-1,979; 5,637]	[2,845; 10,980]	
Veränderung zu Woche 24			
n/N (%)	46/131 (35)	32/117 (27)	
MW (SD)	0,36 (27,997)	3,13 (26,246)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	2,26 (1,974)	8,58 (2,153)	LS MD -6,32 [-12,063; -0,579]
95 %-KI	[-1,630; 6,145]	[4,343; 12,814]	
Veränderung zu Woche 36			
n/N (%)	59/117 (50)	36/101 (36)	LS MD -10,56 [-17,289; -3,840]
MW (SD)	2,82 (27,535)	13,43 (26,968)	
LS MW (SE)	3,73 (2,230)	14,29 (2,608)	
95 %-KI	[-0,658; 8,109]	[9,169; 19,412]	
Veränderung zu Woche 48			
n/N (%)	6/101 (6)	1/83 (1)	LS MD -14,81 [-22,932; -6,682]
MW (SD)	13,89 (26,701)	16,67 (NA)	
LS MW (SE)	5,19 (2,621)	20,00 (3,223)	
95 %-KI	[0,049; 10,339]	[13,677; 26,326]	
<b>Stadium bei der Diagnose: I-III</b>			
Baseline			
n/N (%)	113/141 (80)	112/144 (78)	-
MW (SD)	27,73 (26,221)	29,76 (28,336)	
Absolute Werte zum Studienende			
n/N (%)	6/91 (7)	4/76 (5)	-
MW (SD)	27,78 (34,427)	12,50 (8,333)	
Effekt über Studiendauer			
n	113	112	LS MD -1,28 [-6,896; 4,343] 0,6549
LS MW (SE)	1,07 (1,988)	2,35 (2,049)	
95 %-KI	[-2,849; 4,989]	[-1,691; 6,384]	Hedges' g -0,06 [-0,321; 0,202]
Veränderung zu Woche 3/4			
n/N (%)	73/137 (53)	79/138 (57)	LS MD 1,21 [-4,646; 7,057]
MW (SD)	3,65 (26,242)	-4,64 (24,010)	
LS MW (SE)	-0,30 (2,079)	-1,51 (2,129)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-4,398; 3,790]	[-5,701; 2,682]	
Veränderung zu Woche 8/9			
n/N (%)	93/136 (68)	88/129 (68)	LS MD 0,12 [-5,546; 5,790]
MW (SD)	-1,25 (30,120)	0,76 (29,568)	
LS MW (SE)	0,30 (2,014)	0,17 (2,059)	
95 %-KI	[-3,673; 4,265]	[-3,882; 4,231]	
Veränderung zu Woche 12			
n/N (%)	63/133 (47)	49/128 (38)	LS MD -0,64 [-6,252; 4,978]
MW (SD)	-4,76 (29,849)	2,04 (17,224)	
LS MW (SE)	0,72 (1,992)	1,35 (2,042)	
95 %-KI	[-3,210; 4,642]	[-2,671; 5,377]	
Veränderung zu Woche 15/16			
n/N (%)	64/130 (49)	34/125 (27)	LS MD -1,40 [-7,021; 4,230]
MW (SD)	2,86 (28,102)	-6,86 (25,332)	
LS MW (SE)	1,14 (1,989)	2,53 (2,053)	
95 %-KI	[-2,784; 5,057]	[-1,513; 6,577]	
Veränderung zu Woche 20/21			
n/N (%)	45/123 (37)	34/116 (29)	LS MD -2,48 [-8,230; 3,271]
MW (SD)	-1,85 (30,198)	-5,39 (29,508)	
LS MW (SE)	1,74 (2,019)	4,22 (2,114)	
95 %-KI	[-2,241; 5,714]	[0,052; 8,380]	
Veränderung zu Woche 24			
n/N (%)	35/121 (29)	27/109 (25)	LS MD -3,24 [-9,150; 2,673]
MW (SD)	1,90 (23,836)	1,23 (28,467)	
LS MW (SE)	2,16 (2,062)	5,39 (2,188)	
95 %-KI	[-1,905; 6,219]	[1,089; 9,701]	
Veränderung zu Woche 36			
n/N (%)	53/105 (50)	35/92 (38)	
MW (SD)	1,26 (27,898)	11,43 (32,532)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	3,60 (2,336)	9,44 (2,593)	LS MD -5,84 [-12,689; 1,010]
95 %-KI	[-0,996; 8,190]	[4,342; 14,531]	
Veränderung zu Woche 48			
n/N (%)	5/91 (5)	4/76 (5)	LS MD -8,44 [-16,655; -0,227]
MW (SD)	13,33 (29,814)	-12,50 (25,000)	
LS MW (SE)	5,04 (2,753)	13,48 (3,159)	
95 %-KI	[-0,368; 10,443]	[7,277; 19,679]	
<b>Stadium bei der Diagnose: IV</b>			
Baseline			
n/N (%)	58/72 (81)	44/60 (73)	-
MW (SD)	20,69 (28,666)	29,55 (27,105)	
Absolute Werte zum Studienende			
n/N (%)	4/46 (9)	2/33 (6)	-
MW (SD)	29,17 (25,000)	0,00 (0,000)	
Effekt über Studiendauer			
n	58	44	LS MD -6,86 [-15,511; 1,795] 0,1190
LS MW (SE)	-0,64 (2,813)	6,21 (3,308)	
95 %-KI	[-6,226; 4,938]	[-0,347; 12,775]	Hedges' g -0,31 [-0,709; 0,080]
Veränderung zu Woche 3/4			
n/N (%)	38/71 (54)	28/59 (47)	LS MD -4,85 [-13,778; 4,071]
MW (SD)	1,75 (25,933)	-2,38 (19,623)	
LS MW (SE)	-1,46 (2,903)	3,39 (3,419)	
95 %-KI	[-7,218; 4,288]	[-3,382; 10,159]	
Veränderung zu Woche 8/9			
n/N (%)	45/69 (65)	35/56 (62)	LS MD -5,76 [-14,434; 2,920]
MW (SD)	-2,96 (30,002)	-0,48 (28,722)	
LS MW (SE)	-1,09 (2,835)	4,66 (3,305)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,719; 4,530]	[-1,892; 11,217]	
Veränderung zu Woche 12			
n/N (%)	29/67 (43)	22/52 (42)	LS MD -6,39 [-15,015; 2,236]
MW (SD)	-0,57 (22,923)	5,30 (28,815)	
LS MW (SE)	-0,84 (2,814)	5,55 (3,287)	
95 %-KI	[-6,420; 4,749]	[-0,968; 12,075]	
Veränderung zu Woche 15/16			
n/N (%)	29/64 (45)	17/50 (34)	LS MD -7,02 [-15,698; 1,653]
MW (SD)	-6,90 (30,052)	-4,90 (33,729)	
LS MW (SE)	-0,58 (2,815)	6,45 (3,322)	
95 %-KI	[-6,163; 5,010]	[-0,142; 13,033]	
Veränderung zu Woche 20/21			
n/N (%)	18/62 (29)	15/46 (33)	LS MD -7,93 [-16,847; 0,995]
MW (SD)	-5,56 (19,803)	-2,22 (28,078)	
LS MW (SE)	-0,21 (2,855)	7,72 (3,459)	
95 %-KI	[-5,868; 5,455]	[0,871; 14,568]	
Veränderung zu Woche 24			
n/N (%)	18/59 (31)	10/44 (23)	LS MD -8,56 [-17,765; 0,649]
MW (SD)	-0,93 (29,963)	-3,33 (18,922)	
LS MW (SE)	0,05 (2,908)	8,61 (3,610)	
95 %-KI	[-5,710; 5,816]	[1,473; 15,748]	
Veränderung zu Woche 36			
n/N (%)	27/52 (52)	10/41 (24)	LS MD -10,73 [-21,510; 0,056]
MW (SD)	-0,62 (22,400)	8,33 (16,197)	
LS MW (SE)	0,94 (3,235)	11,67 (4,397)	
95 %-KI	[-5,447; 7,329]	[3,012; 20,324]	
Veränderung zu Woche 48			
n/N (%)	3/46 (7)	0/33 (0)	
MW (SD)	-16,67 (44,096)	NA (NA)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	1,83 (3,735)	14,73 (5,449)	LS MD -12,90 [-25,903; 0,112]
95 %-KI	[-5,524; 9,183]	[4,017; 25,433]	
<b>BRCA Status: Positiv</b>			
Baseline			
n/N (%)	25/27 (93)	23/35 (66)	-
MW (SD)	32,00 (33,306)	40,58 (31,713)	
Absolute Werte zum Studienende			
n/N (%)	1/19 (5)	0/15 (0)	-
MW (SD)	50,00 (NA)	NA (NA)	
Effekt über Studiendauer			
n	25	23	LS MD -3,32 [-16,212; 9,576] 0,6070
LS MW (SE)	-5,83 (4,352)	-2,51 (4,664)	
95 %-KI	[-14,598; 2,944]	[-11,889; 6,870]	Hedges' g -0,15 [-0,715; 0,419]
Veränderung zu Woche 3/4			
n/N (%)	15/27 (56)	18/35 (51)	LS MD 1,82 [-11,466; 15,114]
MW (SD)	3,33 (19,107)	-8,33 (28,151)	
LS MW (SE)	-2,24 (4,543)	-4,07 (4,782)	
95 %-KI	[-11,356; 6,873]	[-13,656; 5,524]	
Veränderung zu Woche 8/9			
n/N (%)	20/26 (77)	20/30 (67)	LS MD -0,68 [-13,559; 12,198]
MW (SD)	-8,33 (24,483)	-5,83 (36,384)	
LS MW (SE)	-3,99 (4,404)	-3,31 (4,604)	
95 %-KI	[-12,850; 4,875]	[-12,576; 5,960]	
Veränderung zu Woche 12			
n/N (%)	15/26 (58)	11/30 (37)	LS MD -2,43 [-15,270; 10,404]
MW (SD)	-2,22 (26,627)	-7,58 (37,538)	
LS MW (SE)	-5,21 (4,358)	-2,78 (4,615)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-13,992; 3,571]	[-12,068; 6,513]	
Veränderung zu Woche 15/16			
n/N (%)	12/26 (46)	8/29 (28)	LS MD -4,19 [-17,187; 8,814]
MW (SD)	-5,56 (26,905)	-25,00 (25,198)	
LS MW (SE)	-6,43 (4,357)	-2,25 (4,740)	
95 %-KI	[-15,213; 2,348]	[-11,764; 7,270]	
Veränderung zu Woche 20/21			
n/N (%)	10/25 (40)	4/25 (16)	LS MD -6,69 [-20,268; 6,887]
MW (SD)	-11,67 (24,907)	-25,00 (16,667)	
LS MW (SE)	-8,18 (4,433)	-1,49 (5,095)	
95 %-KI	[-17,097; 0,739]	[-11,661; 8,683]	
Veränderung zu Woche 24			
n/N (%)	8/25 (32)	4/24 (17)	LS MD -8,44 [-22,647; 5,761]
MW (SD)	-18,75 (24,296)	-16,67 (23,570)	
LS MW (SE)	-9,40 (4,538)	-0,96 (5,448)	
95 %-KI	[-18,511; -0,292]	[-11,793; 9,876]	
Veränderung zu Woche 36			
n/N (%)	10/21 (48)	4/20 (20)	LS MD -14,45 [-31,897; 2,990]
MW (SD)	-15,00 (16,574)	-8,33 (21,517)	
LS MW (SE)	-13,59 (5,176)	0,86 (7,102)	
95 %-KI	[-23,888; -3,298]	[-13,154; 14,875]	
Veränderung zu Woche 48			
n/N (%)	1/19 (5)	0/15 (0)	LS MD -20,46 [-42,236; 1,308]
MW (SD)	16,67 (NA)	NA (NA)	
LS MW (SE)	-17,78 (6,130)	2,68 (9,143)	
95 %-KI	[-29,903; -5,666]	[-15,322; 20,681]	
<b>BRCA Status: Negativ/Unbekannt</b>			
Baseline			
n/N (%)	151/191 (79)	135/172 (78)	-

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	24,50 (25,878)	27,53 (26,806)	
Absolute Werte zum Studienende			
n/N (%)	9/121 (7)	6/95 (6)	-
MW (SD)	25,93 (30,174)	8,33 (9,129)	
Effekt über Studiendauer			
n	151	135	LS MD -2,65 [-7,660; 2,367] 0,2997  Hedges' g -0,12 [-0,355; 0,110]
LS MW (SE)	2,01 (1,729)	4,66 (1,873)	
95 %-KI	[-1,389; 5,417]	[0,973; 8,347]	
Veränderung zu Woche 3/4			
n/N (%)	101/186 (54)	91/165 (55)	LS MD -0,32 [-5,536; 4,901]
MW (SD)	3,80 (26,758)	-2,20 (23,334)	
LS MW (SE)	0,33 (1,802)	0,64 (1,950)	
95 %-KI	[-3,219; 3,871]	[-3,192; 4,478]	
Veränderung zu Woche 8/9			
n/N (%)	123/184 (67)	104/158 (66)	LS MD -1,33 [-6,386; 3,723]
MW (SD)	-0,27 (30,403)	1,60 (27,530)	
LS MW (SE)	1,06 (1,749)	2,39 (1,884)	
95 %-KI	[-2,381; 4,503]	[-1,315; 6,100]	
Veränderung zu Woche 12			
n/N (%)	82/179 (46)	61/153 (40)	LS MD -2,04 [-7,049; 2,966]
MW (SD)	-2,44 (29,177)	4,92 (16,484)	
LS MW (SE)	1,58 (1,731)	3,62 (1,867)	
95 %-KI	[-1,832; 4,983]	[-0,058; 7,293]	
Veränderung zu Woche 15/16			
n/N (%)	84/173 (49)	45/149 (30)	LS MD -2,75 [-7,770; 2,267]
MW (SD)	-0,00 (29,041)	-0,74 (29,720)	
LS MW (SE)	2,09 (1,730)	4,84 (1,876)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-1,315; 5,495]	[1,149; 8,534]	
Veränderung zu Woche 20/21			
n/N (%)	56/165 (34)	46/140 (33)	LS MD -3,77 [-8,899; 1,367]
MW (SD)	-2,08 (28,615)	-2,17 (28,891)	
LS MW (SE)	2,82 (1,756)	6,59 (1,931)	
95 %-KI	[-0,632; 6,282]	[2,791; 10,391]	
Veränderung zu Woche 24			
n/N (%)	47/159 (30)	34/131 (26)	LS MD -4,48 [-9,754; 0,802]
MW (SD)	3,19 (25,452)	3,92 (27,846)	
LS MW (SE)	3,34 (1,794)	7,82 (1,998)	
95 %-KI	[-0,191; 6,870]	[3,886; 11,745]	
Veränderung zu Woche 36			
n/N (%)	71/139 (51)	42/114 (37)	LS MD -6,91 [-13,032; -0,789]
MW (SD)	3,05 (26,324)	13,89 (30,559)	
LS MW (SE)	5,10 (2,030)	12,01 (2,368)	
95 %-KI	[1,115; 9,092]	[7,363; 16,664]	
Veränderung zu Woche 48			
n/N (%)	7/121 (6)	4/95 (4)	LS MD -9,34 [-16,692; -1,998]
MW (SD)	0,00 (38,490)	-12,50 (25,000)	
LS MW (SE)	6,87 (2,387)	16,21 (2,887)	
95 %-KI	[2,181; 11,553]	[10,547; 21,877]	
<b>Baseline ECOG PS: 0</b>			
Baseline			
n/N (%)	101/128 (79)	96/113 (85)	-
MW (SD)	20,63 (24,054)	22,40 (24,040)	
Absolute Werte zum Studienende			
n/N (%)	7/87 (8)	3/72 (4)	-
MW (SD)	35,71 (31,074)	5,56 (9,623)	
Effekt über Studiendauer			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n	101	96	LS MD -4,34 [-9,827; 1,139] 0,1198  Hedges' g -0,22 [-0,502; 0,059]
LS MW (SE)	2,07 (1,916)	6,41 (2,020)	
95 %-KI	[-1,712; 5,849]	[2,429; 10,395]	
Veränderung zu Woche 3/4			
n/N (%)	67/127 (53)	63/111 (57)	LS MD -2,52 [-8,308; 3,276]
MW (SD)	2,24 (20,287)	0,79 (22,084)	
LS MW (SE)	0,50 (2,025)	3,02 (2,138)	
95 %-KI	[-3,486; 4,492]	[-1,193; 7,230]	
Veränderung zu Woche 8/9			
n/N (%)	84/126 (67)	74/108 (69)	LS MD -3,30 [-8,858; 2,250]
MW (SD)	-0,00 (30,060)	3,83 (28,207)	
LS MW (SE)	1,18 (1,949)	4,48 (2,040)	
95 %-KI	[-2,665; 5,020]	[0,459; 8,503]	
Veränderung zu Woche 12			
n/N (%)	53/122 (43)	46/108 (43)	LS MD -3,86 [-9,336; 1,625]
MW (SD)	-0,31 (29,866)	5,80 (24,144)	
LS MW (SE)	1,65 (1,922)	5,51 (2,013)	
95 %-KI	[-2,141; 5,440]	[1,535; 9,476]	
Veränderung zu Woche 15/16			
n/N (%)	56/120 (47)	33/105 (31)	LS MD -4,41 [-9,895; 1,081]
MW (SD)	4,76 (28,018)	4,04 (30,055)	
LS MW (SE)	2,12 (1,917)	6,53 (2,023)	
95 %-KI	[-1,659; 5,904]	[2,541; 10,518]	
Veränderung zu Woche 20/21			
n/N (%)	40/117 (34)	31/101 (31)	LS MD -5,20 [-10,832; 0,442]
MW (SD)	1,67 (27,164)	5,38 (27,684)	
LS MW (SE)	2,80 (1,949)	7,99 (2,097)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-1,047; 6,641]	[3,859; 12,125]	
Veränderung zu Woche 24			
n/N (%)	28/112 (25)	22/96 (23)	LS MD -5,75 [-11,580; 0,086]
MW (SD)	3,57 (24,155)	7,58 (26,591)	
LS MW (SE)	3,27 (1,998)	9,02 (2,189)	
95 %-KI	[-0,669; 7,208]	[4,705; 13,327]	
Veränderung zu Woche 36			
n/N (%)	51/99 (52)	34/87 (39)	LS MD -7,64 [-14,604; -0,673]
MW (SD)	3,27 (28,091)	12,25 (31,598)	
LS MW (SE)	4,89 (2,306)	12,53 (2,694)	
95 %-KI	[0,354; 9,424]	[7,235; 17,820]	
Veränderung zu Woche 48			
n/N (%)	5/87 (6)	2/72 (3)	LS MD -9,53 [-18,110; -0,949]
MW (SD)	3,33 (47,726)	-33,33 (0,000)	
LS MW (SE)	6,51 (2,769)	16,04 (3,383)	
95 %-KI	[1,072; 11,945]	[9,398; 22,678]	
<b>Baseline ECOG PS: 1</b>			
Baseline			
n/N (%)	75/90 (83)	61/91 (67)	-
MW (SD)	32,22 (29,553)	40,44 (30,194)	
Absolute Werte zum Studienende			
n/N (%)	3/53 (6)	3/37 (8)	-
MW (SD)	11,11 (19,245)	11,11 (9,623)	
Effekt über Studiendauer			
n	75	61	LS MD -0,70 [-9,082; 7,675] 0,8683
LS MW (SE)	-0,84 (2,792)	-0,14 (3,164)	
95 %-KI	[-6,363; 4,684]	[-6,393; 6,121]	Hedges' g -0,03 [-0,367; 0,309]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	49/86 (57)	45/87 (52)	LS MD 3,63 [-4,938; 12,189]
MW (SD)	5,78 (32,014)	-8,89 (26,256)	
LS MW (SE)	-1,09 (2,871)	-4,72 (3,225)	
95 %-KI	[-6,768; 4,581]	[-11,091; 1,653]	
Veränderung zu Woche 8/9			
n/N (%)	59/84 (70)	49/78 (63)	LS MD 1,64 [-6,752; 10,032]
MW (SD)	-3,39 (29,325)	-5,78 (29,177)	
LS MW (SE)	-0,98 (2,811)	-2,62 (3,158)	
95 %-KI	[-6,536; 4,582]	[-8,861; 3,627]	
Veränderung zu Woche 12			
n/N (%)	44/83 (53)	25/74 (34)	LS MD 0,25 [-8,109; 8,609]
MW (SD)	-4,92 (27,275)	-2,00 (13,878)	
LS MW (SE)	-0,90 (2,793)	-1,15 (3,150)	
95 %-KI	[-6,420; 4,629]	[-7,376; 5,085]	
Veränderung zu Woche 15/16			
n/N (%)	40/79 (51)	20/72 (28)	LS MD -1,14 [-9,538; 7,259]
MW (SD)	-8,33 (28,244)	-18,33 (25,305)	
LS MW (SE)	-0,81 (2,795)	0,33 (3,176)	
95 %-KI	[-6,343; 4,716]	[-5,954; 6,605]	
Veränderung zu Woche 20/21			
n/N (%)	26/73 (36)	18/63 (29)	LS MD -3,13 [-11,704; 5,453]
MW (SD)	-11,54 (28,193)	-19,44 (24,421)	
LS MW (SE)	-0,70 (2,834)	2,43 (3,268)	
95 %-KI	[-6,301; 4,906]	[-4,028; 8,883]	
Veränderung zu Woche 24			
n/N (%)	27/72 (38)	15/58 (26)	LS MD -4,52 [-13,302; 4,272]
MW (SD)	-3,70 (28,244)	-7,78 (28,776)	
LS MW (SE)	-0,62 (2,885)	3,90 (3,368)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,317; 5,085]	[-2,749; 10,547]	
Veränderung zu Woche 36			
n/N (%)	30/61 (49)	12/46 (26)	LS MD -9,28 [-19,230; 0,669]
MW (SD)	-3,33 (21,620)	11,11 (27,828)	
LS MW (SE)	-0,34 (3,192)	8,94 (3,900)	
95 %-KI	[-6,628; 5,955]	[1,268; 16,620]	
Veränderung zu Woche 48			
n/N (%)	3/53 (6)	2/37 (5)	LS MD -14,05 [-25,681; -2,411]
MW (SD)	0,00 (0,000)	8,33 (11,785)	
LS MW (SE)	-0,06 (3,660)	13,99 (4,639)	
95 %-KI	[-7,256; 7,143]	[4,874; 23,104]	
<b>Anzahl vorheriger Therapielinien: 1</b>			
Baseline			
n/N (%)	24/31 (77)	23/29 (79)	-
MW (SD)	30,56 (31,341)	23,19 (22,326)	
Absolute Werte zum Studienende			
n/N (%)	1/22 (5)	0/14 (0)	-
MW (SD)	0,00 (NA)	NA (NA)	
Effekt über Studiendauer			
n	24	23	LS MD -11,85 [-24,000; 0,291] 0,0555
LS MW (SE)	-6,22 (4,182)	5,64 (4,312)	
95 %-KI	[-14,654; 2,220]	[-3,046; 14,321]	Hedges' g -0,57 [-1,151; 0,018]
Veränderung zu Woche 3/4			
n/N (%)	16/31 (52)	15/29 (52)	LS MD -5,46 [-18,221; 7,304]
MW (SD)	-5,21 (30,863)	-4,44 (18,330)	
LS MW (SE)	-8,98 (4,420)	-3,52 (4,563)	
95 %-KI	[-17,847; -0,113]	[-12,660; 5,617]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	20/31 (65)	18/26 (69)	LS MD -8,15 [-20,441; 4,142]
MW (SD)	-10,83 (24,348)	-0,93 (32,070)	
LS MW (SE)	-7,82 (4,265)	0,33 (4,350)	
95 %-KI	[-16,404; 0,769]	[-8,418; 9,082]	
Veränderung zu Woche 12			
n/N (%)	14/31 (45)	12/24 (50)	LS MD -10,03 [-22,176; 2,110]
MW (SD)	-14,29 (27,625)	4,17 (20,257)	
LS MW (SE)	-7,00 (4,203)	3,03 (4,292)	
95 %-KI	[-15,479; 1,472]	[-5,618; 11,676]	
Veränderung zu Woche 15/16			
n/N (%)	15/31 (48)	11/22 (50)	LS MD -11,92 [-24,065; 0,231]
MW (SD)	-4,44 (21,331)	-1,52 (32,876)	
LS MW (SE)	-6,19 (4,182)	5,73 (4,314)	
95 %-KI	[-14,627; 2,247]	[-2,961; 14,414]	
Veränderung zu Woche 20/21			
n/N (%)	11/30 (37)	9/22 (41)	LS MD -14,61 [-27,028; -2,187]
MW (SD)	-4,55 (23,677)	-7,41 (22,222)	
LS MW (SE)	-5,03 (4,221)	9,58 (4,479)	
95 %-KI	[-13,537; 3,481]	[0,591; 18,569]	
Veränderung zu Woche 24			
n/N (%)	9/30 (30)	11/20 (55)	LS MD -16,49 [-29,281; -3,702]
MW (SD)	-5,56 (22,048)	1,52 (20,350)	
LS MW (SE)	-4,21 (4,298)	12,28 (4,680)	
95 %-KI	[-12,861; 4,432]	[2,916; 21,639]	
Veränderung zu Woche 36			
n/N (%)	15/26 (58)	6/18 (33)	LS MD -22,95 [-37,964; -7,936]
MW (SD)	1,11 (22,242)	19,44 (12,546)	
LS MW (SE)	-1,42 (4,828)	21,53 (5,781)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-11,047; 8,199]	[10,079; 32,973]	
Veränderung zu Woche 48			
n/N (%)	0/22 (0)	0/14 (0)	LS MD -29,41 [-47,703; -11,114]
MW (SD)	NA (NA)	NA (NA)	
LS MW (SE)	1,37 (5,674)	30,77 (7,279)	
95 %-KI	[-9,862; 12,592]	[16,425; 45,122]	
<b>Anzahl vorheriger Therapielinien: 2</b>			
Baseline			
n/N (%)	75/89 (84)	65/83 (78)	-
MW (SD)	23,11 (24,027)	30,77 (26,717)	
Absolute Werte zum Studienende			
n/N (%)	4/59 (7)	2/50 (4)	-
MW (SD)	41,67 (34,694)	8,33 (11,785)	
Effekt über Studiendauer			
n	75	65	LS MD 0,66 [-6,041; 7,353] 0,8467  Hedges' g 0,03 [-0,299; 0,365]
LS MW (SE)	1,32 (2,258)	0,66 (2,500)	
95 %-KI	[-3,146; 5,786]	[-4,278; 5,605]	
Veränderung zu Woche 3/4			
n/N (%)	52/86 (60)	46/80 (57)	LS MD 3,71 [-3,296; 10,718]
MW (SD)	4,17 (23,309)	-7,61 (26,225)	
LS MW (SE)	1,01 (2,371)	-2,70 (2,611)	
95 %-KI	[-3,674; 5,690]	[-7,856; 2,450]	
Veränderung zu Woche 8/9			
n/N (%)	63/85 (74)	52/77 (68)	LS MD 2,34 [-4,410; 9,085]
MW (SD)	0,79 (25,476)	-2,24 (24,484)	
LS MW (SE)	1,15 (2,289)	-1,19 (2,505)	
95 %-KI	[-3,377; 5,673]	[-6,140; 3,761]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	39/83 (47)	31/75 (41)	LS MD 1,38 [-5,306; 8,057]
MW (SD)	3,42 (27,354)	5,38 (20,361)	
LS MW (SE)	1,25 (2,261)	-0,13 (2,485)	
95 %-KI	[-3,227; 5,719]	[-5,042; 4,783]	
Veränderung zu Woche 15/16			
n/N (%)	41/80 (51)	19/74 (26)	LS MD 0,41 [-6,300; 7,129]
MW (SD)	-2,85 (31,381)	-7,02 (27,395)	
LS MW (SE)	1,34 (2,260)	0,93 (2,511)	
95 %-KI	[-3,126; 5,814]	[-4,032; 5,892]	
Veränderung zu Woche 20/21			
n/N (%)	31/78 (40)	21/68 (31)	LS MD -0,96 [-7,889; 5,970]
MW (SD)	-2,69 (21,983)	-3,97 (30,689)	
LS MW (SE)	1,48 (2,302)	2,44 (2,625)	
95 %-KI	[-3,067; 6,036]	[-2,737; 7,625]	
Veränderung zu Woche 24			
n/N (%)	27/74 (36)	13/65 (20)	LS MD -1,92 [-9,111; 5,268]
MW (SD)	-4,32 (25,146)	0,00 (35,355)	
LS MW (SE)	1,58 (2,362)	3,50 (2,753)	
95 %-KI	[-3,084; 6,249]	[-1,925; 8,932]	
Veränderung zu Woche 36			
n/N (%)	33/65 (51)	19/58 (33)	LS MD -5,22 [-13,850; 3,414]
MW (SD)	0,51 (21,034)	10,53 (25,586)	
LS MW (SE)	1,92 (2,726)	7,14 (3,419)	
95 %-KI	[-3,450; 7,287]	[0,416; 13,858]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	1/50 (2)	LS MD -8,51 [-19,158; 2,128]
MW (SD)	20,83 (31,549)	0,00 (NA)	
LS MW (SE)	2,25 (3,267)	10,77 (4,302)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-4,165; 8,675]	[2,324; 19,216]	
<b>Anzahl vorheriger Therapielinien: 3</b>			
Baseline			
n/N (%)	77/98 (79)	70/95 (74)	-
MW (SD)	26,41 (28,530)	30,24 (30,468)	
Absolute Werte zum Studienende			
n/N (%)	5/59 (8)	4/46 (9)	-
MW (SD)	23,33 (25,276)	8,33 (9,623)	
Effekt über Studiendauer			
n	77	70	LS MD -2,64 [-10,206; 4,924] 0,4913  Hedges' g -0,11 [-0,437; 0,211]
LS MW (SE)	2,90 (2,614)	5,54 (2,811)	
95 %-KI	[-2,264; 8,072]	[-0,011; 11,101]	
Veränderung zu Woche 3/4			
n/N (%)	48/96 (50)	48/91 (53)	LS MD -1,42 [-9,222; 6,390]
MW (SD)	6,25 (26,548)	1,39 (23,276)	
LS MW (SE)	1,78 (2,706)	3,20 (2,898)	
95 %-KI	[-3,564; 7,124]	[-2,526; 8,918]	
Veränderung zu Woche 8/9			
n/N (%)	60/94 (64)	54/85 (64)	LS MD -1,96 [-9,566; 5,650]
MW (SD)	-0,56 (34,848)	3,40 (32,276)	
LS MW (SE)	2,28 (2,637)	4,24 (2,821)	
95 %-KI	[-2,935; 7,490]	[-1,339; 9,810]	
Veränderung zu Woche 12			
n/N (%)	44/91 (48)	29/84 (35)	LS MD -2,34 [-9,893; 5,218]
MW (SD)	-3,79 (29,392)	-0,00 (22,713)	
LS MW (SE)	2,63 (2,616)	4,96 (2,803)	
95 %-KI	[-2,545; 7,797]	[-0,577; 10,504]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	40/88 (45)	23/82 (28)	LS MD -2,72 [-10,292; 4,858]
MW (SD)	2,92 (28,467)	-3,62 (32,160)	
LS MW (SE)	2,97 (2,616)	5,69 (2,816)	
95 %-KI	[-2,198; 8,146]	[0,125; 11,257]	
Veränderung zu Woche 20/21			
n/N (%)	24/82 (29)	20/75 (27)	LS MD -3,26 [-10,987; 4,468]
MW (SD)	-4,17 (36,860)	-2,50 (30,240)	
LS MW (SE)	3,47 (2,656)	6,73 (2,887)	
95 %-KI	[-1,776; 8,719]	[1,029; 12,433]	
Veränderung zu Woche 24			
n/N (%)	19/80 (24)	14/70 (20)	LS MD -3,64 [-11,556; 4,278]
MW (SD)	8,77 (28,528)	3,57 (27,095)	
LS MW (SE)	3,82 (2,710)	7,46 (2,972)	
95 %-KI	[-1,531; 9,171]	[1,594; 13,323]	
Veränderung zu Woche 36			
n/N (%)	33/69 (48)	21/58 (36)	LS MD -4,94 [-13,957; 4,076]
MW (SD)	1,01 (31,988)	11,11 (37,761)	
LS MW (SE)	5,01 (3,037)	9,95 (3,441)	
95 %-KI	[-0,969; 10,996]	[3,182; 16,726]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	3/46 (7)	LS MD -6,24 [-16,875; 4,391]
MW (SD)	-16,67 (33,333)	-16,67 (28,868)	
LS MW (SE)	6,21 (3,535)	12,45 (4,110)	
95 %-KI	[-0,741; 13,156]	[4,375; 20,524]	
<b>Vorherige Verabreichung von Bevacizumab: Ja</b>			
Baseline			
n/N (%)	105/134 (78)	100/132 (76)	-
MW (SD)	23,49 (23,536)	32,50 (29,906)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	3/79 (4)	3/62 (5)	-
MW (SD)	55,56 (25,459)	5,56 (9,623)	
Effekt über Studiendauer			
n	105	100	LS MD -0,89 [-7,004; 5,219] 0,7737  Hedges' g -0,04 [-0,314; 0,234]
LS MW (SE)	2,78 (2,110)	3,68 (2,251)	
95 %-KI	[-1,378; 6,944]	[-0,763; 8,114]	
Veränderung zu Woche 3/4			
n/N (%)	67/130 (52)	69/127 (54)	LS MD 2,62 [-3,732; 8,970]
MW (SD)	6,72 (24,110)	-3,14 (26,240)	
LS MW (SE)	2,76 (2,201)	0,14 (2,332)	
95 %-KI	[-1,573; 7,099]	[-4,450; 4,739]	
Veränderung zu Woche 8/9			
n/N (%)	84/130 (65)	75/119 (63)	LS MD 0,98 [-5,162; 7,127]
MW (SD)	2,18 (27,597)	-1,11 (30,429)	
LS MW (SE)	2,77 (2,133)	1,79 (2,251)	
95 %-KI	[-1,433; 6,978]	[-2,648; 6,227]	
Veränderung zu Woche 12			
n/N (%)	55/126 (44)	38/114 (33)	LS MD -0,16 [-6,261; 5,935]
MW (SD)	2,42 (31,332)	-1,75 (18,900)	
LS MW (SE)	2,78 (2,112)	2,94 (2,239)	
95 %-KI	[-1,386; 6,944]	[-1,473; 7,357]	
Veränderung zu Woche 15/16			
n/N (%)	58/122 (48)	32/112 (29)	LS MD -1,31 [-7,443; 4,826]
MW (SD)	2,59 (29,912)	-6,77 (30,190)	
LS MW (SE)	2,79 (2,113)	4,09 (2,265)	
95 %-KI	[-1,382; 6,952]	[-0,371; 8,559]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	38/114 (33)	28/103 (27)	LS MD -2,94 [-9,272; 3,383]
MW (SD)	-0,44 (28,073)	-9,52 (26,616)	
LS MW (SE)	2,79 (2,153)	5,74 (2,366)	
95 %-KI	[-1,450; 7,039]	[1,080; 10,399]	
Veränderung zu Woche 24			
n/N (%)	30/109 (28)	17/95 (18)	LS MD -4,09 [-10,645; 2,464]
MW (SD)	5,56 (22,030)	5,88 (31,700)	
LS MW (SE)	2,80 (2,207)	6,89 (2,476)	
95 %-KI	[-1,547; 7,150]	[2,019; 11,764]	
Veränderung zu Woche 36			
n/N (%)	44/93 (47)	22/79 (28)	LS MD -8,02 [-15,815; -0,220]
MW (SD)	1,14 (25,769)	13,64 (31,971)	
LS MW (SE)	2,82 (2,529)	10,84 (3,042)	
95 %-KI	[-2,149; 7,797]	[4,866; 16,816]	
Veränderung zu Woche 48			
n/N (%)	3/79 (4)	2/62 (3)	LS MD -11,94 [-21,472; -2,417]
MW (SD)	22,22 (38,490)	-16,67 (23,570)	
LS MW (SE)	2,85 (3,006)	14,79 (3,793)	
95 %-KI	[-3,057; 8,750]	[7,346; 22,235]	
<b>Vorherige Verabreichung von Bevacizumab: Nein</b>			
Baseline			
n/N (%)	71/84 (85)	58/75 (77)	-
MW (SD)	28,64 (31,520)	24,14 (23,189)	
Absolute Werte zum Studienende			
n/N (%)	7/61 (11)	3/48 (6)	-
MW (SD)	16,67 (23,570)	11,11 (9,623)	
Effekt über Studiendauer			
n	71	58	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-2,06 (2,458)	3,61 (2,739)	LS MD -5,66 [-12,952; 1,628] 0,1268  Hedges' g -0,27 [-0,619; 0,078]
95 %-KI	[-6,920; 2,809]	[-1,814; 9,027]	
Veränderung zu Woche 3/4			
n/N (%)	49/83 (59)	40/73 (55)	LS MD -3,73 [-11,339; 3,877]
MW (SD)	-0,34 (27,741)	-3,33 (20,395)	
LS MW (SE)	-4,19 (2,569)	-0,46 (2,865)	
95 %-KI	[-9,268; 0,887]	[-6,119; 5,200]	
Veränderung zu Woche 8/9			
n/N (%)	59/80 (74)	49/69 (71)	LS MD -4,53 [-11,900; 2,841]
MW (SD)	-6,50 (32,017)	2,72 (27,077)	
LS MW (SE)	-3,31 (2,492)	1,22 (2,767)	
95 %-KI	[-8,238; 1,622]	[-4,251; 6,693]	
Veränderung zu Woche 12			
n/N (%)	42/79 (53)	34/69 (49)	LS MD -5,09 [-12,380; 2,204]
MW (SD)	-8,73 (23,639)	8,33 (22,567)	
LS MW (SE)	-2,69 (2,464)	2,40 (2,736)	
95 %-KI	[-7,566; 2,186]	[-3,016; 7,812]	
Veränderung zu Woche 15/16			
n/N (%)	38/77 (49)	21/66 (32)	LS MD -5,65 [-12,936; 1,642]
MW (SD)	-5,70 (26,360)	-0,79 (30,494)	
LS MW (SE)	-2,07 (2,457)	3,57 (2,739)	
95 %-KI	[-6,936; 2,792]	[-1,844; 8,994]	
Veränderung zu Woche 20/21			
n/N (%)	28/76 (37)	22/62 (35)	LS MD -6,45 [-13,860; 0,970]
MW (SD)	-7,74 (28,139)	3,03 (30,271)	
LS MW (SE)	-1,19 (2,487)	5,26 (2,799)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,111; 3,732]	[-0,279; 10,790]	
Veränderung zu Woche 24			
n/N (%)	25/75 (33)	21/60 (35)	LS MD -7,00 [-14,595; 0,587]
MW (SD)	-6,67 (29,659)	-1,59 (24,667)	
LS MW (SE)	-0,57 (2,534)	6,43 (2,879)	
95 %-KI	[-5,583; 4,439]	[0,745; 12,120]	
Veränderung zu Woche 36			
n/N (%)	37/67 (55)	24/55 (44)	LS MD -8,92 [-17,589; -0,251]
MW (SD)	0,45 (26,494)	10,42 (29,411)	
LS MW (SE)	1,55 (2,841)	10,47 (3,349)	
95 %-KI	[-4,053; 7,146]	[3,872; 17,062]	
Veränderung zu Woche 48			
n/N (%)	5/61 (8)	2/48 (4)	LS MD -10,84 [-21,128; -0,544]
MW (SD)	-10,00 (32,489)	-8,33 (35,355)	
LS MW (SE)	3,67 (3,318)	14,50 (4,034)	
95 %-KI	[-2,860; 10,190]	[6,573; 22,429]	
<b>Letztes Platin-freies Intervall: ≤ 3 Monate</b>			
Baseline			
n/N (%)	68/83 (82)	61/91 (67)	-
MW (SD)	20,34 (23,718)	32,79 (29,809)	
Absolute Werte zum Studienende			
n/N (%)	3/55 (5)	5/39 (13)	-
MW (SD)	44,44 (41,944)	6,67 (9,129)	
Effekt über Studiendauer			
n	68	61	LS MD -5,49 [-13,698; 2,726] 0,1885
LS MW (SE)	3,28 (2,772)	8,77 (3,037)	
95 %-KI	[-2,202; 8,771]	[2,761; 14,779]	Hedges' g -0,23 [-0,581; 0,112]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	49/82 (60)	45/86 (52)	LS MD -2,76 [-11,229; 5,703]
MW (SD)	6,80 (27,411)	3,33 (27,432)	
LS MW (SE)	3,98 (2,867)	6,75 (3,123)	
95 %-KI	[-1,685; 9,652]	[0,574; 12,919]	
Veränderung zu Woche 8/9			
n/N (%)	52/81 (64)	45/80 (56)	LS MD -4,02 [-12,268; 4,219]
MW (SD)	5,45 (30,379)	1,48 (34,234)	
LS MW (SE)	3,66 (2,790)	7,68 (3,038)	
95 %-KI	[-1,861; 9,181]	[1,674; 13,695]	
Veränderung zu Woche 12			
n/N (%)	33/78 (42)	25/78 (32)	LS MD -4,91 [-13,103; 3,287]
MW (SD)	1,52 (26,142)	2,67 (27,504)	
LS MW (SE)	3,43 (2,770)	8,34 (3,025)	
95 %-KI	[-2,049; 8,915]	[2,355; 14,326]	
Veränderung zu Woche 15/16			
n/N (%)	35/76 (46)	13/75 (17)	LS MD -5,79 [-14,027; 2,445]
MW (SD)	1,43 (35,785)	-5,13 (36,251)	
LS MW (SE)	3,21 (2,778)	9,00 (3,050)	
95 %-KI	[-2,291; 8,704]	[2,963; 15,031]	
Veränderung zu Woche 20/21			
n/N (%)	22/72 (31)	13/67 (19)	LS MD -7,05 [-15,501; 1,396]
MW (SD)	-3,79 (27,183)	6,41 (30,076)	
LS MW (SE)	2,88 (2,838)	9,94 (3,151)	
95 %-KI	[-2,730; 8,495]	[3,707; 16,163]	
Veränderung zu Woche 24			
n/N (%)	16/72 (22)	12/62 (19)	LS MD -7,94 [-16,634; 0,763]
MW (SD)	-4,17 (23,174)	5,56 (29,588)	
LS MW (SE)	2,66 (2,912)	10,59 (3,264)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,099; 8,410]	[4,147; 17,036]	
Veränderung zu Woche 36			
n/N (%)	28/63 (44)	16/50 (32)	LS MD -10,96 [-21,053; -0,875]
MW (SD)	1,79 (29,165)	10,42 (42,546)	
LS MW (SE)	1,88 (3,339)	12,84 (3,863)	
95 %-KI	[-4,700; 8,456]	[5,239; 20,446]	
Veränderung zu Woche 48			
n/N (%)	2/55 (4)	3/39 (8)	LS MD -13,99 [-26,064; -1,920]
MW (SD)	33,33 (47,140)	-22,22 (19,245)	
LS MW (SE)	1,10 (3,960)	15,09 (4,686)	
95 %-KI	[-6,684; 8,886]	[5,886; 24,300]	
<b>Letztes Platin-freies Intervall: &gt; 3 Monate</b>			
Baseline			
n/N (%)	108/135 (80)	97/116 (84)	-
MW (SD)	28,86 (28,606)	27,32 (26,482)	
Absolute Werte zum Studienende			
n/N (%)	7/85 (8)	1/71 (1)	-
MW (SD)	21,43 (23,002)	16,67 (NA)	
Effekt über Studiendauer			
n	108	97	LS MD -1,46 [-6,999; 4,089] 0,6054
LS MW (SE)	-0,89 (1,916)	0,57 (2,062)	
95 %-KI	[-4,665; 2,891]	[-3,497; 4,633]	Hedges' g -0,07 [-0,346; 0,202]
Veränderung zu Woche 3/4			
n/N (%)	67/131 (51)	64/114 (56)	LS MD 1,90 [-3,917; 7,720]
MW (SD)	1,49 (24,572)	-7,81 (20,567)	
LS MW (SE)	-2,61 (2,013)	-4,51 (2,166)	
95 %-KI	[-6,577; 1,355]	[-8,779; -0,245]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	91/129 (71)	79/108 (73)	LS MD 0,45 [-5,151; 6,060]
MW (SD)	-5,31 (28,747)	-0,21 (25,943)	
LS MW (SE)	-1,87 (1,946)	-2,32 (2,078)	
95 %-KI	[-5,704; 1,969]	[-6,418; 1,773]	
Veränderung zu Woche 12			
n/N (%)	64/127 (50)	47/105 (45)	LS MD -0,56 [-6,099; 4,982]
MW (SD)	-4,43 (29,880)	3,19 (17,250)	
LS MW (SE)	-1,35 (1,921)	-0,79 (2,055)	
95 %-KI	[-5,136; 2,442]	[-4,840; 3,262]	
Veränderung zu Woche 15/16			
n/N (%)	61/123 (50)	40/103 (39)	LS MD -1,57 [-7,120; 3,978]
MW (SD)	-1,91 (23,979)	-4,17 (28,432)	
LS MW (SE)	-0,83 (1,916)	0,74 (2,065)	
95 %-KI	[-4,606; 2,952]	[-3,327; 4,814]	
Veränderung zu Woche 20/21			
n/N (%)	44/118 (37)	37/98 (38)	LS MD -3,02 [-8,703; 2,667]
MW (SD)	-3,41 (28,885)	-7,66 (27,665)	
LS MW (SE)	-0,08 (1,942)	2,93 (2,136)	
95 %-KI	[-3,913; 3,745]	[-1,275; 7,142]	
Veränderung zu Woche 24			
n/N (%)	39/112 (35)	26/93 (28)	LS MD -4,03 [-9,894; 1,833]
MW (SD)	1,71 (27,518)	0,00 (27,487)	
LS MW (SE)	0,44 (1,983)	4,47 (2,223)	
95 %-KI	[-3,472; 4,344]	[0,091; 8,843]	
Veränderung zu Woche 36			
n/N (%)	53/97 (55)	30/84 (36)	LS MD -7,50 [-14,404; -0,601]
MW (SD)	0,31 (24,348)	12,78 (22,181)	
LS MW (SE)	2,22 (2,247)	9,72 (2,699)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-2,200; 6,639]	[4,421; 15,024]	
Veränderung zu Woche 48			
n/N (%)	6/85 (7)	1/71 (1)	LS MD -10,98 [-19,374; -2,576]
MW (SD)	-8,33 (29,345)	16,67 (NA)	
LS MW (SE)	4,00 (2,654)	14,98 (3,354)	
95 %-KI	[-1,210; 9,216]	[8,396; 21,560]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Pegyliertes liposomales Doxorubicin</b>			
Baseline			
n/N (%)	61/80 (76)	57/76 (75)	-
MW (SD)	27,05 (26,730)	29,24 (25,448)	
Absolute Werte zum Studienende			
n/N (%)	3/51 (6)	3/41 (7)	-
MW (SD)	16,67 (28,868)	11,11 (9,623)	
Effekt über Studiendauer			
n	61	57	LS MD -6,23 [-13,094; 0,644] 0,0753  Hedges' g -0,33 [-0,693; 0,035]
LS MW (SE)	-2,51 (2,365)	3,72 (2,534)	
95 %-KI	[-7,198; 2,178]	[-1,303; 8,734]	
Veränderung zu Woche 3/4			
n/N (%)	38/76 (50)	43/74 (58)	LS MD -3,12 [-10,379; 4,147]
MW (SD)	-1,75 (24,748)	-1,16 (20,378)	
LS MW (SE)	-2,73 (2,535)	0,39 (2,657)	
95 %-KI	[-7,736; 2,284]	[-4,862; 5,641]	
Veränderung zu Woche 8/9			
n/N (%)	51/76 (67)	43/66 (65)	LS MD -4,46 [-11,406; 2,485]
MW (SD)	-3,59 (27,144)	-0,39 (25,325)	
LS MW (SE)	-2,63 (2,421)	1,83 (2,537)	
95 %-KI	[-7,426; 2,161]	[-3,195; 6,851]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	32/75 (43)	23/64 (36)	LS MD -5,40 [-12,257; 1,454]
MW (SD)	-4,69 (28,155)	5,80 (17,844)	
LS MW (SE)	-2,57 (2,378)	2,83 (2,513)	
95 %-KI	[-7,278; 2,144]	[-2,143; 7,813]	
Veränderung zu Woche 15/16			
n/N (%)	34/74 (46)	18/62 (29)	LS MD -6,34 [-13,222; 0,535]
MW (SD)	-1,96 (27,144)	-4,63 (30,682)	
LS MW (SE)	-2,50 (2,366)	3,84 (2,541)	
95 %-KI	[-7,190; 2,187]	[-1,189; 8,872]	
Veränderung zu Woche 20/21			
n/N (%)	26/72 (36)	18/59 (31)	LS MD -7,69 [-14,792; -0,583]
MW (SD)	-5,13 (28,193)	-10,19 (23,666)	
LS MW (SE)	-2,41 (2,404)	5,28 (2,665)	
95 %-KI	[-7,169; 2,354]	[0,011; 10,550]	
Veränderung zu Woche 24			
n/N (%)	22/69 (32)	16/54 (30)	LS MD -8,63 [-16,018; -1,240]
MW (SD)	-4,55 (25,811)	-1,04 (20,610)	
LS MW (SE)	-2,34 (2,468)	6,29 (2,806)	
95 %-KI	[-7,226; 2,542]	[0,747; 11,827]	
Veränderung zu Woche 36			
n/N (%)	30/60 (50)	16/48 (33)	LS MD -11,86 [-20,847; -2,867]
MW (SD)	-0,56 (27,152)	9,38 (31,013)	
LS MW (SE)	-2,12 (2,884)	9,74 (3,534)	
95 %-KI	[-7,801; 3,567]	[2,789; 16,690]	
Veränderung zu Woche 48			
n/N (%)	2/51 (4)	2/41 (5)	LS MD -15,08 [-26,304; -3,864]
MW (SD)	8,33 (11,785)	-16,67 (23,570)	
LS MW (SE)	-1,89 (3,512)	13,19 (4,489)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-8,797; 5,012]	[4,374; 22,010]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Paclitaxel</b>			
Baseline			
n/N (%)	76/88 (86)	69/82 (84)	-
MW (SD)	27,63 (28,357)	32,37 (30,098)	
Absolute Werte zum Studienende			
n/N (%)	1/56 (2)	1/49 (2)	-
MW (SD)	83,33 (NA)	0,00 (NA)	
Effekt über Studiendauer			
n	76	69	LS MD -0,03 [-7,451; 7,386] 0,9931  Hedges' g -0,00 [-0,327; 0,324]
LS MW (SE)	1,69 (2,561)	1,72 (2,747)	
95 %-KI	[-3,373; 6,755]	[-3,705; 7,152]	
Veränderung zu Woche 3/4			
n/N (%)	55/87 (63)	48/81 (59)	LS MD 1,62 [-6,086; 9,332]
MW (SD)	5,15 (22,193)	-5,56 (29,240)	
LS MW (SE)	-1,21 (2,663)	-2,83 (2,858)	
95 %-KI	[-6,471; 4,047]	[-8,476; 2,807]	
Veränderung zu Woche 8/9			
n/N (%)	62/86 (72)	54/79 (68)	LS MD 0,87 [-6,604; 8,338]
MW (SD)	-1,34 (33,510)	-2,78 (33,136)	
LS MW (SE)	0,11 (2,586)	-0,75 (2,760)	
95 %-KI	[-4,998; 5,226]	[-6,206; 4,700]	
Veränderung zu Woche 12			
n/N (%)	44/84 (52)	37/77 (48)	LS MD 0,34 [-7,072; 7,747]
MW (SD)	-1,89 (31,585)	2,25 (26,106)	
LS MW (SE)	1,04 (2,563)	0,70 (2,738)	
95 %-KI	[-4,025; 6,108]	[-4,708; 6,116]	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	46/81 (57)	27/76 (36)	LS MD -0,19 [-7,628; 7,245]
MW (SD)	-0,36 (31,523)	-7,41 (33,440)	
LS MW (SE)	1,97 (2,565)	2,16 (2,756)	
95 %-KI	[-3,101; 7,040]	[-3,286; 7,609]	
Veränderung zu Woche 20/21			
n/N (%)	29/77 (38)	25/73 (34)	LS MD -0,95 [-8,574; 6,678]
MW (SD)	1,72 (30,971)	-0,67 (35,185)	
LS MW (SE)	3,30 (2,612)	4,24 (2,850)	
95 %-KI	[-1,866; 8,456]	[-1,384; 9,870]	
Veränderung zu Woche 24			
n/N (%)	22/74 (30)	19/72 (26)	LS MD -1,48 [-9,336; 6,382]
MW (SD)	5,30 (26,917)	4,39 (35,067)	
LS MW (SE)	4,22 (2,674)	5,70 (2,959)	
95 %-KI	[-1,058; 9,504]	[-0,136; 11,537]	
Veränderung zu Woche 36			
n/N (%)	36/64 (56)	22/63 (35)	LS MD -3,29 [-12,473; 5,889]
MW (SD)	5,09 (26,373)	13,64 (33,585)	
LS MW (SE)	7,40 (3,048)	10,70 (3,549)	
95 %-KI	[1,402; 13,406]	[3,717; 17,675]	
Veränderung zu Woche 48			
n/N (%)	1/56 (2)	0/49 (0)	LS MD -5,11 [-16,181; 5,968]
MW (SD)	66,67 (NA)	NA (NA)	
LS MW (SE)	10,59 (3,604)	15,69 (4,361)	
95 %-KI	[3,503; 17,668]	[7,129; 24,255]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Topotecan</b>			
Baseline			
n/N (%)	39/50 (78)	32/49 (65)	-
MW (SD)	19,23 (24,643)	23,44 (26,727)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	6/33 (18)	2/20 (10)	-
MW (SD)	25,00 (22,973)	8,33 (11,785)	
Effekt über Studiendauer			
n	39	32	LS MD -3,06 [-14,173; 8,053] 0,5845  Hedges' g -0,13 [-0,597; 0,339]
LS MW (SE)	5,20 (3,711)	8,26 (4,180)	
95 %-KI	[-2,209; 12,604]	[-0,080; 16,595]	
Veränderung zu Woche 3/4			
n/N (%)	23/50 (46)	18/45 (40)	LS MD 0,74 [-10,571; 12,054]
MW (SD)	9,42 (34,018)	-1,85 (17,044)	
LS MW (SE)	5,92 (3,776)	5,18 (4,269)	
95 %-KI	[-1,608; 13,448]	[-3,325; 13,682]	
Veränderung zu Woche 8/9			
n/N (%)	30/48 (62)	27/43 (63)	LS MD -0,88 [-12,016; 10,258]
MW (SD)	2,22 (25,795)	8,02 (25,474)	
LS MW (SE)	5,61 (3,724)	6,49 (4,190)	
95 %-KI	[-1,820; 13,043]	[-1,866; 14,848]	
Veränderung zu Woche 12			
n/N (%)	21/46 (46)	12/42 (29)	LS MD -2,01 [-13,108; 9,080]
MW (SD)	0,00 (23,570)	0,00 (0,000)	
LS MW (SE)	5,40 (3,709)	7,41 (4,171)	
95 %-KI	[-2,007; 12,800]	[-0,911; 15,731]	
Veränderung zu Woche 15/16			
n/N (%)	16/44 (36)	8/40 (20)	LS MD -3,15 [-14,265; 7,969]
MW (SD)	1,04 (24,697)	6,25 (12,400)	
LS MW (SE)	5,18 (3,712)	8,33 (4,181)	
95 %-KI	[-2,228; 12,589]	[-0,012; 16,670]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	11/41 (27)	7/33 (21)	LS MD -4,77 [-16,033; 6,495]
MW (SD)	-13,64 (16,361)	0,00 (0,000)	
LS MW (SE)	4,87 (3,746)	9,64 (4,248)	
95 %-KI	[-2,599; 12,344]	[1,177; 18,106]	
Veränderung zu Woche 24			
n/N (%)	11/41 (27)	3/29 (10)	LS MD -5,90 [-17,349; 5,542]
MW (SD)	-1,52 (26,304)	0,00 (0,000)	
LS MW (SE)	4,66 (3,791)	10,56 (4,328)	
95 %-KI	[-2,898; 12,212]	[1,945; 19,176]	
Veränderung zu Woche 36			
n/N (%)	15/36 (42)	8/23 (35)	LS MD -9,79 [-22,304; 2,717]
MW (SD)	-6,67 (21,639)	12,50 (21,362)	
LS MW (SE)	3,92 (4,066)	13,71 (4,797)	
95 %-KI	[-4,154; 11,989]	[4,209; 23,213]	
Veränderung zu Woche 48			
n/N (%)	5/33 (15)	2/20 (10)	LS MD -13,68 [-27,828; 0,461]
MW (SD)	-13,33 (29,814)	-8,33 (35,355)	
LS MW (SE)	3,18 (4,498)	16,86 (5,497)	
95 %-KI	[-5,718; 12,074]	[6,014; 27,709]	
<p><i>Analysepopulation: ITT</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023</i></p> <p><i>Modell: Veränderung zu Baseline ~ Behandlung + Baseline-Wert * Zeit in Wochen + Behandlung * Zeit in Wochen + zufällige Effekte durch die Patientin</i></p> <p><i>Die Berechnung des LS-MWs erfolgt durch ein MMRM mit dem oben angegebenen Modell. Basierend hierauf werden KI und p-Wert ermittelt. Hedges' g basiert ebenfalls auf den LS-MW und ist somit auf das Modell angepasst.</i></p> <p><i>Es werden ausschließlich gemeinsame Analysezeitpunkte dargestellt.</i></p> <p><i>Ein LS MD und Hedges' g kleiner als Null bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

## 2.9 EORTC QLQ-C30 globaler Gesundheitsstatus

### EORTC QLQ-C30 globaler Gesundheitsstatus: Subgruppenanalyse

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
<b>EORTC QLQ-C30 globaler Gesundheitsstatus</b>			
<b>Alter: &lt; 65 Jahre</b>			
Baseline			
n/N (%)	95/115 (83)	92/119 (77)	-
MW (SD)	66,75 (22,397)	63,04 (20,461)	
Absolute Werte zum Studienende			
n/N (%)	4/73 (5)	4/64 (6)	-
MW (SD)	64,58 (29,950)	56,25 (18,478)	
Effekt über Studiendauer			
n	95	92	LS MD 7,59 [3,186; 11,999] 0,0008  Hedges' g 0,50 [0,205; 0,787]
LS MW (SE)	0,51 (1,530)	-7,08 (1,625)	
95 %-KI	[-2,512; 3,529]	[-10,290; -3,879]	
Veränderung zu Woche 3/4			
n/N (%)	61/113 (54)	61/115 (53)	LS MD 6,03 [1,060; 10,992]
MW (SD)	2,73 (15,570)	-1,09 (16,560)	
LS MW (SE)	1,35 (1,736)	-4,68 (1,827)	
95 %-KI	[-2,070; 4,766]	[-8,273; -1,083]	
Veränderung zu Woche 8/9			
n/N (%)	76/112 (68)	72/108 (67)	LS MD 6,72 [2,173; 11,257]
MW (SD)	-0,55 (28,230)	-8,22 (21,326)	
LS MW (SE)	0,98 (1,593)	-5,74 (1,662)	
95 %-KI	[-2,163; 4,119]	[-9,012; -2,462]	
Veränderung zu Woche 12			
n/N (%)	48/110 (44)	40/105 (38)	
MW (SD)	4,69 (27,714)	-4,38 (16,450)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	0,72 (1,540)	-6,48 (1,615)	LS MD 7,20 [2,791; 11,605]
95 %-KI	[-2,320; 3,760]	[-9,665; -3,292]	
Veränderung zu Woche 15/16			
n/N (%)	55/107 (51)	33/102 (32)	LS MD 7,68 [3,261; 12,101]
MW (SD)	0,30 (25,957)	-6,57 (20,598)	
LS MW (SE)	0,46 (1,532)	-7,22 (1,633)	
95 %-KI	[-2,563; 3,485]	[-10,441; -3,999]	
Veränderung zu Woche 20/21			
n/N (%)	37/101 (37)	30/96 (31)	LS MD 8,37 [3,682; 13,060]
MW (SD)	2,25 (27,544)	-4,17 (17,473)	
LS MW (SE)	0,09 (1,597)	-8,28 (1,763)	
95 %-KI	[-3,059; 3,242]	[-11,752; -4,807]	
Veränderung zu Woche 24			
n/N (%)	25/99 (25)	19/91 (21)	LS MD 8,85 [3,823; 13,885]
MW (SD)	0,33 (25,851)	-2,63 (14,972)	
LS MW (SE)	-0,17 (1,692)	-9,02 (1,915)	
95 %-KI	[-3,501; 3,168]	[-12,789; -5,252]	
Veränderung zu Woche 36			
n/N (%)	42/86 (49)	28/79 (35)	LS MD 10,51 [3,661; 17,358]
MW (SD)	-0,79 (20,808)	-11,90 (17,337)	
LS MW (SE)	-1,05 (2,235)	-11,56 (2,676)	
95 %-KI	[-5,444; 3,338]	[-16,820; -6,306]	
Veränderung zu Woche 48			
n/N (%)	4/73 (5)	3/64 (5)	LS MD 12,17 [2,984; 21,346]
MW (SD)	-2,08 (41,037)	-5,56 (12,729)	
LS MW (SE)	-1,94 (2,960)	-14,10 (3,619)	
95 %-KI	[-7,752; 3,873]	[-21,212; -6,998]	
<b>Alter: ≥ 65 Jahre</b>			
Baseline			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	83/103 (81)	67/88 (76)	-
MW (SD)	65,06 (21,873)	66,29 (22,258)	
Absolute Werte zum Studienende			
n/N (%)	6/67 (9)	2/46 (4)	-
MW (SD)	62,50 (15,590)	83,33 (0,000)	
Effekt über Studiendauer			
n	83	67	LS MD 6,43 [1,890; 10,974] 0,0058  Hedges' g 0,46 [0,133; 0,786]
LS MW (SE)	-1,38 (1,491)	-7,81 (1,751)	
95 %-KI	[-4,333; 1,568]	[-11,275; -4,354]	
Veränderung zu Woche 3/4			
n/N (%)	62/100 (62)	49/85 (58)	LS MD 8,24 [2,978; 13,496]
MW (SD)	-5,24 (21,138)	-9,35 (19,810)	
LS MW (SE)	-2,28 (1,751)	-10,52 (2,022)	
95 %-KI	[-5,731; 1,170]	[-14,498; -6,536]	
Veränderung zu Woche 8/9			
n/N (%)	70/98 (71)	55/80 (69)	LS MD 7,44 [2,730; 12,141]
MW (SD)	0,00 (20,609)	-8,18 (25,685)	
LS MW (SE)	-1,88 (1,571)	-9,32 (1,795)	
95 %-KI	[-4,983; 1,220]	[-12,860; -5,774]	
Veränderung zu Woche 12			
n/N (%)	51/95 (54)	32/78 (41)	LS MD 6,87 [2,339; 11,409]
MW (SD)	1,96 (26,905)	-10,94 (22,143)	
LS MW (SE)	-1,60 (1,504)	-8,48 (1,735)	
95 %-KI	[-4,576; 1,372]	[-11,904; -5,049]	
Veränderung zu Woche 15/16			
n/N (%)	42/92 (46)	22/76 (29)	
MW (SD)	2,78 (16,428)	-8,71 (29,933)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-1,32 (1,494)	-7,64 (1,766)	LS MD 6,31 [1,747; 10,879]
95 %-KI	[-4,280; 1,633]	[-11,125; -4,148]	
Veränderung zu Woche 20/21			
n/N (%)	31/89 (35)	21/69 (30)	LS MD 5,51 [0,564; 10,459]
MW (SD)	2,42 (22,068)	-2,78 (21,624)	
LS MW (SE)	-0,92 (1,581)	-6,44 (1,957)	
95 %-KI	[-4,047; 2,198]	[-10,296; -2,576]	
Veränderung zu Woche 24			
n/N (%)	30/85 (35)	19/64 (30)	LS MD 4,95 [-0,462; 10,363]
MW (SD)	1,94 (25,208)	-1,32 (19,097)	
LS MW (SE)	-0,65 (1,703)	-5,60 (2,173)	
95 %-KI	[-4,004; 2,713]	[-9,875; -1,317]	
Veränderung zu Woche 36			
n/N (%)	41/74 (55)	20/55 (36)	LS MD 3,03 [-4,732; 10,785]
MW (SD)	-2,03 (23,701)	-6,25 (14,016)	
LS MW (SE)	0,31 (2,369)	-2,72 (3,198)	
95 %-KI	[-4,346; 4,969]	[-8,998; 3,568]	
Veränderung zu Woche 48			
n/N (%)	4/67 (6)	2/46 (4)	LS MD 1,10 [-9,546; 11,751]
MW (SD)	-10,42 (28,362)	0,00 (11,785)	
LS MW (SE)	1,27 (3,226)	0,17 (4,418)	
95 %-KI	[-5,069; 7,606]	[-8,512; 8,844]	
<b>Region: USA</b>			
Baseline			
n/N (%)	49/65 (75)	34/51 (67)	-
MW (SD)	68,88 (21,162)	68,38 (20,899)	
Absolute Werte zum Studienende			
n/N (%)	2/39 (5)	3/27 (11)	-
MW (SD)	83,33 (11,785)	72,22 (19,245)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Effekt über Studiendauer			
n	49	34	LS MD 8,48 [2,221; 14,742] 0,0086  Hedges' g 0,60 [0,150; 1,045]
LS MW (SE)	-2,08 (1,990)	-10,56 (2,443)	
95 %-KI	[-6,041; 1,889]	[-15,420; -5,694]	
Veränderung zu Woche 3/4			
n/N (%)	34/64 (53)	21/49 (43)	LS MD 8,12 [1,027; 15,222]
MW (SD)	-5,39 (13,744)	-7,54 (15,790)	
LS MW (SE)	-4,22 (2,253)	-12,35 (2,801)	
95 %-KI	[-8,686; 0,238]	[-17,892; -6,804]	
Veränderung zu Woche 8/9			
n/N (%)	42/62 (68)	30/46 (65)	LS MD 8,29 [1,806; 14,765]
MW (SD)	-2,38 (21,089)	-14,44 (25,609)	
LS MW (SE)	-3,25 (2,061)	-11,54 (2,539)	
95 %-KI	[-7,348; 0,845]	[-16,581; -6,494]	
Veränderung zu Woche 12			
n/N (%)	26/59 (44)	16/45 (36)	LS MD 8,40 [2,122; 14,676]
MW (SD)	-0,96 (17,690)	-17,71 (21,054)	
LS MW (SE)	-2,57 (1,996)	-10,97 (2,451)	
95 %-KI	[-6,547; 1,405]	[-15,847; -6,093]	
Veränderung zu Woche 15/16			
n/N (%)	21/56 (38)	11/44 (25)	LS MD 8,51 [2,229; 14,795]
MW (SD)	2,78 (18,130)	-7,58 (20,226)	
LS MW (SE)	-1,89 (1,996)	-10,40 (2,452)	
95 %-KI	[-5,868; 2,087]	[-15,283; -5,522]	
Veränderung zu Woche 20/21			
n/N (%)	13/54 (24)	9/40 (22)	
MW (SD)	-1,28 (11,709)	-6,48 (22,737)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-0,92 (2,108)	-9,59 (2,607)	LS MD 8,67 [2,024; 15,323]
95 %-KI	[-5,107; 3,271]	[-14,767; -4,417]	
Veränderung zu Woche 24			
n/N (%)	9/53 (17)	6/38 (16)	LS MD 8,79 [1,658; 15,916]
MW (SD)	6,48 (18,993)	-2,78 (21,517)	
LS MW (SE)	-0,24 (2,255)	-9,02 (2,808)	
95 %-KI	[-4,706; 4,231]	[-14,585; -3,464]	
Veränderung zu Woche 36			
n/N (%)	22/43 (51)	10/33 (30)	LS MD 9,17 [-0,540; 18,889]
MW (SD)	0,38 (23,356)	-7,50 (10,722)	
LS MW (SE)	2,10 (3,045)	-7,08 (3,873)	
95 %-KI	[-3,906; 8,098]	[-14,711; 0,554]	
Veränderung zu Woche 48			
n/N (%)	2/39 (5)	3/27 (11)	LS MD 9,56 [-3,495; 22,620]
MW (SD)	25,00 (47,140)	-5,56 (12,729)	
LS MW (SE)	4,43 (4,069)	-5,13 (5,230)	
95 %-KI	[-3,582; 12,441]	[-15,430; 5,164]	
<b>Region: Rest der Welt</b>			
Baseline			
n/N (%)	129/153 (84)	125/156 (80)	-
MW (SD)	64,86 (22,437)	63,33 (21,272)	
Absolute Werte zum Studienende			
n/N (%)	8/101 (8)	3/83 (4)	-
MW (SD)	58,33 (19,920)	58,33 (22,048)	
Effekt über Studiendauer			
n	129	125	LS MD 6,71 [3,071; 10,356] 0,0003 Hedges' g
LS MW (SE)	0,14 (1,259)	-6,57 (1,356)	
95 %-KI	[-2,337; 2,624]	[-9,241; -3,899]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
			0,45 [0,205; 0,704]
Veränderung zu Woche 3/4			
n/N (%)	89/149 (60)	89/151 (59)	LS MD 6,62 [2,448; 10,799]
MW (SD)	0,28 (20,430)	-4,12 (19,058)	
LS MW (SE)	1,06 (1,462)	-5,57 (1,541)	
95 %-KI	[-1,819; 3,930]	[-8,596; -2,539]	
Veränderung zu Woche 8/9			
n/N (%)	104/148 (70)	97/142 (68)	LS MD 6,66 [2,897; 10,429]
MW (SD)	0,56 (26,179)	-6,27 (22,212)	
LS MW (SE)	0,66 (1,323)	-6,01 (1,382)	
95 %-KI	[-1,949; 3,260]	[-8,728; -3,288]	
Veränderung zu Woche 12			
n/N (%)	73/146 (50)	56/138 (41)	LS MD 6,69 [3,053; 10,328]
MW (SD)	4,79 (29,818)	-4,32 (17,908)	
LS MW (SE)	0,38 (1,270)	-6,32 (1,341)	
95 %-KI	[-2,128; 2,878]	[-8,957; -3,674]	
Veränderung zu Woche 15/16			
n/N (%)	76/143 (53)	44/134 (33)	LS MD 6,72 [3,062; 10,375]
MW (SD)	0,99 (23,372)	-7,39 (25,683)	
LS MW (SE)	0,09 (1,260)	-6,62 (1,365)	
95 %-KI	[-2,388; 2,578]	[-9,311; -3,936]	
Veränderung zu Woche 20/21			
n/N (%)	55/136 (40)	42/125 (34)	LS MD 6,76 [2,827; 10,688]
MW (SD)	3,18 (27,240)	-2,98 (18,481)	
LS MW (SE)	-0,31 (1,320)	-7,06 (1,503)	
95 %-KI	[-2,904; 2,293]	[-10,020; -4,106]	
Veränderung zu Woche 24			
n/N (%)	46/131 (35)	32/117 (27)	
MW (SD)	0,18 (26,381)	-1,82 (16,359)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-0,59 (1,408)	-7,37 (1,659)	LS MD 6,79 [2,516; 11,055]
95 %-KI	[-3,356; 2,185]	[-10,630; -4,111]	
Veränderung zu Woche 36			
n/N (%)	61/117 (52)	38/101 (38)	LS MD 6,88 [0,872; 12,888]
MW (SD)	-2,05 (21,872)	-10,09 (17,346)	
LS MW (SE)	-1,55 (1,911)	-8,43 (2,402)	
95 %-KI	[-5,298; 2,206]	[-13,140; -3,712]	
Veränderung zu Woche 48			
n/N (%)	6/101 (6)	2/83 (2)	LS MD 6,97 [-1,204; 15,153]
MW (SD)	-16,67 (23,570)	0,00 (11,785)	
LS MW (SE)	-2,51 (2,573)	-9,48 (3,294)	
95 %-KI	[-7,556; 2,542]	[-15,946; -3,017]	
<b>Stadium bei der Diagnose: I-III</b>			
Baseline			
n/N (%)	113/141 (80)	112/144 (78)	-
MW (SD)	67,26 (20,944)	65,10 (21,180)	
Absolute Werte zum Studienende			
n/N (%)	6/91 (7)	4/76 (5)	-
MW (SD)	56,94 (21,995)	72,92 (15,775)	
Effekt über Studiendauer			
n	113	112	LS MD 7,55 [3,610; 11,497] 0,0002
LS MW (SE)	-0,86 (1,373)	-8,42 (1,455)	
95 %-KI	[-3,571; 1,843]	[-11,285; -5,550]	Hedges' g 0,50 [0,236; 0,767]
Veränderung zu Woche 3/4			
n/N (%)	76/137 (55)	79/138 (57)	LS MD 7,71 [3,207; 12,222]
MW (SD)	-1,86 (20,888)	-5,38 (18,250)	
LS MW (SE)	-0,45 (1,589)	-8,16 (1,651)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,570; 2,679]	[-11,407; -4,914]	
Veränderung zu Woche 8/9			
n/N (%)	94/136 (69)	89/129 (69)	LS MD 7,64 [3,556; 11,733]
MW (SD)	-1,68 (26,482)	-9,46 (22,724)	
LS MW (SE)	-0,63 (1,441)	-8,27 (1,492)	
95 %-KI	[-3,468; 2,211]	[-11,212; -5,334]	
Veränderung zu Woche 12			
n/N (%)	63/133 (47)	49/128 (38)	LS MD 7,60 [3,646; 11,545]
MW (SD)	3,84 (29,702)	-7,82 (18,195)	
LS MW (SE)	-0,76 (1,385)	-8,35 (1,447)	
95 %-KI	[-3,488; 1,975]	[-11,203; -5,501]	
Veränderung zu Woche 15/16			
n/N (%)	64/130 (49)	35/125 (28)	LS MD 7,55 [3,592; 11,500]
MW (SD)	-1,69 (23,718)	-8,33 (20,710)	
LS MW (SE)	-0,88 (1,374)	-8,43 (1,462)	
95 %-KI	[-3,594; 1,825]	[-11,310; -5,550]	
Veränderung zu Woche 20/21			
n/N (%)	46/123 (37)	34/116 (29)	LS MD 7,48 [3,271; 11,681]
MW (SD)	1,63 (29,325)	-5,39 (21,308)	
LS MW (SE)	-1,07 (1,436)	-8,54 (1,583)	
95 %-KI	[-3,897; 1,763]	[-11,658; -5,428]	
Veränderung zu Woche 24			
n/N (%)	35/121 (29)	27/109 (25)	LS MD 7,43 [2,896; 11,957]
MW (SD)	0,48 (29,075)	-0,62 (15,833)	
LS MW (SE)	-1,19 (1,529)	-8,62 (1,725)	
95 %-KI	[-4,205; 1,815]	[-12,014; -5,228]	
Veränderung zu Woche 36			
n/N (%)	54/105 (51)	36/92 (39)	
MW (SD)	-1,70 (26,021)	-9,72 (16,607)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-1,63 (2,061)	-8,89 (2,437)	LS MD 7,26 [1,005; 13,511]
95 %-KI	[-5,680; 2,413]	[-13,676; -4,106]	
Veränderung zu Woche 48			
n/N (%)	5/91 (5)	4/76 (5)	LS MD 7,09 [-1,361; 15,539]
MW (SD)	-15,00 (26,615)	-2,08 (12,500)	
LS MW (SE)	-2,07 (2,764)	-9,16 (3,313)	
95 %-KI	[-7,499; 3,355]	[-15,665; -2,657]	
<b>Stadium bei der Diagnose: IV</b>			
Baseline			
n/N (%)	60/72 (83)	45/60 (75)	-
MW (SD)	64,17 (24,225)	62,22 (21,142)	
Absolute Werte zum Studienende			
n/N (%)	4/46 (9)	2/33 (6)	-
MW (SD)	72,92 (17,180)	50,00 (23,570)	
Effekt über Studiendauer			
n	60	45	LS MD 6,09 [0,879; 11,309] 0,0225  Hedges' g 0,46 [0,064; 0,847]
LS MW (SE)	0,91 (1,682)	-5,18 (2,028)	
95 %-KI	[-2,427; 4,256]	[-9,203; -1,157]	
Veränderung zu Woche 3/4			
n/N (%)	42/71 (59)	29/59 (49)	LS MD 5,64 [-0,366; 11,644]
MW (SD)	0,20 (15,453)	-1,44 (18,240)	
LS MW (SE)	0,66 (1,945)	-4,98 (2,351)	
95 %-KI	[-3,180; 4,499]	[-9,617; -0,342]	
Veränderung zu Woche 8/9			
n/N (%)	47/69 (68)	36/56 (64)	LS MD 5,84 [0,477; 11,210]
MW (SD)	2,66 (21,147)	-5,32 (24,893)	
LS MW (SE)	0,77 (1,758)	-5,07 (2,072)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-2,709; 4,257]	[-9,172; -0,967]	
Veränderung zu Woche 12			
n/N (%)	31/67 (46)	22/52 (42)	LS MD 5,99 [0,799; 11,175]
MW (SD)	3,76 (18,363)	-7,20 (21,867)	
LS MW (SE)	0,85 (1,692)	-5,13 (2,003)	
95 %-KI	[-2,504; 4,213]	[-9,106; -1,160]	
Veränderung zu Woche 15/16			
n/N (%)	30/64 (47)	18/50 (36)	LS MD 6,13 [0,875; 11,385]
MW (SD)	6,67 (18,749)	-3,24 (25,104)	
LS MW (SE)	0,93 (1,687)	-5,20 (2,051)	
95 %-KI	[-2,416; 4,285]	[-9,263; -1,129]	
Veränderung zu Woche 20/21			
n/N (%)	19/62 (31)	16/46 (35)	LS MD 6,34 [0,580; 12,090]
MW (SD)	1,75 (11,646)	-0,52 (13,767)	
LS MW (SE)	1,05 (1,786)	-5,29 (2,305)	
95 %-KI	[-2,490; 4,588]	[-9,844; -0,729]	
Veränderung zu Woche 24			
n/N (%)	18/59 (31)	10/44 (23)	LS MD 6,48 [0,141; 12,816]
MW (SD)	0,93 (17,360)	-5,00 (20,861)	
LS MW (SE)	1,13 (1,920)	-5,35 (2,583)	
95 %-KI	[-2,667; 4,925]	[-10,444; -0,254]	
Veränderung zu Woche 36			
n/N (%)	28/52 (54)	11/41 (27)	LS MD 6,97 [-2,225; 16,164]
MW (SD)	-0,89 (12,697)	-9,09 (16,010)	
LS MW (SE)	1,40 (2,644)	-5,57 (3,866)	
95 %-KI	[-3,800; 6,608]	[-13,171; 2,040]	
Veränderung zu Woche 48			
n/N (%)	3/46 (7)	1/33 (3)	
MW (SD)	8,33 (43,301)	-8,33 (NA)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	1,68 (3,574)	-5,78 (5,370)	LS MD 7,46 [-5,198; 20,120]
95 %-KI	[-5,350; 8,708]	[-16,343; 4,779]	
<b>BRCA Status: Positiv</b>			
Baseline			
n/N (%)	25/27 (93)	23/35 (66)	-
MW (SD)	68,33 (20,694)	53,26 (21,867)	
Absolute Werte zum Studienende			
n/N (%)	1/19 (5)	0/15 (0)	-
MW (SD)	58,33 (NA)	NA (NA)	
Effekt über Studiendauer			
n	25	23	LS MD 6,82 [-3,257; 16,901] 0,1793
LS MW (SE)	2,15 (3,265)	-4,67 (3,641)	
95 %-KI	[-4,448; 8,747]	[-11,998; 2,653]	Hedges' g 0,40 [-0,175; 0,970]
Veränderung zu Woche 3/4			
n/N (%)	16/27 (59)	18/35 (51)	LS MD 3,66 [-7,472; 14,800]
MW (SD)	-1,04 (26,506)	1,85 (16,309)	
LS MW (SE)	0,59 (3,721)	-3,08 (3,989)	
95 %-KI	[-6,839; 8,013]	[-11,031; 4,877]	
Veränderung zu Woche 8/9			
n/N (%)	20/26 (77)	20/30 (67)	LS MD 5,20 [-4,985; 15,378]
MW (SD)	-1,25 (22,826)	-0,83 (21,272)	
LS MW (SE)	1,35 (3,398)	-3,85 (3,582)	
95 %-KI	[-5,487; 8,177]	[-11,057; 3,355]	
Veränderung zu Woche 12			
n/N (%)	15/26 (58)	11/30 (37)	LS MD 6,27 [-3,736; 16,274]
MW (SD)	2,78 (25,717)	2,27 (22,697)	
LS MW (SE)	1,88 (3,284)	-4,39 (3,561)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-4,753; 8,504]	[-11,570; 2,784]	
Veränderung zu Woche 15/16			
n/N (%)	12/26 (46)	8/29 (28)	LS MD 7,34 [-2,908; 17,591]
MW (SD)	1,39 (17,707)	4,17 (30,211)	
LS MW (SE)	2,41 (3,273)	-4,94 (3,767)	
95 %-KI	[-4,207; 9,020]	[-12,496; 2,626]	
Veränderung zu Woche 20/21			
n/N (%)	10/25 (40)	4/25 (16)	LS MD 8,87 [-2,405; 20,153]
MW (SD)	10,00 (24,152)	4,17 (8,333)	
LS MW (SE)	3,16 (3,436)	-5,71 (4,383)	
95 %-KI	[-3,751; 10,080]	[-14,435; 3,017]	
Veränderung zu Woche 24			
n/N (%)	8/25 (32)	4/24 (17)	LS MD 9,95 [-2,450; 22,343]
MW (SD)	12,50 (26,352)	0,00 (13,608)	
LS MW (SE)	3,70 (3,663)	-6,25 (4,973)	
95 %-KI	[-3,641; 11,031]	[-16,115; 3,612]	
Veränderung zu Woche 36			
n/N (%)	10/21 (48)	5/20 (25)	LS MD 13,62 [-4,111; 31,359]
MW (SD)	2,50 (23,257)	-5,00 (11,180)	
LS MW (SE)	5,51 (4,919)	-8,11 (7,498)	
95 %-KI	[-4,228; 15,257]	[-22,923; 6,704]	
Veränderung zu Woche 48			
n/N (%)	1/19 (5)	0/15 (0)	LS MD 17,30 [-6,865; 41,468]
MW (SD)	-16,67 (NA)	NA (NA)	
LS MW (SE)	7,33 (6,567)	-9,97 (10,352)	
95 %-KI	[-5,640; 20,308]	[-30,416; 10,481]	
<b>BRCA Status: Negativ/Unbekannt</b>			
Baseline			
n/N (%)	153/191 (80)	136/172 (79)	-



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	65,58 (22,371)	66,30 (20,610)	
Absolute Werte zum Studienende			
n/N (%)	9/121 (7)	6/95 (6)	-
MW (SD)	63,89 (22,048)	65,28 (20,012)	
Effekt über Studiendauer			
n	153	136	LS MD 6,95 [3,588; 10,313] 0,0001  Hedges' g 0,48 [0,245; 0,714]
LS MW (SE)	-0,93 (1,143)	-7,88 (1,270)	
95 %-KI	[-3,182; 1,320]	[-10,381; -5,381]	
Veränderung zu Woche 3/4			
n/N (%)	107/186 (58)	92/165 (56)	LS MD 7,06 [3,206; 10,911]
MW (SD)	-1,32 (17,702)	-6,07 (18,659)	
LS MW (SE)	-0,61 (1,318)	-7,67 (1,453)	
95 %-KI	[-3,198; 1,981]	[-10,522; -4,812]	
Veränderung zu Woche 8/9			
n/N (%)	126/184 (68)	107/158 (68)	LS MD 7,01 [3,525; 10,498]
MW (SD)	-0,13 (25,166)	-9,58 (23,397)	
LS MW (SE)	-0,75 (1,196)	-7,76 (1,308)	
95 %-KI	[-3,103; 1,605]	[-10,334; -5,187]	
Veränderung zu Woche 12			
n/N (%)	84/179 (47)	61/153 (40)	LS MD 6,98 [3,612; 10,344]
MW (SD)	3,37 (27,597)	-9,02 (18,339)	
LS MW (SE)	-0,85 (1,152)	-7,83 (1,265)	
95 %-KI	[-3,115; 1,420]	[-10,315; -5,336]	
Veränderung zu Woche 15/16			
n/N (%)	85/173 (49)	47/149 (32)	LS MD 6,95 [3,574; 10,317]
MW (SD)	1,37 (22,925)	-9,40 (23,223)	
LS MW (SE)	-0,95 (1,145)	-7,89 (1,275)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,200; 1,308]	[-10,400; -5,381]	
Veränderung zu Woche 20/21			
n/N (%)	58/165 (35)	47/140 (34)	LS MD 6,90 [3,304; 10,492]
MW (SD)	1,01 (25,125)	-4,26 (19,649)	
LS MW (SE)	-1,09 (1,201)	-7,98 (1,379)	
95 %-KI	[-3,449; 1,277]	[-10,696; -5,272]	
Veränderung zu Woche 24			
n/N (%)	47/159 (30)	34/131 (26)	LS MD 6,86 [2,984; 10,745]
MW (SD)	-0,71 (24,869)	-2,21 (17,445)	
LS MW (SE)	-1,18 (1,281)	-8,05 (1,505)	
95 %-KI	[-3,704; 1,335]	[-11,006; -5,093]	
Veränderung zu Woche 36			
n/N (%)	73/139 (53)	43/114 (38)	LS MD 6,75 [1,366; 12,136]
MW (SD)	-1,94 (22,114)	-10,08 (16,623)	
LS MW (SE)	-1,52 (1,733)	-8,27 (2,133)	
95 %-KI	[-4,924; 1,881]	[-12,459; -4,086]	
Veränderung zu Woche 48			
n/N (%)	7/121 (6)	5/95 (5)	LS MD 6,64 [-0,657; 13,932]
MW (SD)	-4,76 (35,309)	-3,33 (11,180)	
LS MW (SE)	-1,86 (2,327)	-8,50 (2,908)	
95 %-KI	[-6,425; 2,707]	[-14,204; -2,789]	
<b>Baseline ECOG PS: 0</b>			
Baseline			
n/N (%)	102/128 (80)	97/113 (86)	-
MW (SD)	71,24 (20,265)	68,13 (20,235)	
Absolute Werte zum Studienende			
n/N (%)	7/87 (8)	3/72 (4)	-
MW (SD)	59,52 (21,746)	55,56 (25,459)	
Effekt über Studiendauer			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n	102	97	LS MD 5,68 [1,557; 9,800] 0,0072  Hedges' g 0,38 [0,104; 0,665]
LS MW (SE)	-3,54 (1,424)	-9,22 (1,529)	
95 %-KI	[-6,347; -0,727]	[-12,231; -6,200]	
Veränderung zu Woche 3/4			
n/N (%)	72/127 (57)	64/111 (58)	LS MD 6,01 [1,272; 10,751]
MW (SD)	-2,08 (18,276)	-5,99 (19,272)	
LS MW (SE)	-2,93 (1,638)	-8,95 (1,765)	
95 %-KI	[-6,157; 0,288]	[-12,418; -5,473]	
Veränderung zu Woche 8/9			
n/N (%)	85/126 (67)	76/108 (70)	LS MD 5,87 [1,577; 10,158]
MW (SD)	-4,61 (24,005)	-10,86 (22,237)	
LS MW (SE)	-3,19 (1,492)	-9,06 (1,585)	
95 %-KI	[-6,136; -0,253]	[-12,184; -5,940]	
Veränderung zu Woche 12			
n/N (%)	54/122 (44)	46/108 (43)	LS MD 5,77 [1,632; 9,902]
MW (SD)	-0,15 (23,318)	-7,79 (19,673)	
LS MW (SE)	-3,38 (1,437)	-9,14 (1,527)	
95 %-KI	[-6,211; -0,542]	[-12,154; -6,133]	
Veränderung zu Woche 15/16			
n/N (%)	56/120 (47)	35/105 (33)	LS MD 5,67 [1,538; 9,795]
MW (SD)	-3,27 (23,872)	-10,95 (24,899)	
LS MW (SE)	-3,56 (1,425)	-9,23 (1,533)	
95 %-KI	[-6,370; -0,747]	[-12,248; -6,202]	
Veränderung zu Woche 20/21			
n/N (%)	41/117 (35)	32/101 (32)	LS MD 5,52 [1,150; 9,896]
MW (SD)	-2,64 (21,606)	-5,47 (17,533)	
LS MW (SE)	-3,82 (1,485)	-9,34 (1,651)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,746; -0,891]	[-12,593; -6,090]	
Veränderung zu Woche 24			
n/N (%)	28/112 (25)	22/96 (23)	LS MD 5,42 [0,721; 10,124]
MW (SD)	-4,76 (26,588)	-2,65 (17,703)	
LS MW (SE)	-4,00 (1,575)	-9,42 (1,797)	
95 %-KI	[-7,104; -0,898]	[-12,959; -5,887]	
Veränderung zu Woche 36			
n/N (%)	52/99 (53)	35/87 (40)	LS MD 5,08 [-1,399; 11,554]
MW (SD)	-5,45 (23,564)	-10,00 (16,764)	
LS MW (SE)	-4,63 (2,100)	-9,70 (2,544)	
95 %-KI	[-8,751; -0,500]	[-14,700; -4,706]	
Veränderung zu Woche 48			
n/N (%)	5/87 (6)	3/72 (4)	LS MD 4,73 [-4,024; 13,490]
MW (SD)	0,00 (34,861)	-5,56 (12,729)	
LS MW (SE)	-5,25 (2,801)	-9,98 (3,474)	
95 %-KI	[-10,749; 0,250]	[-16,803; -3,162]	
<b>Baseline ECOG PS: 1</b>			
Baseline			
n/N (%)	76/90 (84)	61/91 (67)	-
MW (SD)	58,88 (22,622)	58,88 (21,670)	
Absolute Werte zum Studienende			
n/N (%)	3/53 (6)	3/37 (8)	-
MW (SD)	72,22 (19,245)	75,00 (8,333)	
Effekt über Studiendauer			
n	76	61	LS MD 9,59 [4,587; 14,591] 0,0002
LS MW (SE)	4,01 (1,633)	-5,58 (1,932)	
95 %-KI	[0,781; 7,246]	[-9,396; -1,754]	Hedges' g 0,65 [0,306; 0,998]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	51/86 (59)	45/87 (52)	LS MD 8,30 [2,666; 13,930]
MW (SD)	-0,16 (19,965)	-3,52 (17,270)	
LS MW (SE)	3,28 (1,887)	-5,02 (2,150)	
95 %-KI	[-0,440; 6,999]	[-9,255; -0,783]	
Veränderung zu Woche 8/9			
n/N (%)	61/84 (73)	50/78 (64)	LS MD 8,89 [3,785; 13,995]
MW (SD)	5,74 (24,793)	-4,83 (24,169)	
LS MW (SE)	3,62 (1,705)	-5,27 (1,943)	
95 %-KI	[0,247; 6,985]	[-9,112; -1,436]	
Veränderung zu Woche 12			
n/N (%)	45/83 (54)	25/74 (34)	LS MD 9,30 [4,333; 14,275]
MW (SD)	7,41 (30,989)	-8,00 (17,592)	
LS MW (SE)	3,85 (1,641)	-5,45 (1,904)	
95 %-KI	[0,603; 7,100]	[-9,217; -1,687]	
Veränderung zu Woche 15/16			
n/N (%)	41/79 (52)	20/72 (28)	LS MD 9,72 [4,669; 14,767]
MW (SD)	7,72 (18,294)	-1,25 (23,144)	
LS MW (SE)	4,09 (1,638)	-5,63 (1,960)	
95 %-KI	[0,843; 7,331]	[-9,505; -1,757]	
Veränderung zu Woche 20/21			
n/N (%)	27/73 (37)	18/63 (29)	LS MD 10,31 [4,805; 15,815]
MW (SD)	9,88 (28,216)	-3,24 (18,333)	
LS MW (SE)	4,42 (1,738)	-5,89 (2,187)	
95 %-KI	[0,987; 7,860]	[-10,199; -1,573]	
Veränderung zu Woche 24			
n/N (%)	27/72 (38)	15/58 (26)	LS MD 10,72 [4,700; 16,748]
MW (SD)	7,41 (22,685)	-1,11 (16,923)	
LS MW (SE)	4,66 (1,872)	-6,06 (2,426)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[0,965; 8,353]	[-10,842; -1,287]	
Veränderung zu Woche 36			
n/N (%)	31/61 (51)	13/46 (28)	LS MD 12,14 [3,580; 20,706]
MW (SD)	5,38 (17,944)	-8,33 (14,829)	
LS MW (SE)	5,47 (2,589)	-6,68 (3,526)	
95 %-KI	[0,376; 10,557]	[-13,607; 0,254]	
Veränderung zu Woche 48			
n/N (%)	3/53 (6)	2/37 (5)	LS MD 13,56 [1,902; 25,224]
MW (SD)	-16,67 (33,333)	0,00 (11,785)	
LS MW (SE)	6,27 (3,504)	-7,29 (4,824)	
95 %-KI	[-0,612; 13,161]	[-16,769; 2,191]	
<b>Anzahl vorheriger Therapielinien: 1</b>			
Baseline			
n/N (%)	24/31 (77)	23/29 (79)	-
MW (SD)	60,07 (24,694)	69,57 (20,963)	
Absolute Werte zum Studienende			
n/N (%)	1/22 (5)	0/14 (0)	-
MW (SD)	41,67 (NA)	NA (NA)	
Effekt über Studiendauer			
n	24	23	LS MD 8,45 [1,231; 15,668] 0,0229  Hedges' g 0,69 [0,097; 1,277]
LS MW (SE)	1,84 (2,397)	-6,60 (2,596)	
95 %-KI	[-3,011; 6,701]	[-11,841; -1,368]	
Veränderung zu Woche 3/4			
n/N (%)	16/31 (52)	15/29 (52)	LS MD 11,56 [2,531; 20,594]
MW (SD)	0,52 (16,796)	-8,89 (25,289)	
LS MW (SE)	3,21 (3,079)	-8,36 (3,311)	
95 %-KI	[-2,911; 9,324]	[-14,924; -1,789]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	20/31 (65)	18/26 (69)	LS MD 10,25 [2,486; 18,020]
MW (SD)	3,75 (15,643)	-11,57 (23,245)	
LS MW (SE)	2,63 (2,659)	-7,62 (2,781)	
95 %-KI	[-2,695; 7,962]	[-13,179; -2,059]	
Veränderung zu Woche 12			
n/N (%)	14/31 (45)	12/24 (50)	LS MD 9,34 [2,043; 16,629]
MW (SD)	13,69 (26,475)	-12,50 (20,566)	
LS MW (SE)	2,23 (2,472)	-7,10 (2,594)	
95 %-KI	[-2,756; 7,221]	[-12,324; -1,883]	
Veränderung zu Woche 15/16			
n/N (%)	15/31 (48)	11/22 (50)	LS MD 8,42 [1,197; 15,642]
MW (SD)	7,78 (19,279)	-15,91 (28,977)	
LS MW (SE)	1,83 (2,397)	-6,59 (2,600)	
95 %-KI	[-3,023; 6,687]	[-11,831; -1,344]	
Veränderung zu Woche 20/21			
n/N (%)	11/30 (37)	9/22 (41)	LS MD 7,11 [-0,709; 14,928]
MW (SD)	6,82 (14,346)	-12,04 (22,481)	
LS MW (SE)	1,26 (2,500)	-5,85 (2,931)	
95 %-KI	[-3,782; 6,300]	[-11,724; 0,023]	
Veränderung zu Woche 24			
n/N (%)	9/30 (30)	11/20 (55)	LS MD 6,19 [-2,463; 14,848]
MW (SD)	0,93 (21,018)	6,82 (13,343)	
LS MW (SE)	0,86 (2,708)	-5,33 (3,336)	
95 %-KI	[-4,563; 6,279]	[-11,983; 1,314]	
Veränderung zu Woche 36			
n/N (%)	15/26 (58)	6/18 (33)	LS MD 3,05 [-10,022; 16,121]
MW (SD)	-2,22 (25,679)	-15,28 (24,391)	
LS MW (SE)	-0,52 (3,943)	-3,57 (5,260)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-8,310; 7,277]	[-13,965; 6,833]	
Veränderung zu Woche 48			
n/N (%)	0/22 (0)	0/14 (0)	LS MD -0,09 [-18,596; 18,409]
MW (SD)	NA (NA)	NA (NA)	
LS MW (SE)	-1,89 (5,546)	-1,80 (7,506)	
95 %-KI	[-12,837; 9,055]	[-16,618; 13,023]	
<b>Anzahl vorheriger Therapielinien: 2</b>			
Baseline			
n/N (%)	76/89 (85)	65/83 (78)	-
MW (SD)	65,24 (21,011)	64,36 (20,912)	
Absolute Werte zum Studienende			
n/N (%)	4/59 (7)	2/50 (4)	-
MW (SD)	50,00 (18,002)	75,00 (11,785)	
Effekt über Studiendauer			
n	76	65	LS MD 4,83 [0,105; 9,563] 0,0452  Hedges' g 0,34 [0,008; 0,675]
LS MW (SE)	0,11 (1,560)	-4,73 (1,811)	
95 %-KI	[-2,982; 3,197]	[-8,305; -1,148]	
Veränderung zu Woche 3/4			
n/N (%)	54/86 (63)	46/80 (57)	LS MD 4,00 [-1,392; 9,389]
MW (SD)	-1,39 (20,461)	-2,54 (17,021)	
LS MW (SE)	1,17 (1,811)	-2,83 (2,054)	
95 %-KI	[-2,403; 4,737]	[-6,877; 1,214]	
Veränderung zu Woche 8/9			
n/N (%)	63/85 (74)	53/77 (69)	LS MD 4,37 [-0,479; 9,229]
MW (SD)	3,04 (21,961)	-3,93 (23,886)	
LS MW (SE)	0,69 (1,637)	-3,68 (1,832)	
95 %-KI	[-2,545; 3,925]	[-7,302; -0,067]	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	40/83 (48)	31/75 (41)	LS MD 4,64 [-0,067; 9,343]
MW (SD)	-0,21 (23,456)	-4,30 (18,493)	
LS MW (SE)	0,36 (1,573)	-4,28 (1,783)	
95 %-KI	[-2,756; 3,469]	[-7,807; -0,757]	
Veränderung zu Woche 15/16			
n/N (%)	42/80 (52)	20/74 (27)	LS MD 4,90 [0,138; 9,665]
MW (SD)	1,19 (23,323)	-2,92 (19,734)	
LS MW (SE)	0,02 (1,563)	-4,88 (1,832)	
95 %-KI	[-3,072; 3,118]	[-8,499; -1,259]	
Veränderung zu Woche 20/21			
n/N (%)	32/78 (41)	21/68 (31)	LS MD 5,28 [0,088; 10,467]
MW (SD)	2,86 (20,588)	-4,37 (12,533)	
LS MW (SE)	-0,45 (1,645)	-5,73 (2,054)	
95 %-KI	[-3,706; 2,798]	[-9,782; -1,682]	
Veränderung zu Woche 24			
n/N (%)	27/74 (36)	13/65 (20)	LS MD 5,54 [-0,145; 11,226]
MW (SD)	6,48 (22,329)	-3,21 (17,526)	
LS MW (SE)	-0,79 (1,762)	-6,33 (2,292)	
95 %-KI	[-4,265; 2,689]	[-10,840; -1,817]	
Veränderung zu Woche 36			
n/N (%)	34/65 (52)	19/58 (33)	LS MD 6,44 [-1,692; 14,578]
MW (SD)	-2,45 (19,303)	-10,09 (15,855)	
LS MW (SE)	-1,93 (2,409)	-8,38 (3,386)	
95 %-KI	[-6,669; 2,804]	[-15,029; -1,722]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	1/50 (2)	LS MD 7,35 [-3,782; 18,473]
MW (SD)	-25,00 (21,517)	-8,33 (NA)	
LS MW (SE)	-3,08 (3,252)	-10,42 (4,671)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-9,466; 3,312]	[-19,600; -1,246]	
<b>Anzahl vorheriger Therapielinien: 3</b>			
Baseline			
n/N (%)	78/98 (80)	71/95 (75)	-
MW (SD)	68,48 (22,217)	62,79 (21,631)	
Absolute Werte zum Studienende			
n/N (%)	5/59 (8)	4/46 (9)	-
MW (SD)	78,33 (12,638)	60,42 (22,948)	
Effekt über Studiendauer			
n	78	71	LS MD 9,19 [3,984; 14,399] 0,0006  Hedges' g 0,57 [0,243; 0,899]
LS MW (SE)	-1,57 (1,780)	-10,76 (1,940)	
95 %-KI	[-5,091; 1,950]	[-14,597; -6,927]	
Veränderung zu Woche 3/4			
n/N (%)	53/96 (55)	49/91 (54)	LS MD 7,95 [2,147; 13,754]
MW (SD)	-1,73 (18,225)	-5,61 (17,463)	
LS MW (SE)	-2,96 (1,992)	-10,91 (2,164)	
95 %-KI	[-6,887; 0,966]	[-15,175; -6,646]	
Veränderung zu Woche 8/9			
n/N (%)	63/94 (67)	56/85 (66)	LS MD 8,50 [3,153; 13,845]
MW (SD)	-4,89 (29,008)	-11,16 (22,320)	
LS MW (SE)	-2,35 (1,836)	-10,84 (1,988)	
95 %-KI	[-5,972; 1,281]	[-14,770; -6,920]	
Veränderung zu Woche 12			
n/N (%)	45/91 (49)	29/84 (35)	LS MD 8,88 [3,679; 14,088]
MW (SD)	3,15 (30,114)	-8,33 (19,796)	
LS MW (SE)	-1,92 (1,784)	-10,80 (1,936)	
95 %-KI	[-5,443; 1,612]	[-14,624; -6,974]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	40/88 (45)	24/82 (29)	LS MD 9,27 [4,044; 14,492]
MW (SD)	-0,83 (22,233)	-7,29 (25,926)	
LS MW (SE)	-1,48 (1,784)	-10,75 (1,948)	
95 %-KI	[-5,014; 2,044]	[-14,602; -6,904]	
Veränderung zu Woche 20/21			
n/N (%)	25/82 (30)	21/75 (28)	LS MD 9,82 [4,291; 15,343]
MW (SD)	-0,33 (33,114)	0,79 (22,346)	
LS MW (SE)	-0,87 (1,874)	-10,69 (2,074)	
95 %-KI	[-4,572; 2,832]	[-14,779; -6,595]	
Veränderung zu Woche 24			
n/N (%)	19/80 (24)	14/70 (20)	LS MD 10,20 [4,295; 16,107]
MW (SD)	-6,14 (30,026)	-7,74 (17,130)	
LS MW (SE)	-0,44 (1,993)	-10,64 (2,227)	
95 %-KI	[-4,371; 3,491]	[-15,031; -6,251]	
Veränderung zu Woche 36			
n/N (%)	34/69 (49)	23/58 (40)	LS MD 11,52 [3,587; 19,451]
MW (SD)	-0,00 (23,748)	-7,61 (14,194)	
LS MW (SE)	1,04 (2,643)	-10,48 (3,024)	
95 %-KI	[-4,161; 6,232]	[-16,428; -4,539]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	4/46 (9)	LS MD 12,84 [2,283; 23,390]
MW (SD)	12,50 (33,679)	-2,08 (12,500)	
LS MW (SE)	2,51 (3,495)	-10,33 (4,037)	
95 %-KI	[-4,356; 9,378]	[-18,258; -2,393]	
<b>Vorherige Verabreichung von Bevacizumab: Ja</b>			
Baseline			
n/N (%)	106/134 (79)	100/132 (76)	-
MW (SD)	68,08 (20,749)	62,83 (21,757)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	3/79 (4)	3/62 (5)	-
MW (SD)	50,00 (25,000)	66,67 (16,667)	
Effekt über Studiendauer			
n	106	100	LS MD 5,68 [1,467; 9,895] 0,0085  Hedges' g 0,37 [0,094; 0,646]
LS MW (SE)	-3,01 (1,435)	-8,69 (1,584)	
95 %-KI	[-5,841; -0,177]	[-11,811; -5,568]	
Veränderung zu Woche 3/4			
n/N (%)	70/130 (54)	69/127 (54)	LS MD 5,44 [0,654; 10,224]
MW (SD)	-3,21 (15,817)	-6,16 (18,171)	
LS MW (SE)	-2,86 (1,648)	-8,30 (1,784)	
95 %-KI	[-6,103; 0,382]	[-11,809; -4,790]	
Veränderung zu Woche 8/9			
n/N (%)	87/130 (67)	77/119 (65)	LS MD 5,55 [1,233; 9,870]
MW (SD)	-2,87 (23,599)	-7,25 (23,777)	
LS MW (SE)	-2,93 (1,495)	-8,48 (1,600)	
95 %-KI	[-5,876; 0,017]	[-11,634; -5,329]	
Veränderung zu Woche 12			
n/N (%)	56/126 (44)	38/114 (33)	LS MD 5,63 [1,435; 9,826]
MW (SD)	-3,13 (27,366)	-6,58 (20,242)	
LS MW (SE)	-2,98 (1,442)	-8,61 (1,563)	
95 %-KI	[-5,824; -0,133]	[-11,691; -5,527]	
Veränderung zu Woche 15/16			
n/N (%)	59/122 (48)	32/112 (29)	LS MD 5,71 [1,452; 9,968]
MW (SD)	-2,40 (20,060)	-6,51 (27,332)	
LS MW (SE)	-3,03 (1,441)	-8,74 (1,610)	
95 %-KI	[-5,870; -0,184]	[-11,910; -5,563]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	40/114 (35)	28/103 (27)	LS MD 5,82 [1,172; 10,474]
MW (SD)	-2,29 (23,112)	-2,98 (20,058)	
LS MW (SE)	-3,10 (1,527)	-8,92 (1,806)	
95 %-KI	[-6,105; -0,087]	[-12,473; -5,364]	
Veränderung zu Woche 24			
n/N (%)	30/109 (28)	17/95 (18)	LS MD 5,90 [0,802; 11,002]
MW (SD)	-5,28 (18,110)	-4,90 (14,451)	
LS MW (SE)	-3,14 (1,640)	-9,05 (2,013)	
95 %-KI	[-6,374; 0,085]	[-13,004; -5,089]	
Veränderung zu Woche 36			
n/N (%)	46/93 (49)	22/79 (28)	LS MD 6,17 [-1,119; 13,464]
MW (SD)	-4,17 (14,777)	-7,95 (14,429)	
LS MW (SE)	-3,31 (2,251)	-9,48 (2,960)	
95 %-KI	[-7,733; 1,111]	[-15,297; -3,670]	
Veränderung zu Woche 48			
n/N (%)	3/79 (4)	2/62 (3)	LS MD 6,44 [-3,513; 16,401]
MW (SD)	-30,56 (20,972)	-12,50 (5,893)	
LS MW (SE)	-3,48 (3,035)	-9,92 (4,072)	
95 %-KI	[-9,436; 2,482]	[-17,916; -1,926]	
<b>Vorherige Verabreichung von Bevacizumab: Nein</b>			
Baseline			
n/N (%)	72/84 (86)	59/75 (79)	-
MW (SD)	62,85 (23,774)	67,09 (20,202)	
Absolute Werte zum Studienende			
n/N (%)	7/61 (11)	3/48 (6)	-
MW (SD)	69,05 (17,817)	63,89 (26,788)	
Effekt über Studiendauer			
n	72	59	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	3,13 (1,578)	-5,26 (1,794)	LS MD 8,39 [3,651; 13,126] 0,0006  Hedges' g 0,61 [0,262; 0,967]
95 %-KI	[0,003; 6,253]	[-8,812; -1,710]	
Veränderung zu Woche 3/4			
n/N (%)	53/83 (64)	41/73 (56)	LS MD 8,14 [2,637; 13,651]
MW (SD)	1,26 (22,313)	-2,44 (18,934)	
LS MW (SE)	3,14 (1,847)	-5,00 (2,093)	
95 %-KI	[-0,497; 6,787]	[-9,123; -0,875]	
Veränderung zu Woche 8/9			
n/N (%)	59/80 (74)	50/69 (72)	LS MD 8,25 [3,273; 13,217]
MW (SD)	3,53 (26,179)	-9,67 (22,485)	
LS MW (SE)	3,14 (1,668)	-5,11 (1,880)	
95 %-KI	[-0,159; 6,434]	[-8,820; -1,395]	
Veränderung zu Woche 12			
n/N (%)	43/79 (54)	34/69 (49)	LS MD 8,32 [3,544; 13,088]
MW (SD)	11,63 (24,877)	-8,09 (18,519)	
LS MW (SE)	3,13 (1,597)	-5,18 (1,802)	
95 %-KI	[-0,028; 6,293]	[-8,748; -1,618]	
Veränderung zu Woche 15/16			
n/N (%)	38/77 (49)	23/66 (35)	LS MD 8,39 [3,651; 13,123]
MW (SD)	7,24 (24,444)	-8,70 (20,486)	
LS MW (SE)	3,13 (1,578)	-5,26 (1,793)	
95 %-KI	[0,003; 6,252]	[-8,808; -1,709]	
Veränderung zu Woche 20/21			
n/N (%)	28/76 (37)	23/62 (37)	LS MD 8,49 [3,514; 13,461]
MW (SD)	8,93 (26,540)	-4,35 (18,269)	
LS MW (SE)	3,12 (1,643)	-5,37 (1,900)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-0,129; 6,371]	[-9,123; -1,612]	
Veränderung zu Woche 24			
n/N (%)	25/75 (33)	21/60 (35)	LS MD 8,56 [3,238; 13,879]
MW (SD)	9,00 (30,421)	0,40 (18,722)	
LS MW (SE)	3,12 (1,748)	-5,44 (2,048)	
95 %-KI	[-0,336; 6,567]	[-9,484; -1,402]	
Veränderung zu Woche 36			
n/N (%)	37/67 (55)	26/55 (47)	LS MD 8,80 [1,520; 16,083]
MW (SD)	2,03 (28,694)	-10,90 (17,602)	
LS MW (SE)	3,10 (2,361)	-5,70 (2,850)	
95 %-KI	[-1,546; 7,743]	[-11,306; -0,099]	
Veränderung zu Woche 48			
n/N (%)	5/61 (8)	3/48 (6)	LS MD 9,04 [-0,809; 18,897]
MW (SD)	8,33 (31,180)	2,78 (9,623)	
LS MW (SE)	3,08 (3,180)	-5,96 (3,877)	
95 %-KI	[-3,167; 9,330]	[-13,579; 1,654]	
<b>Letztes Platin-freies Intervall: ≤ 3 Monate</b>			
Baseline			
n/N (%)	68/83 (82)	62/91 (68)	-
MW (SD)	70,34 (20,834)	59,95 (20,179)	
Absolute Werte zum Studienende			
n/N (%)	3/55 (5)	5/39 (13)	-
MW (SD)	55,56 (29,266)	63,33 (21,731)	
Effekt über Studiendauer			
n	68	62	LS MD 5,52 [-0,072; 11,104] 0,0530
LS MW (SE)	-3,88 (1,870)	-9,39 (2,084)	
95 %-KI	[-7,582; -0,174]	[-13,520; -5,270]	Hedges' g 0,34 [-0,002; 0,692]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	50/82 (61)	46/86 (53)	LS MD 4,33 [-1,836; 10,500]
MW (SD)	-4,83 (19,129)	-2,54 (18,331)	
LS MW (SE)	-4,46 (2,082)	-8,80 (2,290)	
95 %-KI	[-8,572; -0,355]	[-13,312; -4,279]	
Veränderung zu Woche 8/9			
n/N (%)	52/81 (64)	46/80 (57)	LS MD 4,87 [-0,828; 10,576]
MW (SD)	-6,25 (23,155)	-7,43 (21,533)	
LS MW (SE)	-4,20 (1,916)	-9,07 (2,116)	
95 %-KI	[-7,986; -0,406]	[-13,253; -4,886]	
Veränderung zu Woche 12			
n/N (%)	33/78 (42)	25/78 (32)	LS MD 5,25 [-0,321; 10,827]
MW (SD)	-1,26 (22,546)	-7,00 (24,138)	
LS MW (SE)	-4,01 (1,868)	-9,26 (2,073)	
95 %-KI	[-7,707; -0,310]	[-13,364; -5,159]	
Veränderung zu Woche 15/16			
n/N (%)	35/76 (46)	14/75 (19)	LS MD 5,63 [0,011; 11,255]
MW (SD)	-1,67 (26,491)	-5,95 (27,817)	
LS MW (SE)	-3,82 (1,881)	-9,45 (2,100)	
95 %-KI	[-7,545; -0,096]	[-13,609; -5,298]	
Veränderung zu Woche 20/21			
n/N (%)	22/72 (31)	14/67 (21)	LS MD 6,18 [0,192; 12,159]
MW (SD)	-4,17 (24,227)	1,79 (21,725)	
LS MW (SE)	-3,55 (2,003)	-9,73 (2,253)	
95 %-KI	[-7,512; 0,406]	[-14,179; -5,278]	
Veränderung zu Woche 24			
n/N (%)	16/72 (22)	12/62 (19)	LS MD 6,55 [0,139; 12,971]
MW (SD)	-5,73 (29,458)	-6,25 (17,453)	
LS MW (SE)	-3,37 (2,150)	-9,92 (2,428)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-7,609; 0,878]	[-14,710; -5,131]	
Veränderung zu Woche 36			
n/N (%)	28/63 (44)	18/50 (36)	LS MD 7,86 [-0,800; 16,513]
MW (SD)	-4,76 (23,617)	-8,80 (15,252)	
LS MW (SE)	-2,72 (2,914)	-10,58 (3,305)	
95 %-KI	[-8,454; 3,008]	[-17,079; -4,078]	
Veränderung zu Woche 48			
n/N (%)	2/55 (4)	4/39 (10)	LS MD 9,16 [-2,357; 20,672]
MW (SD)	-25,00 (11,785)	-6,25 (10,486)	
LS MW (SE)	-2,08 (3,884)	-11,24 (4,402)	
95 %-KI	[-9,715; 5,555]	[-19,891; -2,583]	
<b>Letztes Platin-freies Intervall: &gt; 3 Monate</b>			
Baseline			
n/N (%)	110/135 (81)	97/116 (84)	-
MW (SD)	63,26 (22,528)	67,27 (21,491)	
Absolute Werte zum Studienende			
n/N (%)	7/85 (8)	1/71 (1)	-
MW (SD)	66,67 (18,002)	75,00 (NA)	
Effekt über Studiendauer			
n	110	97	LS MD 7,58 [3,707; 11,444] 0,0002  Hedges' g 0,54 [0,261; 0,817]
LS MW (SE)	1,47 (1,304)	-6,10 (1,459)	
95 %-KI	[-1,099; 4,048]	[-8,979; -3,225]	
Veränderung zu Woche 3/4			
n/N (%)	73/131 (56)	64/114 (56)	LS MD 7,89 [3,353; 12,421]
MW (SD)	1,14 (18,546)	-6,38 (18,530)	
LS MW (SE)	1,99 (1,537)	-5,90 (1,714)	
95 %-KI	[-1,033; 5,013]	[-9,268; -2,526]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	94/129 (73)	81/108 (75)	LS MD 7,75 [3,708; 11,796]
MW (SD)	3,01 (25,159)	-8,64 (24,240)	
LS MW (SE)	1,77 (1,383)	-5,99 (1,512)	
95 %-KI	[-0,959; 4,492]	[-8,963; -3,008]	
Veränderung zu Woche 12			
n/N (%)	66/127 (52)	47/105 (45)	LS MD 7,66 [3,780; 11,535]
MW (SD)	5,56 (29,138)	-7,45 (16,506)	
LS MW (SE)	1,61 (1,322)	-6,05 (1,451)	
95 %-KI	[-0,997; 4,216]	[-8,907; -3,189]	
Veränderung zu Woche 15/16			
n/N (%)	62/123 (50)	41/103 (40)	LS MD 7,56 [3,684; 11,442]
MW (SD)	3,09 (19,513)	-7,93 (23,640)	
LS MW (SE)	1,45 (1,305)	-6,11 (1,466)	
95 %-KI	[-1,122; 4,027]	[-9,000; -3,220]	
Veränderung zu Woche 20/21			
n/N (%)	46/118 (39)	37/98 (38)	LS MD 7,43 [3,261; 11,595]
MW (SD)	5,43 (25,044)	-5,63 (17,900)	
LS MW (SE)	1,23 (1,360)	-6,20 (1,615)	
95 %-KI	[-1,453; 3,910]	[-9,378; -3,020]	
Veränderung zu Woche 24			
n/N (%)	39/112 (35)	26/93 (28)	LS MD 7,33 [2,794; 11,873]
MW (SD)	4,06 (23,169)	-0,00 (16,667)	
LS MW (SE)	1,07 (1,450)	-6,26 (1,790)	
95 %-KI	[-1,782; 3,927]	[-9,782; -2,740]	
Veränderung zu Woche 36			
n/N (%)	55/97 (57)	30/84 (36)	LS MD 7,01 [0,534; 13,484]
MW (SD)	0,30 (21,395)	-10,00 (16,867)	
LS MW (SE)	0,53 (1,971)	-6,47 (2,641)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,337; 4,407]	[-11,661; -1,288]	
Veränderung zu Woche 48			
n/N (%)	6/85 (7)	1/71 (1)	LS MD 6,69 [-2,207; 15,578]
MW (SD)	0,00 (36,132)	8,33 (NA)	
LS MW (SE)	-0,00 (2,665)	-6,69 (3,663)	
95 %-KI	[-5,235; 5,230]	[-13,879; 0,503]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Pegyliertes liposomales Doxorubicin</b>			
Baseline			
n/N (%)	63/80 (79)	57/76 (75)	-
MW (SD)	63,10 (22,033)	67,84 (20,620)	
Absolute Werte zum Studienende			
n/N (%)	3/51 (6)	3/41 (7)	-
MW (SD)	55,56 (12,729)	77,78 (9,623)	
Effekt über Studiendauer			
n	63	57	LS MD 5,45 [0,244; 10,654] 0,0403  Hedges' g 0,38 [0,018; 0,741]
LS MW (SE)	0,25 (1,744)	-5,20 (1,952)	
95 %-KI	[-3,205; 3,711]	[-9,060; -1,333]	
Veränderung zu Woche 3/4			
n/N (%)	43/76 (57)	43/74 (58)	LS MD 6,25 [0,212; 12,295]
MW (SD)	0,58 (20,765)	-6,78 (18,833)	
LS MW (SE)	0,56 (2,081)	-5,69 (2,240)	
95 %-KI	[-3,543; 4,665]	[-10,109; -1,276]	
Veränderung zu Woche 8/9			
n/N (%)	52/76 (68)	44/66 (67)	LS MD 5,90 [0,499; 11,304]
MW (SD)	-0,32 (25,025)	-7,95 (23,430)	
LS MW (SE)	0,43 (1,860)	-5,48 (1,990)	
95 %-KI	[-3,253; 4,105]	[-9,408; -1,543]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	34/75 (45)	23/64 (36)	LS MD 5,66 [0,456; 10,855]
MW (SD)	7,84 (28,125)	-9,06 (17,751)	
LS MW (SE)	0,33 (1,770)	-5,32 (1,925)	
95 %-KI	[-3,176; 3,840]	[-9,136; -1,512]	
Veränderung zu Woche 15/16			
n/N (%)	35/74 (47)	19/62 (31)	LS MD 5,41 [0,185; 10,634]
MW (SD)	3,81 (24,946)	-10,09 (24,935)	
LS MW (SE)	0,24 (1,744)	-5,17 (1,965)	
95 %-KI	[-3,221; 3,696]	[-9,062; -1,282]	
Veränderung zu Woche 20/21			
n/N (%)	27/72 (38)	18/59 (31)	LS MD 5,06 [-0,585; 10,700]
MW (SD)	6,79 (23,687)	-4,17 (17,445)	
LS MW (SE)	0,10 (1,821)	-4,96 (2,187)	
95 %-KI	[-3,503; 3,708]	[-9,275; -0,636]	
Veränderung zu Woche 24			
n/N (%)	22/69 (32)	16/54 (30)	LS MD 4,81 [-1,351; 10,974]
MW (SD)	5,30 (29,044)	2,60 (14,181)	
LS MW (SE)	0,01 (1,947)	-4,80 (2,433)	
95 %-KI	[-3,840; 3,856]	[-9,601; -0,006]	
Veränderung zu Woche 36			
n/N (%)	31/60 (52)	16/48 (33)	LS MD 3,97 [-4,848; 12,783]
MW (SD)	-0,54 (28,701)	-10,42 (19,837)	
LS MW (SE)	-0,32 (2,683)	-4,28 (3,591)	
95 %-KI	[-5,594; 4,963]	[-11,345; 2,779]	
Veränderung zu Woche 48			
n/N (%)	2/51 (4)	2/41 (5)	LS MD 3,12 [-8,979; 15,226]
MW (SD)	-8,33 (11,785)	0,00 (11,785)	
LS MW (SE)	-0,64 (3,655)	-3,76 (4,963)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-7,824; 6,545]	[-13,519; 5,993]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Paclitaxel</b>			
Baseline			
n/N (%)	76/88 (86)	70/82 (85)	-
MW (SD)	67,43 (23,261)	60,48 (22,907)	
Absolute Werte zum Studienende			
n/N (%)	1/56 (2)	1/49 (2)	-
MW (SD)	25,00 (NA)	33,33 (NA)	
Effekt über Studiendauer			
n	76	70	LS MD 6,81 [1,856; 11,755] 0,0074  Hedges' g 0,45 [0,121; 0,779]
LS MW (SE)	-1,04 (1,688)	-7,85 (1,841)	
95 %-KI	[-4,384; 2,295]	[-11,489; -4,211]	
Veränderung zu Woche 3/4			
n/N (%)	56/87 (64)	49/81 (60)	LS MD 6,59 [0,962; 12,224]
MW (SD)	-1,49 (15,416)	-0,68 (19,157)	
LS MW (SE)	0,13 (1,918)	-6,46 (2,102)	
95 %-KI	[-3,651; 3,910]	[-10,604; -2,324]	
Veränderung zu Woche 8/9			
n/N (%)	64/86 (74)	56/79 (71)	LS MD 6,69 [1,572; 11,807]
MW (SD)	-0,00 (27,257)	-6,40 (22,585)	
LS MW (SE)	-0,40 (1,751)	-7,09 (1,898)	
95 %-KI	[-3,859; 3,058]	[-10,837; -3,343]	
Veränderung zu Woche 12			
n/N (%)	44/84 (52)	37/77 (48)	LS MD 6,76 [1,802; 11,711]
MW (SD)	0,19 (26,987)	-6,76 (21,770)	
LS MW (SE)	-0,77 (1,694)	-7,53 (1,837)	
95 %-KI	[-4,123; 2,578]	[-11,160; -3,898]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	46/81 (57)	28/76 (37)	LS MD 6,82 [1,852; 11,796]
MW (SD)	0,18 (19,680)	-4,76 (26,588)	
LS MW (SE)	-1,14 (1,693)	-7,97 (1,853)	
95 %-KI	[-4,493; 2,206]	[-11,629; -4,306]	
Veränderung zu Woche 20/21			
n/N (%)	30/77 (39)	26/73 (36)	LS MD 6,92 [1,618; 12,222]
MW (SD)	-3,89 (25,022)	-3,21 (21,612)	
LS MW (SE)	-1,67 (1,788)	-8,59 (2,001)	
95 %-KI	[-5,206; 1,858]	[-12,543; -4,645]	
Veränderung zu Woche 24			
n/N (%)	22/74 (30)	19/72 (26)	LS MD 6,99 [1,269; 12,705]
MW (SD)	-3,41 (21,309)	-5,70 (19,652)	
LS MW (SE)	-2,05 (1,914)	-9,03 (2,180)	
95 %-KI	[-5,820; 1,729]	[-13,327; -4,738]	
Veränderung zu Woche 36			
n/N (%)	37/64 (58)	24/63 (38)	LS MD 7,22 [-0,686; 15,122]
MW (SD)	-3,38 (16,252)	-9,72 (16,051)	
LS MW (SE)	-3,32 (2,593)	-10,54 (3,076)	
95 %-KI	[-8,416; 1,779]	[-16,581; -4,492]	
Veränderung zu Woche 48			
n/N (%)	1/56 (2)	1/49 (2)	LS MD 7,45 [-3,231; 18,128]
MW (SD)	-33,33 (NA)	-8,33 (NA)	
LS MW (SE)	-4,59 (3,472)	-12,04 (4,184)	
95 %-KI	[-11,412; 2,229]	[-20,259; -3,821]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Topotecan</b>			
Baseline			
n/N (%)	39/50 (78)	32/49 (65)	-
MW (SD)	67,74 (19,884)	66,93 (17,259)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	6/33 (18)	2/20 (10)	-
MW (SD)	73,61 (16,173)	62,50 (17,678)	
Effekt über Studiendauer			
n	39	32	LS MD 10,41 [2,995; 17,831] 0,0066  Hedges' g 0,66 [0,182; 1,143]
LS MW (SE)	-0,61 (2,440)	-11,02 (2,814)	
95 %-KI	[-5,486; 4,269]	[-16,632; -5,411]	
Veränderung zu Woche 3/4			
n/N (%)	24/50 (48)	18/45 (40)	LS MD 9,00 [0,916; 17,080]
MW (SD)	-4,17 (23,052)	-11,11 (13,098)	
LS MW (SE)	-2,73 (2,662)	-11,73 (3,092)	
95 %-KI	[-8,020; 2,558]	[-17,865; -5,593]	
Veränderung zu Woche 8/9			
n/N (%)	30/48 (62)	27/43 (63)	LS MD 9,60 [2,052; 17,157]
MW (SD)	-0,83 (18,870)	-12,35 (24,500)	
LS MW (SE)	-1,82 (2,497)	-11,43 (2,864)	
95 %-KI	[-6,803; 3,159]	[-17,128; -5,724]	
Veränderung zu Woche 12			
n/N (%)	21/46 (46)	12/42 (29)	LS MD 10,03 [2,632; 17,425]
MW (SD)	2,38 (26,371)	-5,56 (14,794)	
LS MW (SE)	-1,19 (2,442)	-11,21 (2,799)	
95 %-KI	[-6,066; 3,696]	[-16,795; -5,633]	
Veränderung zu Woche 15/16			
n/N (%)	16/44 (36)	8/40 (20)	LS MD 10,45 [3,024; 17,882]
MW (SD)	-0,52 (24,050)	-10,42 (15,905)	
LS MW (SE)	-0,55 (2,442)	-11,00 (2,820)	
95 %-KI	[-5,431; 4,333]	[-16,623; -5,381]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	11/41 (27)	7/33 (21)	LS MD 11,06 [3,265; 18,853]
MW (SD)	8,33 (26,615)	-3,57 (15,105)	
LS MW (SE)	0,36 (2,535)	-10,70 (2,992)	
95 %-KI	[-4,697; 5,418]	[-16,648; -4,750]	
Veränderung zu Woche 24			
n/N (%)	11/41 (27)	3/29 (10)	LS MD 11,48 [3,231; 19,736]
MW (SD)	2,27 (25,301)	-2,78 (4,811)	
LS MW (SE)	1,00 (2,660)	-10,49 (3,200)	
95 %-KI	[-4,297; 6,290]	[-16,834; -4,139]	
Veränderung zu Woche 36			
n/N (%)	15/36 (42)	8/23 (35)	LS MD 12,94 [2,191; 23,685]
MW (SD)	1,67 (20,217)	-7,29 (6,954)	
LS MW (SE)	3,18 (3,367)	-9,76 (4,281)	
95 %-KI	[-3,476; 9,833]	[-18,208; -1,311]	
Veränderung zu Woche 48			
n/N (%)	5/33 (15)	2/20 (10)	LS MD 14,39 [0,339; 28,447]
MW (SD)	0,00 (40,397)	-4,17 (17,678)	
LS MW (SE)	5,36 (4,330)	-9,03 (5,664)	
95 %-KI	[-3,178; 13,899]	[-20,199; 2,134]	
<p><i>Analysepopulation: ITT</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023</i></p> <p><i>Modell: Veränderung zu Baseline ~ Behandlung + Baseline-Wert * Zeit in Wochen + Behandlung * Zeit in Wochen + zufällige Effekte durch die Patientin</i></p> <p><i>Die Berechnung des LS-MWs erfolgt durch ein MMRM mit dem oben angegebenen Modell. Basierend hierauf werden KI und p-Wert ermittelt. Hedges' g basiert ebenfalls auf den LS-MW und ist somit auf das Modell angepasst.</i></p> <p><i>Es werden ausschließlich gemeinsame Analysezeitpunkte dargestellt.</i></p> <p><i>Ein LS MD und Hedges' g größer als Null bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			



## 2.10 EORTC QLQ-C30 kognitive Funktion

### EORTC QLQ-C30 kognitive Funktion: Subgruppenanalyse

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
<b>EORTC QLQ-C30 kognitive Funktion</b>			
<b>Alter: &lt; 65 Jahre</b>			
Baseline			
n/N (%)	94/115 (82)	91/119 (76)	-
MW (SD)	81,38 (21,287)	79,67 (20,608)	
Absolute Werte zum Studienende			
n/N (%)	4/73 (5)	4/64 (6)	-
MW (SD)	62,50 (28,464)	70,83 (8,333)	
Effekt über Studiendauer			
n	94	91	LS MD 3,33 [-1,124; 7,785] 0,1419
LS MW (SE)	0,18 (1,568)	-3,15 (1,624)	
95 %-KI	[-2,916; 3,273]	[-6,355; 0,051]	Hedges' g 0,22 [-0,073; 0,505]
Veränderung zu Woche 3/4			
n/N (%)	59/113 (52)	59/115 (51)	LS MD 0,31 [-4,336; 4,950]
MW (SD)	2,54 (16,613)	0,56 (18,037)	
LS MW (SE)	1,22 (1,639)	0,91 (1,691)	
95 %-KI	[-2,015; 4,448]	[-2,423; 4,242]	
Veränderung zu Woche 8/9			
n/N (%)	75/112 (67)	71/108 (66)	LS MD 1,64 [-2,853; 6,126]
MW (SD)	-0,44 (21,395)	-0,70 (17,914)	
LS MW (SE)	0,76 (1,587)	-0,88 (1,631)	
95 %-KI	[-2,371; 3,891]	[-4,093; 2,340]	
Veränderung zu Woche 12			
n/N (%)	47/110 (43)	39/105 (37)	
MW (SD)	-0,00 (15,148)	-3,42 (16,303)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	0,44 (1,570)	-2,13 (1,617)	LS MD 2,57 [-1,880; 7,015]
95 %-KI	[-2,657; 3,538]	[-5,317; 1,063]	
Veränderung zu Woche 15/16			
n/N (%)	52/107 (49)	32/102 (31)	LS MD 3,50 [-0,963; 7,959]
MW (SD)	-2,56 (16,953)	-1,56 (20,894)	
LS MW (SE)	0,12 (1,569)	-3,38 (1,627)	
95 %-KI	[-2,976; 3,217]	[-6,587; -0,167]	
Veränderung zu Woche 20/21			
n/N (%)	35/101 (35)	29/96 (30)	LS MD 4,83 [0,252; 9,403]
MW (SD)	2,86 (17,844)	-2,30 (14,587)	
LS MW (SE)	-0,34 (1,597)	-5,16 (1,683)	
95 %-KI	[-3,487; 2,815]	[-8,481; -1,846]	
Veränderung zu Woche 24			
n/N (%)	25/99 (25)	19/91 (21)	LS MD 5,76 [1,040; 10,477]
MW (SD)	0,67 (17,665)	-4,39 (15,558)	
LS MW (SE)	-0,66 (1,636)	-6,41 (1,748)	
95 %-KI	[-3,881; 2,570]	[-9,857; -2,971]	
Veränderung zu Woche 36			
n/N (%)	41/86 (48)	27/79 (34)	LS MD 8,95 [3,415; 14,484]
MW (SD)	-0,41 (18,815)	-3,09 (19,080)	
LS MW (SE)	-1,75 (1,873)	-10,70 (2,102)	
95 %-KI	[-5,436; 1,933]	[-14,832; -6,570]	
Veränderung zu Woche 48			
n/N (%)	4/73 (5)	3/64 (5)	LS MD 12,14 [5,437; 18,844]
MW (SD)	0,00 (13,608)	-11,11 (9,623)	
LS MW (SE)	-2,85 (2,227)	-14,99 (2,589)	
95 %-KI	[-7,221; 1,526]	[-20,071; -9,905]	
<b>Alter: ≥ 65 Jahre</b>			
Baseline			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	80/103 (78)	66/88 (75)	-
MW (SD)	80,83 (19,685)	85,35 (18,378)	
Absolute Werte zum Studienende			
n/N (%)	6/67 (9)	2/46 (4)	-
MW (SD)	88,89 (13,608)	75,00 (11,785)	
Effekt über Studiendauer			
n	80	66	LS MD 2,19 [-2,153; 6,529] 0,3207  Hedges' g 0,17 [-0,161; 0,492]
LS MW (SE)	-2,67 (1,450)	-4,86 (1,639)	
95 %-KI	[-5,538; 0,195]	[-8,099; -1,620]	
Veränderung zu Woche 3/4			
n/N (%)	59/100 (59)	48/85 (56)	LS MD 2,84 [-1,746; 7,432]
MW (SD)	2,82 (13,544)	-3,12 (14,447)	
LS MW (SE)	-0,69 (1,537)	-3,54 (1,732)	
95 %-KI	[-3,727; 2,340]	[-6,954; -0,119]	
Veränderung zu Woche 8/9			
n/N (%)	66/98 (67)	52/80 (65)	LS MD 2,55 [-1,836; 6,943]
MW (SD)	-2,53 (14,094)	-5,45 (17,993)	
LS MW (SE)	-1,57 (1,474)	-4,12 (1,649)	
95 %-KI	[-4,483; 1,344]	[-7,381; -0,864]	
Veränderung zu Woche 12			
n/N (%)	48/95 (51)	30/78 (38)	LS MD 2,35 [-1,984; 6,684]
MW (SD)	-2,43 (16,122)	-10,00 (18,362)	
LS MW (SE)	-2,18 (1,453)	-4,53 (1,630)	
95 %-KI	[-5,055; 0,690]	[-7,755; -1,311]	
Veränderung zu Woche 15/16			
n/N (%)	40/92 (43)	21/76 (28)	
MW (SD)	-2,50 (15,354)	-2,38 (16,060)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-2,80 (1,451)	-4,94 (1,645)	LS MD 2,15 [-2,203; 6,497]
95 %-KI	[-5,665; 0,072]	[-8,194; -1,693]	
Veränderung zu Woche 20/21			
n/N (%)	30/89 (34)	21/69 (30)	LS MD 1,86 [-2,640; 6,354]
MW (SD)	-3,89 (15,588)	-1,59 (17,404)	
LS MW (SE)	-3,67 (1,481)	-5,53 (1,722)	
95 %-KI	[-6,599; -0,745]	[-8,928; -2,131]	
Veränderung zu Woche 24			
n/N (%)	28/85 (33)	18/64 (28)	LS MD 1,65 [-3,026; 6,334]
MW (SD)	-2,38 (21,138)	-1,85 (19,711)	
LS MW (SE)	-4,29 (1,525)	-5,94 (1,811)	
95 %-KI	[-7,297; -1,274]	[-9,510; -2,369]	
Veränderung zu Woche 36			
n/N (%)	39/74 (53)	19/55 (35)	LS MD 0,96 [-4,743; 6,659]
MW (SD)	-2,99 (14,241)	-3,51 (20,472)	
LS MW (SE)	-6,39 (1,791)	-7,35 (2,280)	
95 %-KI	[-9,914; -2,862]	[-11,828; -2,864]	
Veränderung zu Woche 48			
n/N (%)	4/67 (6)	2/46 (4)	LS MD 0,26 [-6,856; 7,380]
MW (SD)	0,00 (13,608)	-16,67 (0,000)	
LS MW (SE)	-8,49 (2,181)	-8,75 (2,900)	
95 %-KI	[-12,776; -4,205]	[-14,447; -3,058]	
<b>Region: USA</b>			
Baseline			
n/N (%)	48/65 (74)	34/51 (67)	-
MW (SD)	82,64 (20,616)	82,84 (18,571)	
Absolute Werte zum Studienende			
n/N (%)	2/39 (5)	3/27 (11)	-
MW (SD)	58,33 (35,355)	72,22 (9,623)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Effekt über Studiendauer			
n	48	34	LS MD -1,41 [-7,065; 4,246] 0,6212  Hedges' g -0,11 [-0,550; 0,329]
LS MW (SE)	-1,94 (1,824)	-0,54 (2,181)	
95 %-KI	[-5,577; 1,688]	[-4,876; 3,806]	
Veränderung zu Woche 3/4			
n/N (%)	33/64 (52)	21/49 (43)	LS MD -2,53 [-8,470; 3,410]
MW (SD)	-1,01 (17,648)	-1,59 (7,274)	
LS MW (SE)	-3,18 (1,913)	-0,65 (2,304)	
95 %-KI	[-6,982; 0,616]	[-5,226; 3,921]	
Veränderung zu Woche 8/9			
n/N (%)	40/62 (65)	30/46 (65)	LS MD -2,02 [-7,748; 3,703]
MW (SD)	-4,17 (18,393)	-2,22 (18,431)	
LS MW (SE)	-2,62 (1,846)	-0,60 (2,211)	
95 %-KI	[-6,296; 1,051]	[-4,997; 3,799]	
Veränderung zu Woche 12			
n/N (%)	26/59 (44)	16/45 (36)	LS MD -1,67 [-7,327; 3,991]
MW (SD)	-0,64 (13,728)	-6,25 (14,751)	
LS MW (SE)	-2,23 (1,826)	-0,56 (2,183)	
95 %-KI	[-5,865; 1,405]	[-4,906; 3,781]	
Veränderung zu Woche 15/16			
n/N (%)	20/56 (36)	11/44 (25)	LS MD -1,31 [-6,976; 4,352]
MW (SD)	1,67 (11,970)	-4,55 (16,817)	
LS MW (SE)	-1,84 (1,827)	-0,53 (2,185)	
95 %-KI	[-5,475; 1,800]	[-4,873; 3,823]	
Veränderung zu Woche 20/21			
n/N (%)	12/54 (22)	9/40 (22)	
MW (SD)	1,39 (13,216)	1,85 (15,466)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-1,28 (1,868)	-0,47 (2,242)	LS MD -0,80 [-6,599; 4,990]
95 %-KI	[-4,991; 2,437]	[-4,928; 3,983]	
Veränderung zu Woche 24			
n/N (%)	9/53 (17)	6/38 (16)	LS MD -0,45 [-6,417; 5,518]
MW (SD)	-3,70 (11,111)	0,00 (14,907)	
LS MW (SE)	-0,88 (1,921)	-0,43 (2,317)	
95 %-KI	[-4,700; 2,931]	[-5,033; 4,163]	
Veränderung zu Woche 36			
n/N (%)	21/43 (49)	10/33 (30)	LS MD 0,77 [-6,228; 7,765]
MW (SD)	2,38 (9,554)	6,67 (14,055)	
LS MW (SE)	0,46 (2,239)	-0,31 (2,755)	
95 %-KI	[-3,961; 4,883]	[-5,745; 5,129]	
Veränderung zu Woche 48			
n/N (%)	2/39 (5)	3/27 (11)	LS MD 1,99 [-6,511; 10,485]
MW (SD)	8,33 (11,785)	-16,67 (0,000)	
LS MW (SE)	1,81 (2,701)	-0,18 (3,380)	
95 %-KI	[-3,511; 7,124]	[-6,831; 6,471]	
<b>Region: Rest der Welt</b>			
Baseline			
n/N (%)	126/153 (82)	123/156 (79)	-
MW (SD)	80,56 (20,521)	81,84 (20,245)	
Absolute Werte zum Studienende			
n/N (%)	8/101 (8)	3/83 (4)	-
MW (SD)	83,33 (19,920)	72,22 (9,623)	
Effekt über Studiendauer			
n	126	123	LS MD 3,83 [0,087; 7,580] 0,0449  Hedges' g
LS MW (SE)	-0,90 (1,318)	-4,74 (1,370)	
95 %-KI	[-3,499; 1,694]	[-7,434; -2,039]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
			0,25 [0,005; 0,504]
Veränderung zu Woche 3/4			
n/N (%)	85/149 (57)	86/151 (57)	LS MD 2,28 [-1,636; 6,191]
MW (SD)	4,12 (13,827)	-0,97 (18,142)	
LS MW (SE)	1,46 (1,385)	-0,82 (1,427)	
95 %-KI	[-1,267; 4,183]	[-3,627; 1,988]	
Veränderung zu Woche 8/9			
n/N (%)	101/148 (68)	93/142 (65)	LS MD 2,96 [-0,814; 6,732]
MW (SD)	-0,33 (18,254)	-2,87 (17,995)	
LS MW (SE)	0,42 (1,337)	-2,53 (1,371)	
95 %-KI	[-2,209; 3,058]	[-5,235; 0,166]	
Veränderung zu Woche 12			
n/N (%)	69/146 (47)	53/138 (38)	LS MD 3,44 [-0,301; 7,172]
MW (SD)	-1,45 (16,355)	-6,29 (18,265)	
LS MW (SE)	-0,30 (1,321)	-3,73 (1,361)	
95 %-KI	[-2,900; 2,302]	[-6,414; -1,055]	
Veränderung zu Woche 15/16			
n/N (%)	72/143 (50)	42/134 (31)	LS MD 3,91 [0,160; 7,665]
MW (SD)	-3,70 (17,066)	-1,19 (19,614)	
LS MW (SE)	-1,02 (1,319)	-4,93 (1,373)	
95 %-KI	[-3,620; 1,575]	[-7,639; -2,230]	
Veränderung zu Woche 20/21			
n/N (%)	53/136 (39)	41/125 (33)	LS MD 4,59 [0,727; 8,460]
MW (SD)	-0,63 (17,892)	-2,85 (15,768)	
LS MW (SE)	-2,06 (1,341)	-6,65 (1,432)	
95 %-KI	[-4,697; 0,586]	[-9,467; -3,832]	
Veränderung zu Woche 24			
n/N (%)	44/131 (34)	31/117 (26)	
MW (SD)	-0,38 (20,801)	-3,76 (18,110)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-2,78 (1,374)	-7,85 (1,497)	LS MD 5,07 [1,066; 9,075]
95 %-KI	[-5,484; -0,074]	[-10,795; -4,904]	
Veränderung zu Woche 36			
n/N (%)	59/117 (50)	36/101 (36)	LS MD 6,71 [1,930; 11,480]
MW (SD)	-3,11 (18,434)	-6,02 (19,981)	
LS MW (SE)	-5,26 (1,577)	-11,96 (1,843)	
95 %-KI	[-8,359; -2,161]	[-15,583; -8,346]	
Veränderung zu Woche 48			
n/N (%)	6/101 (6)	2/83 (2)	LS MD 8,34 [2,484; 14,195]
MW (SD)	-2,78 (12,546)	-8,33 (11,785)	
LS MW (SE)	-7,74 (1,882)	-16,08 (2,305)	
95 %-KI	[-11,433; -4,046]	[-20,603; -11,557]	
<b>Stadium bei der Diagnose: I-III</b>			
Baseline			
n/N (%)	111/141 (79)	112/144 (78)	-
MW (SD)	83,33 (19,069)	81,99 (20,643)	
Absolute Werte zum Studienende			
n/N (%)	6/91 (7)	4/76 (5)	-
MW (SD)	83,33 (14,907)	75,00 (9,623)	
Effekt über Studiendauer			
n	111	112	LS MD 1,29 [-2,239; 4,825] 0,4714
LS MW (SE)	-2,28 (1,254)	-3,57 (1,281)	
95 %-KI	[-4,751; 0,192]	[-6,097; -1,048]	Hedges' g 0,10 [-0,166; 0,359]
Veränderung zu Woche 3/4			
n/N (%)	73/137 (53)	79/138 (57)	LS MD 0,17 [-3,545; 3,886]
MW (SD)	2,28 (14,250)	-0,84 (15,308)	
LS MW (SE)	-0,56 (1,325)	-0,73 (1,344)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,172; 2,046]	[-3,380; 1,913]	
Veränderung zu Woche 8/9			
n/N (%)	92/136 (68)	87/129 (67)	LS MD 0,66 [-2,909; 4,234]
MW (SD)	-3,62 (14,789)	-2,68 (14,793)	
LS MW (SE)	-1,32 (1,275)	-1,98 (1,289)	
95 %-KI	[-3,827; 1,196]	[-4,518; 0,562]	
Veränderung zu Woche 12			
n/N (%)	60/133 (45)	47/128 (37)	LS MD 1,01 [-2,522; 4,536]
MW (SD)	-1,11 (13,329)	-4,61 (15,812)	
LS MW (SE)	-1,84 (1,257)	-2,85 (1,276)	
95 %-KI	[-4,320; 0,636]	[-5,364; -0,335]	
Veränderung zu Woche 15/16			
n/N (%)	59/130 (45)	35/125 (28)	LS MD 1,35 [-2,185; 4,888]
MW (SD)	-3,39 (16,889)	-3,33 (20,532)	
LS MW (SE)	-2,37 (1,254)	-3,72 (1,284)	
95 %-KI	[-4,842; 0,104]	[-6,251; -1,190]	
Veränderung zu Woche 20/21			
n/N (%)	43/123 (35)	34/116 (29)	LS MD 1,84 [-1,790; 5,478]
MW (SD)	-0,00 (14,086)	-1,96 (16,800)	
LS MW (SE)	-3,12 (1,277)	-4,97 (1,332)	
95 %-KI	[-5,638; -0,605]	[-7,588; -2,343]	
Veränderung zu Woche 24			
n/N (%)	33/121 (27)	26/109 (24)	LS MD 2,19 [-1,571; 5,947]
MW (SD)	-3,03 (19,744)	-2,56 (15,415)	
LS MW (SE)	-3,65 (1,311)	-5,84 (1,388)	
95 %-KI	[-6,230; -1,066]	[-8,569; -3,104]	
Veränderung zu Woche 36			
n/N (%)	52/105 (50)	35/92 (38)	
MW (SD)	-4,81 (15,245)	-4,29 (19,530)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-5,45 (1,520)	-8,82 (1,695)	LS MD 3,37 [-1,104; 7,842]
95 %-KI	[-8,442; -2,467]	[-12,153; -5,494]	
Veränderung zu Woche 48			
n/N (%)	5/91 (5)	4/76 (5)	LS MD 4,55 [-0,939; 10,039]
MW (SD)	-3,33 (13,944)	-16,67 (0,000)	
LS MW (SE)	-7,26 (1,831)	-11,81 (2,114)	
95 %-KI	[-10,856; -3,665]	[-15,958; -7,663]	
<b>Stadium bei der Diagnose: IV</b>			
Baseline			
n/N (%)	58/72 (81)	44/60 (73)	-
MW (SD)	77,30 (23,300)	82,20 (18,115)	
Absolute Werte zum Studienende			
n/N (%)	4/46 (9)	2/33 (6)	-
MW (SD)	70,83 (34,359)	66,67 (0,000)	
Effekt über Studiendauer			
n	58	44	LS MD 3,03 [-3,207; 9,263] 0,3377  Hedges' g 0,19 [-0,201; 0,585]
LS MW (SE)	0,87 (2,036)	-2,16 (2,381)	
95 %-KI	[-3,172; 4,911]	[-6,881; 2,565]	
Veränderung zu Woche 3/4			
n/N (%)	40/71 (56)	27/59 (46)	LS MD 2,06 [-4,447; 8,558]
MW (SD)	2,92 (16,831)	-1,23 (20,110)	
LS MW (SE)	1,28 (2,128)	-0,77 (2,489)	
95 %-KI	[-2,932; 5,498]	[-5,699; 4,154]	
Veränderung zu Woche 8/9			
n/N (%)	44/69 (64)	35/56 (62)	LS MD 2,49 [-3,775; 8,752]
MW (SD)	2,65 (24,097)	-2,38 (24,636)	
LS MW (SE)	1,10 (2,058)	-1,39 (2,383)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-2,984; 5,182]	[-6,114; 3,335]	
Veränderung zu Woche 12			
n/N (%)	30/67 (45)	21/52 (40)	LS MD 2,79 [-3,418; 9,001]
MW (SD)	0,00 (18,570)	-10,32 (20,734)	
LS MW (SE)	0,97 (2,037)	-1,82 (2,363)	
95 %-KI	[-3,072; 5,012]	[-6,510; 2,868]	
Veränderung zu Woche 15/16			
n/N (%)	30/64 (47)	17/50 (34)	LS MD 3,09 [-3,158; 9,347]
MW (SD)	-1,67 (14,746)	0,98 (16,106)	
LS MW (SE)	0,84 (2,038)	-2,25 (2,392)	
95 %-KI	[-3,204; 4,887]	[-6,996; 2,490]	
Veränderung zu Woche 20/21			
n/N (%)	19/62 (31)	15/46 (33)	LS MD 3,53 [-2,950; 10,004]
MW (SD)	0,00 (23,570)	-1,11 (13,313)	
LS MW (SE)	0,66 (2,081)	-2,87 (2,510)	
95 %-KI	[-3,470; 4,784]	[-7,839; 2,099]	
Veränderung zu Woche 24			
n/N (%)	18/59 (31)	10/44 (23)	LS MD 3,83 [-2,910; 10,571]
MW (SD)	3,70 (19,433)	1,67 (9,461)	
LS MW (SE)	0,53 (2,138)	-3,30 (2,642)	
95 %-KI	[-3,707; 4,764]	[-8,523; 1,919]	
Veränderung zu Woche 36			
n/N (%)	27/52 (52)	10/41 (24)	LS MD 4,87 [-3,300; 13,038]
MW (SD)	3,70 (18,101)	5,00 (11,249)	
LS MW (SE)	0,09 (2,475)	-4,78 (3,319)	
95 %-KI	[-4,795; 4,967]	[-11,314; 1,748]	
Veränderung zu Woche 48			
n/N (%)	3/46 (7)	1/33 (3)	
MW (SD)	5,56 (9,623)	0,00 (NA)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-0,36 (2,967)	-6,26 (4,206)	LS MD 5,91 [-4,224; 16,039]
95 %-KI	[-6,193; 5,481]	[-14,527; 2,000]	
<b>BRCA Status: Positiv</b>			
Baseline			
n/N (%)	25/27 (93)	23/35 (66)	-
MW (SD)	84,00 (21,235)	81,16 (20,904)	
Absolute Werte zum Studienende			
n/N (%)	1/19 (5)	0/15 (0)	-
MW (SD)	50,00 (NA)	NA (NA)	
Effekt über Studiendauer			
n	25	23	LS MD 1,66 [-9,145; 12,461] 0,7587
LS MW (SE)	-5,58 (3,633)	-7,24 (3,947)	
95 %-KI	[-12,903; 1,748]	[-15,182; 0,712]	Hedges' g 0,09 [-0,479; 0,655]
Veränderung zu Woche 3/4			
n/N (%)	16/27 (59)	18/35 (51)	LS MD -2,60 [-13,672; 8,474]
MW (SD)	3,13 (13,903)	-3,70 (28,328)	
LS MW (SE)	-6,45 (3,762)	-3,85 (4,033)	
95 %-KI	[-14,010; 1,104]	[-11,953; 4,245]	
Veränderung zu Woche 8/9			
n/N (%)	21/26 (81)	19/30 (63)	LS MD -0,51 [-11,310; 10,290]
MW (SD)	-10,32 (17,854)	-0,88 (18,818)	
LS MW (SE)	-6,02 (3,667)	-5,51 (3,914)	
95 %-KI	[-13,409; 1,362]	[-13,400; 2,373]	
Veränderung zu Woche 12			
n/N (%)	14/26 (54)	10/30 (33)	LS MD 0,95 [-9,818; 11,722]
MW (SD)	-9,52 (16,939)	-10,00 (23,831)	
LS MW (SE)	-5,72 (3,637)	-6,67 (3,919)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-13,054; 1,609]	[-14,570; 1,221]	
Veränderung zu Woche 15/16			
n/N (%)	11/26 (42)	8/29 (28)	LS MD 2,41 [-8,459; 13,287]
MW (SD)	-9,09 (13,670)	2,08 (13,909)	
LS MW (SE)	-5,42 (3,637)	-7,84 (3,996)	
95 %-KI	[-12,755; 1,912]	[-15,871; 0,199]	
Veränderung zu Woche 20/21			
n/N (%)	10/25 (40)	4/25 (16)	LS MD 4,50 [-6,743; 15,750]
MW (SD)	3,33 (13,147)	0,00 (0,000)	
LS MW (SE)	-4,99 (3,691)	-9,50 (4,223)	
95 %-KI	[-12,423; 2,439]	[-17,945; -1,045]	
Veränderung zu Woche 24			
n/N (%)	7/25 (28)	3/24 (12)	LS MD 5,97 [-5,691; 17,622]
MW (SD)	-2,38 (11,501)	0,00 (0,000)	
LS MW (SE)	-4,69 (3,765)	-10,66 (4,453)	
95 %-KI	[-12,256; 2,874]	[-19,535; -1,778]	
Veränderung zu Woche 36			
n/N (%)	10/21 (48)	5/20 (25)	LS MD 10,98 [-2,856; 24,814]
MW (SD)	-6,67 (19,563)	-10,00 (9,129)	
LS MW (SE)	-3,66 (4,216)	-14,64 (5,570)	
95 %-KI	[-12,059; 4,740]	[-25,646; -3,630]	
Veränderung zu Woche 48			
n/N (%)	1/19 (5)	0/15 (0)	LS MD 15,99 [-0,851; 32,836]
MW (SD)	0,00 (NA)	NA (NA)	
LS MW (SE)	-2,63 (4,901)	-18,62 (6,996)	
95 %-KI	[-12,330; 7,073]	[-32,402; -4,838]	
<b>BRCA Status: Negativ/Unbekannt</b>			
Baseline			
n/N (%)	149/191 (78)	134/172 (78)	-

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	80,65 (20,419)	82,21 (19,731)	
Absolute Werte zum Studienende			
n/N (%)	9/121 (7)	6/95 (6)	-
MW (SD)	81,48 (22,737)	72,22 (8,607)	
Effekt über Studiendauer			
n	149	134	LS MD 2,50 [-0,715; 5,706] 0,1271  Hedges' g 0,18 [-0,052; 0,416]
LS MW (SE)	-0,54 (1,110)	-3,04 (1,194)	
95 %-KI	[-2,729; 1,642]	[-5,388; -0,690]	
Veränderung zu Woche 3/4			
n/N (%)	102/186 (55)	89/165 (54)	LS MD 1,52 [-1,861; 4,903]
MW (SD)	2,61 (15,334)	-0,56 (13,164)	
LS MW (SE)	1,24 (1,172)	-0,28 (1,257)	
95 %-KI	[-1,060; 3,549]	[-2,749; 2,197]	
Veränderung zu Woche 8/9			
n/N (%)	120/184 (65)	104/158 (66)	LS MD 1,94 [-1,302; 5,190]
MW (SD)	0,14 (18,012)	-3,04 (17,954)	
LS MW (SE)	0,47 (1,127)	-1,48 (1,203)	
95 %-KI	[-1,750; 2,686]	[-3,844; 0,892]	
Veränderung zu Woche 12			
n/N (%)	81/179 (45)	59/153 (39)	LS MD 2,24 [-0,966; 5,447]
MW (SD)	0,21 (15,022)	-5,65 (16,262)	
LS MW (SE)	-0,08 (1,112)	-2,32 (1,189)	
95 %-KI	[-2,265; 2,114]	[-4,656; 0,025]	
Veränderung zu Woche 15/16			
n/N (%)	81/173 (47)	45/149 (30)	LS MD 2,54 [-0,678; 5,751]
MW (SD)	-1,65 (16,373)	-2,59 (19,770)	
LS MW (SE)	-0,62 (1,111)	-3,16 (1,196)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-2,806; 1,568]	[-5,509; -0,802]	
Veränderung zu Woche 20/21			
n/N (%)	55/165 (33)	46/140 (33)	LS MD 2,96 [-0,349; 6,269]
MW (SD)	-0,91 (17,690)	-2,17 (16,333)	
LS MW (SE)	-1,40 (1,133)	-4,36 (1,240)	
95 %-KI	[-3,625; 0,835]	[-6,795; -1,915]	
Veränderung zu Woche 24			
n/N (%)	46/159 (29)	34/131 (26)	LS MD 3,26 [-0,172; 6,685]
MW (SD)	-0,72 (20,475)	-3,43 (18,248)	
LS MW (SE)	-1,94 (1,165)	-5,19 (1,294)	
95 %-KI	[-4,230; 0,353]	[-7,739; -2,650]	
Veränderung zu Woche 36			
n/N (%)	70/139 (50)	41/114 (36)	LS MD 4,27 [0,164; 8,381]
MW (SD)	-0,95 (16,272)	-2,44 (20,263)	
LS MW (SE)	-3,80 (1,358)	-8,07 (1,586)	
95 %-KI	[-6,468; -1,135]	[-11,188; -4,959]	
Veränderung zu Woche 48			
n/N (%)	7/121 (6)	5/95 (5)	LS MD 5,29 [0,221; 10,356]
MW (SD)	0,00 (13,608)	-13,33 (7,454)	
LS MW (SE)	-5,66 (1,642)	-10,95 (1,985)	
95 %-KI	[-8,886; -2,443]	[-14,847; -7,058]	
<b>Baseline ECOG PS: 0</b>			
Baseline			
n/N (%)	98/128 (77)	95/113 (84)	-
MW (SD)	84,18 (20,500)	84,39 (15,339)	
Absolute Werte zum Studienende			
n/N (%)	7/87 (8)	3/72 (4)	-
MW (SD)	69,05 (22,420)	66,67 (0,000)	
Effekt über Studiendauer			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n	98	95	LS MD 1,05 [-2,937; 5,029] 0,6051  Hedges' g 0,07 [-0,208; 0,357]
LS MW (SE)	-1,91 (1,401)	-2,95 (1,454)	
95 %-KI	[-4,673; 0,857]	[-5,822; -0,086]	
Veränderung zu Woche 3/4			
n/N (%)	67/127 (53)	62/111 (56)	LS MD 1,13 [-3,068; 5,325]
MW (SD)	2,24 (12,612)	-2,15 (17,463)	
LS MW (SE)	-0,66 (1,477)	-1,78 (1,535)	
95 %-KI	[-3,566; 2,254]	[-4,809; 1,240]	
Veränderung zu Woche 8/9			
n/N (%)	81/126 (64)	73/108 (68)	LS MD 1,09 [-2,939; 5,126]
MW (SD)	-3,50 (17,622)	-3,42 (16,657)	
LS MW (SE)	-1,19 (1,424)	-2,29 (1,468)	
95 %-KI	[-4,001; 1,614]	[-5,182; 0,608]	
Veränderung zu Woche 12			
n/N (%)	50/122 (41)	44/108 (41)	LS MD 1,07 [-2,913; 5,050]
MW (SD)	-1,00 (15,212)	-6,06 (19,387)	
LS MW (SE)	-1,57 (1,405)	-2,64 (1,450)	
95 %-KI	[-4,341; 1,201]	[-5,498; 0,221]	
Veränderung zu Woche 15/16			
n/N (%)	52/120 (43)	33/105 (31)	LS MD 1,04 [-2,943; 5,029]
MW (SD)	-3,85 (16,704)	-4,04 (22,060)	
LS MW (SE)	-1,95 (1,402)	-2,99 (1,456)	
95 %-KI	[-4,712; 0,820]	[-5,861; -0,118]	
Veränderung zu Woche 20/21			
n/N (%)	39/117 (33)	31/101 (31)	LS MD 1,01 [-3,079; 5,095]
MW (SD)	-2,14 (16,303)	-1,08 (18,726)	
LS MW (SE)	-2,48 (1,426)	-3,49 (1,507)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-5,296; 0,328]	[-6,461; -0,523]	
Veränderung zu Woche 24			
n/N (%)	27/112 (24)	22/96 (23)	LS MD 0,98 [-3,238; 5,204]
MW (SD)	-1,23 (11,253)	-0,76 (12,037)	
LS MW (SE)	-2,86 (1,461)	-3,84 (1,569)	
95 %-KI	[-5,740; 0,019]	[-6,933; -0,753]	
Veränderung zu Woche 36			
n/N (%)	49/99 (49)	33/87 (38)	LS MD 0,90 [-4,103; 5,899]
MW (SD)	-3,06 (18,842)	1,01 (17,648)	
LS MW (SE)	-4,15 (1,681)	-5,05 (1,915)	
95 %-KI	[-7,457; -0,844]	[-8,811; -1,285]	
Veränderung zu Woche 48			
n/N (%)	5/87 (6)	3/72 (4)	LS MD 0,81 [-5,310; 6,934]
MW (SD)	-3,33 (13,944)	-11,11 (9,623)	
LS MW (SE)	-5,44 (2,013)	-6,25 (2,391)	
95 %-KI	[-9,393; -1,489]	[-10,947; -1,560]	
<b>Baseline ECOG PS: 1</b>			
Baseline			
n/N (%)	76/90 (84)	61/91 (67)	-
MW (SD)	77,19 (19,971)	78,14 (25,008)	
Absolute Werte zum Studienende			
n/N (%)	3/53 (6)	3/37 (8)	-
MW (SD)	100,00 (0,000)	77,78 (9,623)	
Effekt über Studiendauer			
n	76	61	LS MD 4,65 [-0,406; 9,700] 0,0712
LS MW (SE)	-0,23 (1,682)	-4,88 (1,922)	
95 %-KI	[-3,558; 3,099]	[-8,676; -1,077]	Hedges' g 0,31 [-0,027; 0,651]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	51/86 (59)	44/87 (51)	LS MD 0,74 [-4,501; 5,988]
MW (SD)	3,27 (17,957)	0,76 (15,231)	
LS MW (SE)	1,57 (1,763)	0,82 (1,986)	
95 %-KI	[-1,914; 5,050]	[-3,097; 4,747]	
Veränderung zu Woche 8/9			
n/N (%)	60/84 (71)	49/78 (63)	LS MD 2,53 [-2,535; 7,604]
MW (SD)	1,39 (18,988)	-1,36 (20,080)	
LS MW (SE)	0,74 (1,702)	-1,79 (1,917)	
95 %-KI	[-2,623; 4,110]	[-5,581; 1,998]	
Veränderung zu Woche 12			
n/N (%)	45/83 (54)	24/74 (32)	LS MD 3,79 [-1,245; 8,823]
MW (SD)	-1,48 (16,214)	-6,25 (13,737)	
LS MW (SE)	0,17 (1,684)	-3,62 (1,908)	
95 %-KI	[-3,165; 3,496]	[-7,396; 0,150]	
Veränderung zu Woche 15/16			
n/N (%)	40/79 (51)	20/72 (28)	LS MD 5,04 [-0,031; 10,116]
MW (SD)	-0,83 (15,539)	1,67 (11,970)	
LS MW (SE)	-0,41 (1,685)	-5,45 (1,934)	
95 %-KI	[-3,746; 2,922]	[-9,276; -1,633]	
Veränderung zu Woche 20/21			
n/N (%)	26/73 (36)	18/63 (29)	LS MD 6,83 [1,580; 12,088]
MW (SD)	2,56 (18,069)	-2,78 (8,575)	
LS MW (SE)	-1,24 (1,722)	-8,07 (2,025)	
95 %-KI	[-4,641; 2,167]	[-12,069; -4,073]	
Veränderung zu Woche 24			
n/N (%)	26/72 (36)	14/58 (24)	LS MD 8,09 [2,626; 13,549]
MW (SD)	-0,64 (25,595)	-3,57 (20,856)	
LS MW (SE)	-1,81 (1,771)	-9,90 (2,125)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-5,312; 1,683]	[-14,092; -5,713]	
Veränderung zu Woche 36			
n/N (%)	31/61 (51)	13/46 (28)	LS MD 12,39 [5,811; 18,964]
MW (SD)	0,54 (12,534)	-14,10 (20,237)	
LS MW (SE)	-3,79 (2,059)	-16,18 (2,629)	
95 %-KI	[-7,848; 0,259]	[-21,350; -11,015]	
Veränderung zu Woche 48			
n/N (%)	3/53 (6)	2/37 (5)	LS MD 16,69 [8,582; 24,791]
MW (SD)	5,56 (9,623)	-16,67 (0,000)	
LS MW (SE)	-5,77 (2,479)	-22,46 (3,291)	
95 %-KI	[-10,646; -0,904]	[-28,923; -16,001]	
<b>Anzahl vorheriger Therapielinien: 1</b>			
Baseline			
n/N (%)	24/31 (77)	22/29 (76)	-
MW (SD)	77,78 (21,234)	85,61 (16,504)	
Absolute Werte zum Studienende			
n/N (%)	1/22 (5)	0/14 (0)	-
MW (SD)	66,67 (NA)	NA (NA)	
Effekt über Studiendauer			
n	24	22	LS MD 5,70 [-3,856; 15,249] 0,2357  Hedges' g 0,35 [-0,230; 0,937]
LS MW (SE)	-0,03 (3,221)	-5,73 (3,397)	
95 %-KI	[-6,532; 6,468]	[-12,574; 1,116]	
Veränderung zu Woche 3/4			
n/N (%)	16/31 (52)	13/29 (45)	LS MD 10,02 [0,059; 19,972]
MW (SD)	3,12 (12,500)	-2,56 (9,245)	
LS MW (SE)	3,00 (3,363)	-7,02 (3,568)	
95 %-KI	[-3,760; 9,751]	[-14,173; 0,133]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	20/31 (65)	17/26 (65)	LS MD 8,23 [-1,417; 17,870]
MW (SD)	5,00 (15,390)	-15,69 (23,177)	
LS MW (SE)	1,74 (3,267)	-6,49 (3,428)	
95 %-KI	[-4,841; 8,324]	[-13,383; 0,413]	
Veränderung zu Woche 12			
n/N (%)	14/31 (45)	11/24 (46)	LS MD 6,97 [-2,572; 16,520]
MW (SD)	3,57 (19,805)	-1,52 (11,677)	
LS MW (SE)	0,86 (3,231)	-6,11 (3,387)	
95 %-KI	[-5,654; 7,381]	[-12,937; 0,715]	
Veränderung zu Woche 15/16			
n/N (%)	15/31 (48)	10/22 (45)	LS MD 5,72 [-3,830; 15,273]
MW (SD)	-5,56 (17,442)	-1,67 (5,270)	
LS MW (SE)	-0,01 (3,221)	-5,74 (3,397)	
95 %-KI	[-6,514; 6,486]	[-12,580; 1,107]	
Veränderung zu Woche 20/21			
n/N (%)	11/30 (37)	9/22 (41)	LS MD 3,93 [-5,805; 13,670]
MW (SD)	3,03 (17,979)	0,00 (11,785)	
LS MW (SE)	-1,27 (3,252)	-5,20 (3,495)	
95 %-KI	[-7,825; 5,288]	[-12,224; 1,822]	
Veränderung zu Woche 24			
n/N (%)	9/30 (30)	11/20 (55)	LS MD 2,68 [-7,308; 12,669]
MW (SD)	-3,70 (30,932)	1,52 (8,989)	
LS MW (SE)	-2,15 (3,306)	-4,83 (3,619)	
95 %-KI	[-8,799; 4,507]	[-12,078; 2,425]	
Veränderung zu Woche 36			
n/N (%)	15/26 (58)	6/18 (33)	LS MD -1,61 [-13,121; 9,895]
MW (SD)	-0,00 (10,911)	0,00 (18,257)	
LS MW (SE)	-5,16 (3,665)	-3,54 (4,325)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-12,469; 2,157]	[-12,122; 5,037]	
Veränderung zu Woche 48			
n/N (%)	0/22 (0)	0/14 (0)	LS MD -5,91 [-19,694; 7,879]
MW (SD)	NA (NA)	NA (NA)	
LS MW (SE)	-8,17 (4,238)	-2,26 (5,319)	
95 %-KI	[-16,560; 0,229]	[-12,755; 8,238]	
<b>Anzahl vorheriger Therapielinien: 2</b>			
Baseline			
n/N (%)	75/89 (84)	64/83 (77)	-
MW (SD)	81,78 (21,430)	81,51 (22,443)	
Absolute Werte zum Studienende			
n/N (%)	4/59 (7)	2/50 (4)	-
MW (SD)	75,00 (21,517)	75,00 (11,785)	
Effekt über Studiendauer			
n	75	64	LS MD 2,39 [-2,752; 7,525] 0,3600  Hedges' g 0,16 [-0,178; 0,490]
LS MW (SE)	-0,45 (1,739)	-2,84 (1,931)	
95 %-KI	[-3,895; 2,986]	[-6,658; 0,975]	
Veränderung zu Woche 3/4			
n/N (%)	53/86 (62)	45/80 (56)	LS MD 0,44 [-4,912; 5,788]
MW (SD)	2,52 (16,144)	0,37 (17,940)	
LS MW (SE)	1,46 (1,820)	1,02 (2,008)	
95 %-KI	[-2,137; 5,051]	[-2,944; 4,983]	
Veränderung zu Woche 8/9			
n/N (%)	62/85 (73)	51/77 (66)	LS MD 1,31 [-3,854; 6,481]
MW (SD)	0,54 (21,118)	0,65 (17,308)	
LS MW (SE)	0,60 (1,761)	-0,72 (1,932)	
95 %-KI	[-2,884; 4,081]	[-4,534; 3,102]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	39/83 (47)	30/75 (40)	LS MD 1,93 [-3,197; 7,051]
MW (SD)	-1,28 (12,901)	-9,44 (19,906)	
LS MW (SE)	-0,00 (1,742)	-1,93 (1,918)	
95 %-KI	[-3,448; 3,442]	[-5,723; 1,863]	
Veränderung zu Woche 15/16			
n/N (%)	41/80 (51)	19/74 (26)	LS MD 2,54 [-2,612; 7,691]
MW (SD)	-3,66 (14,678)	3,51 (15,294)	
LS MW (SE)	-0,60 (1,741)	-3,14 (1,939)	
95 %-KI	[-4,048; 2,839]	[-6,977; 0,689]	
Veränderung zu Woche 20/21			
n/N (%)	32/78 (41)	20/68 (29)	LS MD 3,42 [-1,898; 8,729]
MW (SD)	-1,56 (18,626)	-5,00 (15,390)	
LS MW (SE)	-1,46 (1,771)	-4,88 (2,025)	
95 %-KI	[-4,965; 2,037]	[-8,876; -0,881]	
Veränderung zu Woche 24			
n/N (%)	27/74 (36)	13/65 (20)	LS MD 4,03 [-1,478; 9,534]
MW (SD)	0,00 (19,059)	-7,69 (22,169)	
LS MW (SE)	-2,07 (1,813)	-6,09 (2,121)	
95 %-KI	[-5,647; 1,517]	[-10,275; -1,911]	
Veränderung zu Woche 36			
n/N (%)	33/65 (51)	18/58 (31)	LS MD 6,13 [-0,439; 12,697]
MW (SD)	-2,53 (20,035)	-4,63 (24,790)	
LS MW (SE)	-4,13 (2,073)	-10,26 (2,617)	
95 %-KI	[-8,210; -0,045]	[-15,402; -5,110]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	1/50 (2)	LS MD 8,23 [0,180; 16,280]
MW (SD)	-4,17 (15,957)	-16,67 (NA)	
LS MW (SE)	-6,19 (2,462)	-14,42 (3,277)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-11,028; -1,350]	[-20,854; -7,985]	
<b>Anzahl vorheriger Therapielinien: 3</b>			
Baseline			
n/N (%)	75/98 (77)	71/95 (75)	-
MW (SD)	81,56 (19,485)	81,46 (18,376)	
Absolute Werte zum Studienende			
n/N (%)	5/59 (8)	4/46 (9)	-
MW (SD)	83,33 (28,868)	70,83 (8,333)	
Effekt über Studiendauer			
n	75	71	LS MD 1,25 [-3,108; 5,600] 0,5724  Hedges' g 0,09 [-0,231; 0,418]
LS MW (SE)	-2,39 (1,521)	-3,64 (1,593)	
95 %-KI	[-5,400; 0,616]	[-6,787; -0,489]	
Veränderung zu Woche 3/4			
n/N (%)	49/96 (51)	49/91 (54)	LS MD -0,91 [-5,490; 3,673]
MW (SD)	2,72 (14,964)	-2,04 (16,885)	
LS MW (SE)	-1,65 (1,608)	-0,74 (1,676)	
95 %-KI	[-4,824; 1,522]	[-4,050; 2,564]	
Veränderung zu Woche 8/9			
n/N (%)	59/94 (63)	55/85 (65)	LS MD 0,05 [-4,351; 4,446]
MW (SD)	-5,65 (15,038)	-1,82 (15,273)	
LS MW (SE)	-1,98 (1,543)	-2,03 (1,605)	
95 %-KI	[-5,029; 1,069]	[-5,200; 1,145]	
Veränderung zu Woche 12			
n/N (%)	42/91 (46)	28/84 (33)	LS MD 0,72 [-3,630; 5,064]
MW (SD)	-2,78 (16,428)	-4,76 (16,265)	
LS MW (SE)	-2,21 (1,522)	-2,93 (1,588)	
95 %-KI	[-5,220; 0,800]	[-6,065; 0,212]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	36/88 (41)	24/82 (29)	LS MD 1,39 [-2,977; 5,748]
MW (SD)	0,00 (17,366)	-6,25 (23,983)	
LS MW (SE)	-2,44 (1,523)	-3,83 (1,598)	
95 %-KI	[-5,451; 0,571]	[-6,984; -0,668]	
Veränderung zu Woche 20/21			
n/N (%)	22/82 (27)	21/75 (28)	LS MD 2,34 [-2,155; 6,839]
MW (SD)	-0,00 (14,548)	-0,00 (17,480)	
LS MW (SE)	-2,77 (1,561)	-5,11 (1,658)	
95 %-KI	[-5,853; 0,315]	[-8,383; -1,838]	
Veränderung zu Woche 24			
n/N (%)	17/80 (21)	13/70 (19)	LS MD 3,01 [-1,655; 7,676]
MW (SD)	-0,98 (12,459)	-2,56 (17,803)	
LS MW (SE)	-3,00 (1,612)	-6,01 (1,729)	
95 %-KI	[-6,181; 0,183]	[-9,420; -2,600]	
Veränderung zu Woche 36			
n/N (%)	32/69 (46)	22/58 (38)	LS MD 5,31 [-0,309; 10,919]
MW (SD)	-1,56 (15,473)	-3,03 (15,115)	
LS MW (SE)	-3,79 (1,911)	-9,09 (2,117)	
95 %-KI	[-7,549; -0,028]	[-13,256; -4,931]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	4/46 (9)	LS MD 7,60 [0,655; 14,543]
MW (SD)	4,17 (8,333)	-12,50 (8,333)	
LS MW (SE)	-4,58 (2,341)	-12,18 (2,645)	
95 %-KI	[-9,175; 0,020]	[-17,370; -6,983]	
<b>Vorherige Verabreichung von Bevacizumab: Ja</b>			
Baseline			
n/N (%)	103/134 (77)	99/132 (75)	-
MW (SD)	83,33 (17,774)	81,48 (20,741)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	3/79 (4)	3/62 (5)	-
MW (SD)	83,33 (16,667)	72,22 (9,623)	
Effekt über Studiendauer			
n	103	99	LS MD 1,40 [-2,535; 5,334] 0,4838  Hedges' g 0,10 [-0,178; 0,374]
LS MW (SE)	-2,41 (1,376)	-3,81 (1,446)	
95 %-KI	[-5,125; 0,303]	[-6,663; -0,959]	
Veränderung zu Woche 3/4			
n/N (%)	67/130 (52)	67/127 (53)	LS MD 1,47 [-2,643; 5,574]
MW (SD)	1,00 (15,042)	-1,24 (14,883)	
LS MW (SE)	0,01 (1,442)	-1,45 (1,509)	
95 %-KI	[-2,831; 2,853]	[-4,426; 1,517]	
Veränderung zu Woche 8/9			
n/N (%)	83/130 (64)	74/119 (62)	LS MD 1,43 [-2,520; 5,390]
MW (SD)	-2,61 (17,746)	-2,48 (17,378)	
LS MW (SE)	-1,12 (1,393)	-2,56 (1,445)	
95 %-KI	[-3,869; 1,623]	[-5,407; 0,292]	
Veränderung zu Woche 12			
n/N (%)	54/126 (43)	37/114 (32)	LS MD 1,41 [-2,509; 5,336]
MW (SD)	-2,16 (15,543)	-5,41 (13,639)	
LS MW (SE)	-1,92 (1,377)	-3,33 (1,437)	
95 %-KI	[-4,633; 0,800]	[-6,162; -0,497]	
Veränderung zu Woche 15/16			
n/N (%)	54/122 (44)	31/112 (28)	LS MD 1,39 [-2,562; 5,345]
MW (SD)	-3,09 (16,212)	-3,23 (17,961)	
LS MW (SE)	-2,71 (1,378)	-4,10 (1,458)	
95 %-KI	[-5,429; 0,008]	[-6,976; -1,228]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	37/114 (32)	28/103 (27)	LS MD 1,36 [-2,745; 5,467]
MW (SD)	-1,80 (17,909)	0,60 (12,408)	
LS MW (SE)	-3,84 (1,408)	-5,20 (1,538)	
95 %-KI	[-6,620; -1,068]	[-8,233; -2,177]	
Veränderung zu Woche 24			
n/N (%)	28/109 (26)	17/95 (18)	LS MD 1,34 [-2,942; 5,621]
MW (SD)	-2,38 (12,599)	-4,90 (22,642)	
LS MW (SE)	-4,64 (1,448)	-5,98 (1,624)	
95 %-KI	[-7,491; -1,784]	[-9,172; -2,782]	
Veränderung zu Woche 36			
n/N (%)	43/93 (46)	21/79 (27)	LS MD 1,27 [-3,954; 6,485]
MW (SD)	-5,04 (17,644)	-1,59 (21,019)	
LS MW (SE)	-7,36 (1,684)	-8,62 (2,056)	
95 %-KI	[-10,670; -4,047]	[-12,662; -4,586]	
Veränderung zu Woche 48			
n/N (%)	3/79 (4)	2/62 (3)	LS MD 1,19 [-5,302; 7,685]
MW (SD)	-0,00 (16,667)	-16,67 (0,000)	
LS MW (SE)	-10,08 (2,029)	-11,27 (2,616)	
95 %-KI	[-14,063; -6,096]	[-16,404; -6,139]	
<b>Vorherige Verabreichung von Bevacizumab: Nein</b>			
Baseline			
n/N (%)	71/84 (85)	58/75 (77)	-
MW (SD)	77,93 (23,700)	83,05 (18,335)	
Absolute Werte zum Studienende			
n/N (%)	7/61 (11)	3/48 (6)	-
MW (SD)	76,19 (26,972)	72,22 (9,623)	
Effekt über Studiendauer			
n	71	58	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	0,57 (1,754)	-3,85 (1,964)	LS MD 4,42 [-0,811; 9,645] 0,0970  Hedges' g 0,30 [-0,053; 0,644]
95 %-KI	[-2,904; 4,040]	[-7,736; 0,037]	
Veränderung zu Woche 3/4			
n/N (%)	51/83 (61)	40/73 (55)	LS MD 1,20 [-4,300; 6,690]
MW (SD)	4,90 (15,016)	-0,83 (19,226)	
LS MW (SE)	0,74 (1,850)	-0,45 (2,066)	
95 %-KI	[-2,914; 4,395]	[-4,536; 3,627]	
Veränderung zu Woche 8/9			
n/N (%)	58/80 (72)	49/69 (71)	LS MD 2,52 [-2,782; 7,818]
MW (SD)	0,29 (19,116)	-3,06 (19,147)	
LS MW (SE)	0,67 (1,784)	-1,85 (1,989)	
95 %-KI	[-2,859; 4,198]	[-5,782; 2,086]	
Veränderung zu Woche 12			
n/N (%)	41/79 (52)	32/69 (46)	LS MD 3,44 [-1,790; 8,677]
MW (SD)	-0,00 (15,811)	-7,29 (21,140)	
LS MW (SE)	0,62 (1,759)	-2,82 (1,964)	
95 %-KI	[-2,862; 4,102]	[-6,710; 1,062]	
Veränderung zu Woche 15/16			
n/N (%)	38/77 (49)	22/66 (33)	LS MD 4,37 [-0,857; 9,597]
MW (SD)	-1,75 (16,343)	0,00 (20,574)	
LS MW (SE)	0,57 (1,754)	-3,80 (1,964)	
95 %-KI	[-2,901; 4,042]	[-7,685; 0,086]	
Veränderung zu Woche 20/21			
n/N (%)	28/76 (37)	22/62 (35)	LS MD 5,69 [0,372; 11,013]
MW (SD)	1,79 (15,934)	-5,30 (18,819)	
LS MW (SE)	0,50 (1,779)	-5,19 (2,006)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,020; 4,019]	[-9,159; -1,227]	
Veränderung zu Woche 24			
n/N (%)	25/75 (33)	20/60 (33)	LS MD 6,62 [1,162; 12,075]
MW (SD)	0,67 (25,221)	-1,67 (11,970)	
LS MW (SE)	0,45 (1,819)	-6,17 (2,064)	
95 %-KI	[-3,146; 4,046]	[-10,247; -2,090]	
Veränderung zu Woche 36			
n/N (%)	37/67 (55)	25/55 (45)	LS MD 9,79 [3,498; 16,088]
MW (SD)	2,25 (14,784)	-4,67 (18,333)	
LS MW (SE)	0,28 (2,076)	-9,51 (2,412)	
95 %-KI	[-3,811; 4,370]	[-14,263; -4,764]	
Veränderung zu Woche 48			
n/N (%)	5/61 (8)	3/48 (6)	LS MD 12,97 [5,414; 20,521]
MW (SD)	0,00 (11,785)	-11,11 (9,623)	
LS MW (SE)	0,11 (2,469)	-12,86 (2,921)	
95 %-KI	[-4,745; 4,964]	[-18,598; -7,119]	
<b>Letztes Platin-freies Intervall: ≤ 3 Monate</b>			
Baseline			
n/N (%)	67/83 (81)	62/91 (68)	-
MW (SD)	83,33 (18,349)	79,30 (20,398)	
Absolute Werte zum Studienende			
n/N (%)	3/55 (5)	5/39 (13)	-
MW (SD)	88,89 (19,245)	70,00 (7,454)	
Effekt über Studiendauer			
n	67	62	LS MD 4,22 [-1,143; 9,575] 0,1220
LS MW (SE)	-0,99 (1,853)	-5,20 (1,969)	
95 %-KI	[-4,656; 2,680]	[-9,099; -1,309]	Hedges' g 0,27 [-0,074; 0,620]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	49/82 (60)	46/86 (53)	LS MD 3,33 [-2,197; 8,861]
MW (SD)	1,02 (14,194)	-1,45 (21,894)	
LS MW (SE)	0,84 (1,921)	-2,50 (2,026)	
95 %-KI	[-2,960; 4,633]	[-6,500; 1,508]	
Veränderung zu Woche 8/9			
n/N (%)	50/81 (62)	46/80 (57)	LS MD 3,74 [-1,640; 9,118]
MW (SD)	-2,67 (17,932)	-1,09 (19,052)	
LS MW (SE)	-0,00 (1,867)	-3,74 (1,969)	
95 %-KI	[-3,698; 3,690]	[-7,639; 0,153]	
Veränderung zu Woche 12			
n/N (%)	33/78 (42)	24/78 (31)	LS MD 4,02 [-1,322; 9,370]
MW (SD)	1,01 (15,556)	-8,33 (20,264)	
LS MW (SE)	-0,59 (1,852)	-4,62 (1,960)	
95 %-KI	[-4,258; 3,074]	[-8,494; -0,737]	
Veränderung zu Woche 15/16			
n/N (%)	33/76 (43)	14/75 (19)	LS MD 4,31 [-1,066; 9,684]
MW (SD)	-0,51 (16,917)	1,19 (20,111)	
LS MW (SE)	-1,18 (1,857)	-5,49 (1,977)	
95 %-KI	[-4,855; 2,495]	[-9,399; -1,578]	
Veränderung zu Woche 20/21			
n/N (%)	22/72 (31)	14/67 (21)	LS MD 4,72 [-0,805; 10,236]
MW (SD)	-3,79 (15,372)	-3,57 (16,249)	
LS MW (SE)	-2,02 (1,897)	-6,74 (2,044)	
95 %-KI	[-5,771; 1,732]	[-10,774; -2,696]	
Veränderung zu Woche 24			
n/N (%)	16/72 (22)	11/62 (18)	LS MD 5,00 [-0,690; 10,691]
MW (SD)	-1,04 (12,865)	-4,55 (18,395)	
LS MW (SE)	-2,61 (1,947)	-7,61 (2,119)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,455; 1,240]	[-11,791; -3,425]	
Veränderung zu Woche 36			
n/N (%)	27/63 (43)	17/50 (34)	LS MD 5,98 [-0,656; 12,610]
MW (SD)	-3,09 (19,080)	0,00 (14,434)	
LS MW (SE)	-4,62 (2,237)	-10,60 (2,515)	
95 %-KI	[-9,030; -0,216]	[-15,550; -5,651]	
Veränderung zu Woche 48			
n/N (%)	2/55 (4)	4/39 (10)	LS MD 6,95 [-1,016; 14,923]
MW (SD)	-8,33 (11,785)	-12,50 (8,333)	
LS MW (SE)	-6,64 (2,659)	-13,59 (3,058)	
95 %-KI	[-11,866; -1,412]	[-19,601; -7,584]	
<b>Letztes Platin-freies Intervall: &gt; 3 Monate</b>			
Baseline			
n/N (%)	107/135 (79)	95/116 (82)	-
MW (SD)	79,75 (21,722)	83,86 (19,365)	
Absolute Werte zum Studienende			
n/N (%)	7/85 (8)	1/71 (1)	-
MW (SD)	73,81 (25,198)	83,33 (NA)	
Effekt über Studiendauer			
n	107	95	LS MD 1,42 [-2,473; 5,319] 0,4721
LS MW (SE)	-1,37 (1,333)	-2,80 (1,450)	
95 %-KI	[-4,002; 1,258]	[-5,654; 0,064]	Hedges' g 0,10 [-0,175; 0,378]
Veränderung zu Woche 3/4			
n/N (%)	69/131 (53)	61/114 (54)	LS MD -0,07 [-4,201; 4,070]
MW (SD)	3,86 (15,693)	-0,82 (11,150)	
LS MW (SE)	-0,10 (1,415)	-0,03 (1,542)	
95 %-KI	[-2,884; 2,692]	[-3,068; 3,006]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	91/129 (71)	77/108 (71)	LS MD 0,58 [-3,375; 4,528]
MW (SD)	-0,73 (18,578)	-3,68 (17,443)	
LS MW (SE)	-0,65 (1,359)	-1,22 (1,466)	
95 %-KI	[-3,325; 2,033]	[-4,111; 1,666]	
Veränderung zu Woche 12			
n/N (%)	62/127 (49)	45/105 (43)	LS MD 1,03 [-2,869; 4,920]
MW (SD)	-2,42 (15,637)	-5,19 (15,820)	
LS MW (SE)	-1,03 (1,338)	-2,06 (1,445)	
95 %-KI	[-3,671; 1,608]	[-4,906; 0,791]	
Veränderung zu Woche 15/16			
n/N (%)	59/123 (48)	39/103 (38)	LS MD 1,47 [-2,425; 5,374]
MW (SD)	-3,67 (15,802)	-2,99 (18,682)	
LS MW (SE)	-1,42 (1,334)	-2,89 (1,452)	
95 %-KI	[-4,047; 1,214]	[-5,755; -0,028]	
Veränderung zu Woche 20/21			
n/N (%)	43/118 (36)	36/98 (37)	LS MD 2,12 [-1,898; 6,131]
MW (SD)	1,55 (17,748)	-1,39 (15,622)	
LS MW (SE)	-1,97 (1,356)	-4,08 (1,511)	
95 %-KI	[-4,640; 0,707]	[-7,061; -1,106]	
Veränderung zu Woche 24			
n/N (%)	37/112 (33)	26/93 (28)	LS MD 2,57 [-1,599; 6,731]
MW (SD)	-0,90 (21,853)	-2,56 (17,443)	
LS MW (SE)	-2,35 (1,391)	-4,92 (1,584)	
95 %-KI	[-5,092; 0,389]	[-8,035; -1,801]	
Veränderung zu Woche 36			
n/N (%)	53/97 (55)	29/84 (35)	LS MD 4,11 [-0,927; 9,140]
MW (SD)	-0,94 (15,475)	-5,17 (21,869)	
LS MW (SE)	-3,67 (1,612)	-7,78 (1,976)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,841; -0,503]	[-11,659; -3,898]	
Veränderung zu Woche 48			
n/N (%)	6/85 (7)	1/71 (1)	LS MD 5,65 [-0,611; 11,905]
MW (SD)	2,78 (12,546)	-16,67 (NA)	
LS MW (SE)	-4,99 (1,944)	-10,64 (2,505)	
95 %-KI	[-8,810; -1,175]	[-15,555; -5,724]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Pegyliertes liposomales Doxorubicin</b>			
Baseline			
n/N (%)	62/80 (78)	56/76 (74)	-
MW (SD)	79,30 (21,485)	86,90 (15,477)	
Absolute Werte zum Studienende			
n/N (%)	3/51 (6)	3/41 (7)	-
MW (SD)	66,67 (16,667)	72,22 (9,623)	
Effekt über Studiendauer			
n	62	56	LS MD -0,41 [-5,762; 4,933] 0,8782  Hedges' g -0,03 [-0,390; 0,333]
LS MW (SE)	-2,58 (1,819)	-2,17 (1,960)	
95 %-KI	[-6,185; 1,025]	[-6,046; 1,716]	
Veränderung zu Woche 3/4			
n/N (%)	41/76 (54)	42/74 (57)	LS MD -0,06 [-5,674; 5,559]
MW (SD)	4,47 (12,374)	2,38 (13,052)	
LS MW (SE)	-0,29 (1,930)	-0,23 (2,048)	
95 %-KI	[-4,104; 3,525]	[-4,280; 3,816]	
Veränderung zu Woche 8/9			
n/N (%)	51/76 (67)	43/66 (65)	LS MD -0,21 [-5,615; 5,191]
MW (SD)	-0,98 (20,659)	-7,36 (21,301)	
LS MW (SE)	-1,28 (1,855)	-1,07 (1,965)	
95 %-KI	[-4,953; 2,393]	[-4,957; 2,822]	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	32/75 (43)	22/64 (34)	LS MD -0,32 [-5,661; 5,020]
MW (SD)	1,04 (18,902)	-8,33 (16,060)	
LS MW (SE)	-1,97 (1,827)	-1,65 (1,947)	
95 %-KI	[-5,592; 1,647]	[-5,509; 2,203]	
Veränderung zu Woche 15/16			
n/N (%)	34/74 (46)	18/62 (29)	LS MD -0,43 [-5,782; 4,925]
MW (SD)	-4,90 (19,038)	-5,56 (8,085)	
LS MW (SE)	-2,67 (1,819)	-2,24 (1,964)	
95 %-KI	[-6,271; 0,939]	[-6,126; 1,651]	
Veränderung zu Woche 20/21			
n/N (%)	27/72 (38)	18/59 (31)	LS MD -0,58 [-6,083; 4,917]
MW (SD)	-1,85 (19,792)	0,00 (9,901)	
LS MW (SE)	-3,66 (1,845)	-3,07 (2,046)	
95 %-KI	[-7,311; -0,002]	[-7,119; 0,972]	
Veränderung zu Woche 24			
n/N (%)	22/69 (32)	16/54 (30)	LS MD -0,69 [-6,378; 4,997]
MW (SD)	-5,30 (20,821)	1,04 (9,562)	
LS MW (SE)	-4,35 (1,888)	-3,66 (2,140)	
95 %-KI	[-8,085; -0,614]	[-7,885; 0,568]	
Veränderung zu Woche 36			
n/N (%)	31/60 (52)	16/48 (33)	LS MD -1,06 [-7,825; 5,702]
MW (SD)	-2,15 (15,361)	-2,08 (19,124)	
LS MW (SE)	-6,73 (2,166)	-5,66 (2,638)	
95 %-KI	[-10,997; -2,455]	[-10,855; -0,474]	
Veränderung zu Woche 48			
n/N (%)	2/51 (4)	2/41 (5)	LS MD -1,43 [-9,729; 6,865]
MW (SD)	-8,33 (11,785)	-16,67 (0,000)	
LS MW (SE)	-9,10 (2,593)	-7,67 (3,306)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-14,202; -4,003]	[-14,165; -1,176]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Paclitaxel</b>			
Baseline			
n/N (%)	73/88 (83)	69/82 (84)	-
MW (SD)	81,51 (19,157)	78,74 (22,666)	
Absolute Werte zum Studienende			
n/N (%)	1/56 (2)	1/49 (2)	-
MW (SD)	66,67 (NA)	66,67 (NA)	
Effekt über Studiendauer			
n	73	69	LS MD 2,39 [-2,547; 7,331] 0,3400  Hedges' g 0,16 [-0,170; 0,490]
LS MW (SE)	-1,26 (1,719)	-3,65 (1,812)	
95 %-KI	[-4,662; 2,136]	[-7,236; -0,073]	
Veränderung zu Woche 3/4			
n/N (%)	54/87 (62)	47/81 (58)	LS MD 1,18 [-3,996; 6,346]
MW (SD)	1,54 (16,907)	-1,77 (18,790)	
LS MW (SE)	0,70 (1,800)	-0,48 (1,902)	
95 %-KI	[-2,859; 4,250]	[-4,234; 3,275]	
Veränderung zu Woche 8/9			
n/N (%)	60/86 (70)	53/79 (67)	LS MD 1,73 [-3,254; 6,713]
MW (SD)	-0,56 (18,145)	0,94 (17,114)	
LS MW (SE)	-0,20 (1,738)	-1,93 (1,825)	
95 %-KI	[-3,634; 3,239]	[-5,534; 1,681]	
Veränderung zu Woche 12			
n/N (%)	42/84 (50)	35/77 (45)	LS MD 2,12 [-2,815; 7,051]
MW (SD)	-3,97 (13,679)	-8,10 (19,542)	
LS MW (SE)	-0,82 (1,719)	-2,94 (1,807)	
95 %-KI	[-4,222; 2,579]	[-6,512; 0,632]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	42/81 (52)	27/76 (36)	LS MD 2,51 [-2,446; 7,458]
MW (SD)	-3,97 (14,636)	-0,00 (25,737)	
LS MW (SE)	-1,45 (1,721)	-3,95 (1,818)	
95 %-KI	[-4,851; 1,958]	[-7,547; -0,359]	
Veränderung zu Woche 20/21			
n/N (%)	27/77 (35)	25/73 (34)	LS MD 3,06 [-2,036; 8,157]
MW (SD)	-1,85 (12,518)	-6,00 (18,559)	
LS MW (SE)	-2,34 (1,760)	-5,40 (1,885)	
95 %-KI	[-5,818; 1,139]	[-9,123; -1,677]	
Veränderung zu Woche 24			
n/N (%)	20/74 (27)	18/72 (25)	LS MD 3,45 [-1,827; 8,725]
MW (SD)	0,83 (19,850)	-7,41 (23,025)	
LS MW (SE)	-2,96 (1,811)	-6,41 (1,965)	
95 %-KI	[-6,540; 0,612]	[-10,290; -2,536]	
Veränderung zu Woche 36			
n/N (%)	34/64 (53)	22/63 (35)	LS MD 4,78 [-1,505; 11,064]
MW (SD)	-3,43 (17,781)	-3,79 (19,875)	
LS MW (SE)	-5,11 (2,110)	-9,89 (2,397)	
95 %-KI	[-9,259; -0,954]	[-14,600; -5,172]	
Veränderung zu Woche 48			
n/N (%)	1/56 (2)	1/49 (2)	LS MD 6,11 [-1,597; 13,817]
MW (SD)	-16,67 (NA)	0,00 (NA)	
LS MW (SE)	-7,25 (2,543)	-13,36 (2,986)	
95 %-KI	[-12,246; -2,252]	[-19,224; -7,495]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Topotecan</b>			
Baseline			
n/N (%)	39/50 (78)	32/49 (65)	-
MW (SD)	83,33 (21,630)	80,73 (18,984)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	6/33 (18)	2/20 (10)	-
MW (SD)	86,11 (26,701)	75,00 (11,785)	
Effekt über Studiendauer			
n	39	32	LS MD 6,43 [-0,173; 13,027] 0,0561  Hedges' g 0,46 [-0,014; 0,933]
LS MW (SE)	0,60 (2,197)	-5,83 (2,469)	
95 %-KI	[-3,785; 4,989]	[-10,750; -0,901]	
Veränderung zu Woche 3/4			
n/N (%)	23/50 (46)	18/45 (40)	LS MD 1,84 [-4,978; 8,652]
MW (SD)	2,17 (15,328)	-7,41 (16,392)	
LS MW (SE)	-0,23 (2,266)	-2,06 (2,562)	
95 %-KI	[-4,740; 4,288]	[-7,161; 3,035]	
Veränderung zu Woche 8/9			
n/N (%)	30/48 (62)	27/43 (63)	LS MD 3,79 [-2,841; 10,428]
MW (SD)	-3,89 (14,306)	-2,47 (11,968)	
LS MW (SE)	0,13 (2,212)	-3,67 (2,482)	
95 %-KI	[-4,287; 4,541]	[-8,614; 1,281]	
Veränderung zu Woche 12			
n/N (%)	21/46 (46)	12/42 (29)	LS MD 5,16 [-1,423; 11,750]
MW (SD)	0,79 (13,412)	2,78 (9,623)	
LS MW (SE)	0,37 (2,196)	-4,79 (2,461)	
95 %-KI	[-4,010; 4,758]	[-9,699; 0,120]	
Veränderung zu Woche 15/16			
n/N (%)	16/44 (36)	8/40 (20)	LS MD 6,53 [-0,071; 13,137]
MW (SD)	6,25 (10,319)	0,00 (0,000)	
LS MW (SE)	0,62 (2,198)	-5,91 (2,471)	
95 %-KI	[-3,768; 5,010]	[-10,840; -0,984]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	11/41 (27)	7/33 (21)	LS MD 8,49 [1,747; 15,233]
MW (SD)	7,58 (18,803)	7,14 (13,113)	
LS MW (SE)	0,97 (2,233)	-7,52 (2,537)	
95 %-KI	[-3,479; 5,427]	[-12,568; -2,464]	
Veränderung zu Woche 24			
n/N (%)	11/41 (27)	3/29 (10)	LS MD 9,86 [2,944; 16,776]
MW (SD)	4,55 (15,076)	0,00 (0,000)	
LS MW (SE)	1,22 (2,278)	-8,64 (2,618)	
95 %-KI	[-3,317; 5,759]	[-13,843; -3,435]	
Veränderung zu Woche 36			
n/N (%)	15/36 (42)	8/23 (35)	LS MD 14,56 [6,635; 22,477]
MW (SD)	3,33 (16,903)	-4,17 (21,362)	
LS MW (SE)	2,07 (2,550)	-12,49 (3,069)	
95 %-KI	[-2,985; 7,120]	[-18,553; -6,423]	
Veränderung zu Woche 48			
n/N (%)	5/33 (15)	2/20 (10)	LS MD 19,25 [9,853; 28,652]
MW (SD)	6,67 (9,129)	-16,67 (0,000)	
LS MW (SE)	2,91 (2,960)	-16,34 (3,708)	
95 %-KI	[-2,926; 8,755]	[-23,642; -9,033]	
<p><i>Analysepopulation: ITT</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023</i></p> <p><i>Modell: Veränderung zu Baseline ~ Behandlung + Baseline-Wert * Zeit in Wochen + Behandlung * Zeit in Wochen + zufällige Effekte durch die Patientin</i></p> <p><i>Die Berechnung des LS-MWs erfolgt durch ein MMRM mit dem oben angegebenen Modell. Basierend hierauf werden KI und p-Wert ermittelt. Hedges' g basiert ebenfalls auf den LS-MW und ist somit auf das Modell angepasst.</i></p> <p><i>Es werden ausschließlich gemeinsame Analysezeitpunkte dargestellt.</i></p> <p><i>Ein LS MD und Hedges' g größer als Null bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

## 2.11 EORTC QLQ-C30 emotionale Funktion

### EORTC QLQ-C30 emotionale Funktion: Subgruppenanalyse

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
<b>EORTC QLQ-C30 emotionale Funktion</b>			
<b>Alter: &lt; 65 Jahre</b>			
Baseline			
n/N (%)	94/115 (82)	91/119 (76)	-
MW (SD)	71,99 (20,698)	68,59 (23,768)	
Absolute Werte zum Studienende			
n/N (%)	4/73 (5)	4/64 (6)	-
MW (SD)	64,58 (29,167)	77,08 (10,486)	
Effekt über Studiendauer			
n	94	91	LS MD 5,28 [0,643; 9,912] 0,0258
LS MW (SE)	3,19 (1,635)	-2,09 (1,683)	
95 %-KI	[-0,039; 6,415]	[-5,409; 1,230]	Hedges' g 0,33 [0,039; 0,620]
Veränderung zu Woche 3/4			
n/N (%)	59/113 (52)	59/115 (51)	LS MD 2,81 [-1,930; 7,550]
MW (SD)	6,36 (16,834)	5,37 (16,578)	
LS MW (SE)	4,68 (1,676)	1,87 (1,720)	
95 %-KI	[1,378; 7,987]	[-1,519; 5,264]	
Veränderung zu Woche 8/9			
n/N (%)	75/112 (67)	71/108 (66)	LS MD 3,90 [-0,756; 8,549]
MW (SD)	2,78 (21,415)	-1,53 (20,573)	
LS MW (SE)	4,02 (1,646)	0,13 (1,686)	
95 %-KI	[0,777; 7,272]	[-3,197; 3,454]	
Veränderung zu Woche 12			
n/N (%)	47/110 (43)	39/105 (37)	
MW (SD)	6,38 (21,083)	-0,85 (16,199)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	3,56 (1,636)	-1,09 (1,678)	LS MD 4,66 [0,027; 9,286]
95 %-KI	[0,335; 6,793]	[-4,404; 2,219]	
Veränderung zu Woche 15/16			
n/N (%)	53/107 (50)	32/102 (31)	LS MD 5,42 [0,779; 10,055]
MW (SD)	1,57 (20,547)	5,21 (22,175)	
LS MW (SE)	3,10 (1,636)	-2,31 (1,685)	
95 %-KI	[-0,124; 6,331]	[-5,637; 1,010]	
Veränderung zu Woche 20/21			
n/N (%)	35/101 (35)	29/96 (30)	LS MD 6,50 [1,798; 11,209]
MW (SD)	2,38 (22,739)	5,75 (17,832)	
LS MW (SE)	2,45 (1,651)	-4,06 (1,718)	
95 %-KI	[-0,813; 5,704]	[-7,445; -0,671]	
Veränderung zu Woche 24			
n/N (%)	24/99 (24)	19/91 (21)	LS MD 7,26 [2,474; 12,053]
MW (SD)	3,82 (22,519)	0,44 (11,612)	
LS MW (SE)	1,98 (1,674)	-5,28 (1,756)	
95 %-KI	[-1,316; 5,286]	[-8,740; -1,817]	
Veränderung zu Woche 36			
n/N (%)	41/86 (48)	27/79 (34)	LS MD 9,87 [4,585; 15,155]
MW (SD)	4,07 (18,364)	-4,63 (19,927)	
LS MW (SE)	0,41 (1,813)	-9,46 (1,975)	
95 %-KI	[-3,164; 3,975]	[-13,350; -5,579]	
Veränderung zu Woche 48			
n/N (%)	4/73 (5)	3/64 (5)	LS MD 12,48 [6,441; 18,514]
MW (SD)	8,33 (36,004)	-5,56 (17,347)	
LS MW (SE)	-1,17 (2,033)	-13,65 (2,295)	
95 %-KI	[-5,170; 2,824]	[-18,158; -9,143]	
<b>Alter: ≥ 65 Jahre</b>			
Baseline			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	81/103 (79)	66/88 (75)	-
MW (SD)	72,02 (22,719)	71,84 (23,377)	
Absolute Werte zum Studienende			
n/N (%)	6/67 (9)	2/46 (4)	-
MW (SD)	88,89 (12,546)	83,33 (11,785)	
Effekt über Studiendauer			
n	81	66	LS MD 2,61 [-2,123; 7,352] 0,2772  Hedges' g 0,18 [-0,146; 0,505]
LS MW (SE)	0,63 (1,596)	-1,98 (1,797)	
95 %-KI	[-2,520; 3,789]	[-5,531; 1,570]	
Veränderung zu Woche 3/4			
n/N (%)	60/100 (60)	48/85 (56)	LS MD 3,96 [-0,886; 8,797]
MW (SD)	3,19 (17,634)	-0,69 (17,517)	
LS MW (SE)	4,08 (1,634)	0,12 (1,836)	
95 %-KI	[0,853; 7,307]	[-3,501; 3,750]	
Veränderung zu Woche 8/9			
n/N (%)	66/98 (67)	51/80 (64)	LS MD 3,36 [-1,395; 8,111]
MW (SD)	0,88 (17,549)	-1,31 (21,754)	
LS MW (SE)	2,54 (1,606)	-0,81 (1,798)	
95 %-KI	[-0,630; 5,718]	[-4,367; 2,740]	
Veränderung zu Woche 12			
n/N (%)	49/95 (52)	30/78 (38)	LS MD 2,94 [-1,792; 7,671]
MW (SD)	1,87 (16,776)	-4,72 (19,657)	
LS MW (SE)	1,47 (1,597)	-1,47 (1,791)	
95 %-KI	[-1,687; 4,626]	[-5,010; 2,070]	
Veränderung zu Woche 15/16			
n/N (%)	41/92 (45)	21/76 (28)	
MW (SD)	-0,81 (15,790)	1,98 (22,655)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	0,39 (1,596)	-2,13 (1,800)	LS MD 2,52 [-2,222; 7,264]
95 %-KI	[-2,762; 3,550]	[-5,684; 1,430]	
Veränderung zu Woche 20/21			
n/N (%)	31/89 (35)	20/69 (29)	LS MD 1,92 [-2,895; 6,742]
MW (SD)	-1,08 (17,446)	3,75 (19,209)	
LS MW (SE)	-1,14 (1,611)	-3,07 (1,840)	
95 %-KI	[-4,325; 2,041]	[-6,699; 0,569]	
Veränderung zu Woche 24			
n/N (%)	29/85 (34)	18/64 (28)	LS MD 1,51 [-3,405; 6,415]
MW (SD)	-0,86 (17,157)	1,85 (19,711)	
LS MW (SE)	-2,22 (1,631)	-3,72 (1,886)	
95 %-KI	[-5,439; 1,005]	[-7,445; 0,001]	
Veränderung zu Woche 36			
n/N (%)	40/74 (54)	17/55 (31)	LS MD 0,07 [-5,372; 5,513]
MW (SD)	-4,79 (21,998)	-3,92 (21,270)	
LS MW (SE)	-5,90 (1,759)	-5,97 (2,142)	
95 %-KI	[-9,371; -2,435]	[-10,190; -1,757]	
Veränderung zu Woche 48			
n/N (%)	4/67 (6)	2/46 (4)	LS MD -1,36 [-7,605; 4,878]
MW (SD)	-4,17 (4,811)	4,17 (17,678)	
LS MW (SE)	-9,59 (1,963)	-8,23 (2,509)	
95 %-KI	[-13,453; -5,726]	[-13,156; -3,295]	
<b>Region: USA</b>			
Baseline			
n/N (%)	48/65 (74)	34/51 (67)	-
MW (SD)	74,83 (22,446)	74,75 (22,425)	
Absolute Werte zum Studienende			
n/N (%)	2/39 (5)	3/27 (11)	-
MW (SD)	70,83 (5,893)	77,78 (12,729)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Effekt über Studiendauer			
n	48	34	LS MD 6,48 [0,305; 12,657] 0,0400  Hedges' g 0,46 [0,018; 0,909]
LS MW (SE)	2,83 (1,997)	-3,65 (2,380)	
95 %-KI	[-1,143; 6,809]	[-8,384; 1,088]	
Veränderung zu Woche 3/4			
n/N (%)	33/64 (52)	21/49 (43)	LS MD 5,91 [-0,400; 12,221]
MW (SD)	4,29 (20,425)	-2,38 (15,398)	
LS MW (SE)	3,68 (2,039)	-2,23 (2,440)	
95 %-KI	[-0,373; 7,733]	[-7,080; 2,619]	
Veränderung zu Woche 8/9			
n/N (%)	40/62 (65)	30/46 (65)	LS MD 6,17 [-0,039; 12,377]
MW (SD)	1,04 (19,719)	-2,50 (17,253)	
LS MW (SE)	3,30 (2,007)	-2,87 (2,394)	
95 %-KI	[-0,697; 7,291]	[-7,635; 1,891]	
Veränderung zu Woche 12			
n/N (%)	26/59 (44)	16/45 (36)	LS MD 6,35 [0,172; 12,526]
MW (SD)	6,73 (18,562)	-7,29 (14,554)	
LS MW (SE)	3,03 (1,998)	-3,32 (2,380)	
95 %-KI	[-0,948; 7,005]	[-8,058; 1,416]	
Veränderung zu Woche 15/16			
n/N (%)	21/56 (38)	11/44 (25)	LS MD 6,53 [0,349; 12,710]
MW (SD)	1,98 (23,994)	4,55 (13,624)	
LS MW (SE)	2,76 (1,999)	-3,77 (2,381)	
95 %-KI	[-1,218; 6,738]	[-8,509; 0,970]	
Veränderung zu Woche 20/21			
n/N (%)	12/54 (22)	9/40 (22)	
MW (SD)	0,00 (7,107)	-6,48 (10,015)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	2,38 (2,018)	-4,41 (2,410)	LS MD 6,79 [0,543; 13,031]
95 %-KI	[-1,638; 6,392]	[-9,204; 0,383]	
Veränderung zu Woche 24			
n/N (%)	9/53 (17)	6/38 (16)	LS MD 6,97 [0,639; 13,297]
MW (SD)	-0,93 (15,836)	0,00 (9,129)	
LS MW (SE)	2,11 (2,044)	-4,86 (2,448)	
95 %-KI	[-1,956; 6,172]	[-9,724; 0,005]	
Veränderung zu Woche 36			
n/N (%)	21/43 (49)	10/33 (30)	LS MD 7,59 [0,732; 14,441]
MW (SD)	2,78 (26,917)	-5,00 (15,811)	
LS MW (SE)	1,19 (2,205)	-6,40 (2,680)	
95 %-KI	[-3,180; 5,557]	[-11,703; -1,093]	
Veränderung zu Woche 48			
n/N (%)	2/39 (5)	3/27 (11)	LS MD 8,20 [0,522; 15,887]
MW (SD)	29,17 (41,248)	2,78 (12,729)	
LS MW (SE)	0,27 (2,458)	-7,94 (3,039)	
95 %-KI	[-4,584; 5,120]	[-13,931; -1,943]	
<b>Region: Rest der Welt</b>			
Baseline			
n/N (%)	127/153 (83)	123/156 (79)	-
MW (SD)	70,93 (21,255)	68,63 (23,812)	
Absolute Werte zum Studienende			
n/N (%)	8/101 (8)	3/83 (4)	-
MW (SD)	81,25 (25,491)	80,56 (9,623)	
Effekt über Studiendauer			
n	127	123	LS MD 3,51 [-0,406; 7,421] 0,0790 Hedges' g
LS MW (SE)	1,78 (1,387)	-1,73 (1,438)	
95 %-KI	[-0,943; 4,494]	[-4,551; 1,087]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
			0,22 [-0,027; 0,470]
Veränderung zu Woche 3/4			
n/N (%)	86/149 (58)	86/151 (57)	LS MD 2,67 [-1,333; 6,670]
MW (SD)	4,94 (15,985)	3,88 (17,466)	
LS MW (SE)	4,71 (1,422)	2,04 (1,467)	
95 %-KI	[1,921; 7,496]	[-0,835; 4,915]	
Veränderung zu Woche 8/9			
n/N (%)	101/148 (68)	92/142 (65)	LS MD 3,04 [-0,888; 6,963]
MW (SD)	2,23 (19,716)	-1,09 (22,142)	
LS MW (SE)	3,42 (1,397)	0,38 (1,437)	
95 %-KI	[0,680; 6,157]	[-2,436; 3,198]	
Veränderung zu Woche 12			
n/N (%)	70/146 (48)	53/138 (38)	LS MD 3,30 [-0,612; 7,203]
MW (SD)	3,10 (19,254)	-1,10 (18,493)	
LS MW (SE)	2,52 (1,388)	-0,78 (1,432)	
95 %-KI	[-0,206; 5,237]	[-3,588; 2,027]	
Veränderung zu Woche 15/16			
n/N (%)	73/143 (51)	42/134 (31)	LS MD 3,55 [-0,364; 7,472]
MW (SD)	0,11 (16,868)	3,77 (24,082)	
LS MW (SE)	1,61 (1,388)	-1,94 (1,441)	
95 %-KI	[-1,107; 4,332]	[-4,765; 0,882]	
Veränderung zu Woche 20/21			
n/N (%)	54/136 (40)	40/125 (32)	LS MD 3,92 [-0,060; 7,906]
MW (SD)	0,93 (22,294)	7,50 (18,758)	
LS MW (SE)	0,32 (1,399)	-3,60 (1,475)	
95 %-KI	[-2,420; 3,065]	[-6,491; -0,709]	
Veränderung zu Woche 24			
n/N (%)	44/131 (34)	31/117 (26)	
MW (SD)	1,70 (20,537)	1,34 (16,955)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-0,58 (1,417)	-4,76 (1,514)	LS MD 4,18 [0,119; 8,243]
95 %-KI	[-3,358; 2,197]	[-7,729; -1,795]	
Veränderung zu Woche 36			
n/N (%)	60/117 (51)	34/101 (34)	LS MD 5,07 [0,549; 9,585]
MW (SD)	-1,39 (18,035)	-4,17 (21,541)	
LS MW (SE)	-3,68 (1,529)	-8,74 (1,726)	
95 %-KI	[-6,673; -0,680]	[-12,126; -5,361]	
Veränderung zu Woche 48			
n/N (%)	6/101 (6)	2/83 (2)	LS MD 5,95 [0,757; 11,148]
MW (SD)	-6,94 (11,076)	-8,33 (23,570)	
LS MW (SE)	-6,77 (1,708)	-12,72 (2,027)	
95 %-KI	[-10,120; -3,425]	[-16,699; -8,751]	
<b>Stadium bei der Diagnose: I-III</b>			
Baseline			
n/N (%)	112/141 (79)	112/144 (78)	-
MW (SD)	73,29 (20,721)	69,42 (24,872)	
Absolute Werte zum Studienende			
n/N (%)	6/91 (7)	4/76 (5)	-
MW (SD)	77,78 (24,533)	77,08 (10,486)	
Effekt über Studiendauer			
n	112	112	LS MD 1,56 [-2,372; 5,484] 0,4376
LS MW (SE)	-0,24 (1,403)	-1,80 (1,433)	
95 %-KI	[-2,991; 2,507]	[-4,607; 1,010]	Hedges' g 0,10 [-0,159; 0,365]
Veränderung zu Woche 3/4			
n/N (%)	74/137 (54)	79/138 (57)	LS MD -0,33 [-4,355; 3,689]
MW (SD)	3,15 (16,764)	3,59 (17,637)	
LS MW (SE)	2,59 (1,439)	2,92 (1,465)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-0,233; 5,406]	[0,049; 5,791]	
Veränderung zu Woche 8/9			
n/N (%)	92/136 (68)	86/129 (67)	LS MD 0,50 [-3,447; 4,446]
MW (SD)	-1,63 (16,119)	-0,10 (20,907)	
LS MW (SE)	1,34 (1,413)	0,84 (1,436)	
95 %-KI	[-1,429; 4,109]	[-1,974; 3,655]	
Veränderung zu Woche 12			
n/N (%)	61/133 (46)	47/128 (37)	LS MD 1,08 [-2,844; 5,008]
MW (SD)	0,68 (17,098)	-1,60 (16,359)	
LS MW (SE)	0,47 (1,404)	-0,61 (1,430)	
95 %-KI	[-2,285; 3,219]	[-3,417; 2,187]	
Veränderung zu Woche 15/16			
n/N (%)	61/130 (47)	35/125 (28)	LS MD 1,66 [-2,267; 5,596]
MW (SD)	-2,46 (16,126)	4,05 (21,234)	
LS MW (SE)	-0,41 (1,403)	-2,07 (1,435)	
95 %-KI	[-3,155; 2,344]	[-4,882; 0,742]	
Veränderung zu Woche 20/21			
n/N (%)	44/123 (36)	33/116 (28)	LS MD 2,50 [-1,488; 6,483]
MW (SD)	-0,19 (17,001)	6,06 (19,011)	
LS MW (SE)	-1,65 (1,415)	-4,15 (1,462)	
95 %-KI	[-4,425; 1,121]	[-7,014; -1,284]	
Veränderung zu Woche 24			
n/N (%)	33/121 (27)	26/109 (24)	LS MD 3,08 [-0,974; 7,135]
MW (SD)	-2,02 (18,285)	2,88 (16,320)	
LS MW (SE)	-2,52 (1,432)	-5,60 (1,494)	
95 %-KI	[-5,332; 0,283]	[-8,532; -2,677]	
Veränderung zu Woche 36			
n/N (%)	53/105 (50)	33/92 (36)	
MW (SD)	-5,19 (19,559)	-6,82 (19,704)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-5,52 (1,546)	-10,59 (1,675)	LS MD 5,08 [0,614; 9,543]
95 %-KI	[-8,546; -2,487]	[-13,877; -7,313]	
Veränderung zu Woche 48			
n/N (%)	5/91 (5)	4/76 (5)	LS MD 7,08 [1,988; 12,165]
MW (SD)	-8,33 (10,206)	-4,17 (17,347)	
LS MW (SE)	-8,51 (1,727)	-15,58 (1,940)	
95 %-KI	[-11,893; -5,123]	[-19,387; -11,782]	
<b>Stadium bei der Diagnose: IV</b>			
Baseline			
n/N (%)	58/72 (81)	44/60 (73)	-
MW (SD)	69,25 (23,735)	71,02 (20,372)	
Absolute Werte zum Studienende			
n/N (%)	4/46 (9)	2/33 (6)	-
MW (SD)	81,25 (23,936)	83,33 (11,785)	
Effekt über Studiendauer			
n	58	44	LS MD 8,82 [2,658; 14,990] 0,0055  Hedges' g 0,56 [0,165; 0,964]
LS MW (SE)	7,23 (2,029)	-1,60 (2,351)	
95 %-KI	[3,201; 11,256]	[-6,259; 3,069]	
Veränderung zu Woche 3/4			
n/N (%)	40/71 (56)	27/59 (46)	LS MD 11,64 [5,345; 17,930]
MW (SD)	7,50 (18,852)	0,93 (15,389)	
LS MW (SE)	8,42 (2,075)	-3,22 (2,402)	
95 %-KI	[4,308; 12,534]	[-7,975; 1,542]	
Veränderung zu Woche 8/9			
n/N (%)	44/69 (64)	35/56 (62)	LS MD 10,39 [4,212; 16,558]
MW (SD)	9,09 (25,021)	-4,05 (21,137)	
LS MW (SE)	7,89 (2,040)	-2,49 (2,349)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[3,843; 11,938]	[-7,154; 2,164]	
Veränderung zu Woche 12			
n/N (%)	30/67 (45)	21/52 (40)	LS MD 9,51 [3,359; 15,658]
MW (SD)	12,50 (20,733)	-5,16 (20,995)	
LS MW (SE)	7,52 (2,030)	-1,99 (2,341)	
95 %-KI	[3,491; 11,546]	[-6,633; 2,654]	
Veränderung zu Woche 15/16			
n/N (%)	30/64 (47)	17/50 (34)	LS MD 8,63 [2,456; 14,807]
MW (SD)	6,67 (22,468)	3,43 (25,355)	
LS MW (SE)	7,15 (2,031)	-1,48 (2,357)	
95 %-KI	[3,117; 11,177]	[-6,159; 3,190]	
Veränderung zu Woche 20/21			
n/N (%)	19/62 (31)	15/46 (33)	LS MD 7,38 [1,080; 13,678]
MW (SD)	3,51 (27,261)	2,78 (17,442)	
LS MW (SE)	6,62 (2,052)	-0,76 (2,421)	
95 %-KI	[2,546; 10,686]	[-5,560; 4,034]	
Veränderung zu Woche 24			
n/N (%)	18/59 (31)	10/44 (23)	LS MD 6,50 [0,061; 12,944]
MW (SD)	8,80 (21,289)	0,00 (11,111)	
LS MW (SE)	6,24 (2,080)	-0,26 (2,493)	
95 %-KI	[2,121; 10,369]	[-5,191; 4,676]	
Veränderung zu Woche 36			
n/N (%)	27/52 (52)	10/41 (24)	LS MD 3,50 [-3,749; 10,741]
MW (SD)	9,26 (19,927)	5,83 (19,661)	
LS MW (SE)	4,97 (2,256)	1,47 (2,880)	
95 %-KI	[0,512; 9,429]	[-4,203; 7,152]	
Veränderung zu Woche 48			
n/N (%)	3/46 (7)	1/33 (3)	
MW (SD)	19,44 (34,694)	8,33 (NA)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	3,70 (2,530)	3,21 (3,423)	LS MD 0,49 [-7,931; 8,911]
95 %-KI	[-1,289; 8,682]	[-3,524; 9,937]	
<b>BRCA Status: Positiv</b>			
Baseline			
n/N (%)	25/27 (93)	23/35 (66)	-
MW (SD)	71,33 (24,893)	64,86 (20,865)	
Absolute Werte zum Studienende			
n/N (%)	1/19 (5)	0/15 (0)	-
MW (SD)	50,00 (NA)	NA (NA)	
Effekt über Studiendauer			
n	25	23	LS MD -0,39 [-9,716; 8,945] 0,9340
LS MW (SE)	0,80 (3,123)	1,19 (3,423)	
95 %-KI	[-5,496; 7,099]	[-5,705; 8,078]	Hedges' g -0,02 [-0,590; 0,543]
Veränderung zu Woche 3/4			
n/N (%)	16/27 (59)	18/35 (51)	LS MD -5,29 [-14,856; 4,268]
MW (SD)	3,13 (21,490)	8,33 (21,580)	
LS MW (SE)	1,44 (3,232)	6,74 (3,497)	
95 %-KI	[-5,051; 7,935]	[-0,288; 13,760]	
Veränderung zu Woche 8/9			
n/N (%)	20/26 (77)	19/30 (63)	LS MD -2,89 [-12,221; 6,441]
MW (SD)	-1,25 (20,991)	8,33 (22,567)	
LS MW (SE)	1,13 (3,152)	4,02 (3,397)	
95 %-KI	[-5,220; 7,477]	[-2,826; 10,862]	
Veränderung zu Woche 12			
n/N (%)	15/26 (58)	10/30 (33)	LS MD -1,21 [-10,510; 8,096]
MW (SD)	-3,33 (19,871)	4,17 (26,132)	
LS MW (SE)	0,91 (3,126)	2,12 (3,400)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-5,394; 7,211]	[-4,734; 8,965]	
Veränderung zu Woche 15/16			
n/N (%)	11/26 (42)	8/29 (28)	LS MD 0,48 [-8,911; 9,863]
MW (SD)	-9,09 (18,049)	21,88 (20,382)	
LS MW (SE)	0,69 (3,127)	0,21 (3,462)	
95 %-KI	[-5,615; 6,993]	[-6,750; 7,175]	
Veränderung zu Woche 20/21			
n/N (%)	10/25 (40)	4/25 (16)	LS MD 2,88 [-6,815; 12,575]
MW (SD)	2,50 (14,191)	18,75 (17,180)	
LS MW (SE)	0,37 (3,173)	-2,51 (3,648)	
95 %-KI	[-6,012; 6,762]	[-9,807; 4,797]	
Veränderung zu Woche 24			
n/N (%)	7/25 (28)	3/24 (12)	LS MD 4,56 [-5,472; 14,598]
MW (SD)	-1,19 (13,113)	-0,00 (8,333)	
LS MW (SE)	0,16 (3,235)	-4,41 (3,838)	
95 %-KI	[-6,345; 6,656]	[-12,062; 3,247]	
Veränderung zu Woche 36			
n/N (%)	10/21 (48)	5/20 (25)	LS MD 10,33 [-1,518; 22,184]
MW (SD)	-1,67 (15,615)	1,67 (28,504)	
LS MW (SE)	-0,60 (3,617)	-10,93 (4,766)	
95 %-KI	[-7,804; 6,608]	[-20,349; -1,513]	
Veränderung zu Woche 48			
n/N (%)	1/19 (5)	0/15 (0)	LS MD 16,10 [1,732; 30,473]
MW (SD)	-8,33 (NA)	NA (NA)	
LS MW (SE)	-1,35 (4,198)	-17,45 (5,961)	
95 %-KI	[-9,658; 6,955]	[-29,186; -5,722]	
<b>BRCA Status: Negativ/Unbekannt</b>			
Baseline			
n/N (%)	150/191 (79)	134/172 (78)	-

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	72,11 (21,086)	70,83 (23,982)	
Absolute Werte zum Studienende			
n/N (%)	9/121 (7)	6/95 (6)	-
MW (SD)	82,41 (21,828)	79,17 (10,206)	
Effekt über Studiendauer			
n	150	134	LS MD 5,06 [1,498; 8,622] 0,0054  Hedges' g 0,33 [0,096; 0,565]
LS MW (SE)	2,31 (1,242)	-2,75 (1,328)	
95 %-KI	[-0,119; 4,749]	[-5,349; -0,142]	
Veränderung zu Woche 3/4			
n/N (%)	103/186 (55)	89/165 (54)	LS MD 4,94 [1,299; 8,577]
MW (SD)	5,02 (16,599)	1,50 (16,067)	
LS MW (SE)	5,07 (1,269)	0,13 (1,357)	
95 %-KI	[2,580; 7,556]	[-2,530; 2,788]	
Veränderung zu Woche 8/9			
n/N (%)	121/184 (66)	103/158 (65)	LS MD 4,99 [1,416; 8,567]
MW (SD)	2,41 (19,467)	-3,24 (20,286)	
LS MW (SE)	3,87 (1,249)	-1,12 (1,331)	
95 %-KI	[1,419; 6,316]	[-3,734; 1,485]	
Veränderung zu Woche 12			
n/N (%)	81/179 (45)	59/153 (39)	LS MD 5,03 [1,470; 8,587]
MW (SD)	5,45 (18,688)	-3,67 (15,952)	
LS MW (SE)	3,03 (1,242)	-2,00 (1,326)	
95 %-KI	[0,592; 5,462]	[-4,600; 0,596]	
Veränderung zu Woche 15/16			
n/N (%)	83/173 (48)	45/149 (30)	LS MD 5,07 [1,502; 8,630]
MW (SD)	1,81 (18,361)	0,74 (21,158)	
LS MW (SE)	2,19 (1,242)	-2,88 (1,330)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-0,248; 4,621]	[-5,485; -0,273]	
Veränderung zu Woche 20/21			
n/N (%)	56/165 (34)	45/140 (32)	LS MD 5,12 [1,508; 8,730]
MW (SD)	0,45 (21,345)	3,70 (17,992)	
LS MW (SE)	0,99 (1,252)	-4,13 (1,352)	
95 %-KI	[-1,468; 3,441]	[-6,783; -1,482]	
Veränderung zu Woche 24			
n/N (%)	46/159 (29)	34/131 (26)	LS MD 5,16 [1,486; 8,826]
MW (SD)	1,63 (20,610)	1,23 (16,429)	
LS MW (SE)	0,15 (1,267)	-5,01 (1,380)	
95 %-KI	[-2,337; 2,629]	[-7,714; -2,305]	
Veränderung zu Woche 36			
n/N (%)	71/139 (51)	39/114 (34)	LS MD 5,28 [1,261; 9,306]
MW (SD)	-0,12 (21,292)	-5,13 (19,272)	
LS MW (SE)	-2,73 (1,360)	-8,02 (1,536)	
95 %-KI	[-5,401; -0,069]	[-11,029; -5,007]	
Veränderung zu Woche 48			
n/N (%)	7/121 (6)	5/95 (5)	LS MD 5,41 [0,851; 9,971]
MW (SD)	3,57 (26,289)	-1,67 (16,029)	
LS MW (SE)	-5,62 (1,510)	-11,03 (1,768)	
95 %-KI	[-8,575; -2,656]	[-14,492; -7,561]	
<b>Baseline ECOG PS: 0</b>			
Baseline			
n/N (%)	99/128 (77)	95/113 (84)	-
MW (SD)	75,08 (19,974)	72,02 (21,978)	
Absolute Werte zum Studienende			
n/N (%)	7/87 (8)	3/72 (4)	-
MW (SD)	73,81 (25,653)	83,33 (14,434)	
Effekt über Studiendauer			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n	99	95	LS MD 3,32 [-0,823; 7,456] 0,1157  Hedges' g 0,23 [-0,056; 0,509]
LS MW (SE)	1,04 (1,455)	-2,27 (1,512)	
95 %-KI	[-1,826; 3,915]	[-5,255; 0,710]	
Veränderung zu Woche 3/4			
n/N (%)	68/127 (54)	62/111 (56)	LS MD 3,45 [-0,796; 7,695]
MW (SD)	3,68 (17,059)	1,88 (15,045)	
LS MW (SE)	3,05 (1,493)	-0,40 (1,553)	
95 %-KI	[0,103; 5,988]	[-3,466; 2,657]	
Veränderung zu Woche 8/9			
n/N (%)	81/126 (64)	73/108 (68)	LS MD 3,39 [-0,769; 7,554]
MW (SD)	0,31 (17,502)	-3,65 (18,214)	
LS MW (SE)	2,18 (1,466)	-1,21 (1,519)	
95 %-KI	[-0,708; 5,074]	[-4,204; 1,785]	
Veränderung zu Woche 12			
n/N (%)	51/122 (42)	44/108 (41)	LS MD 3,35 [-0,785; 7,489]
MW (SD)	3,27 (18,935)	-5,68 (17,496)	
LS MW (SE)	1,58 (1,457)	-1,77 (1,510)	
95 %-KI	[-1,295; 4,453]	[-4,751; 1,204]	
Veränderung zu Woche 15/16			
n/N (%)	54/120 (45)	33/105 (31)	LS MD 3,31 [-0,829; 7,453]
MW (SD)	-0,46 (20,375)	-1,52 (22,674)	
LS MW (SE)	0,98 (1,455)	-2,34 (1,513)	
95 %-KI	[-1,896; 3,846]	[-5,322; 0,648]	
Veränderung zu Woche 20/21			
n/N (%)	40/117 (34)	30/101 (30)	LS MD 3,25 [-0,941; 7,451]
MW (SD)	0,62 (19,917)	-2,50 (11,191)	
LS MW (SE)	0,11 (1,468)	-3,14 (1,541)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-2,782; 3,007]	[-6,179; -0,105]	
Veränderung zu Woche 24			
n/N (%)	27/112 (24)	22/96 (23)	LS MD 3,21 [-1,053; 7,482]
MW (SD)	0,93 (18,393)	3,41 (16,196)	
LS MW (SE)	-0,49 (1,486)	-3,71 (1,574)	
95 %-KI	[-3,421; 2,438]	[-6,808; -0,604]	
Veränderung zu Woche 36			
n/N (%)	50/99 (51)	32/87 (37)	LS MD 3,08 [-1,625; 7,779]
MW (SD)	-1,00 (22,502)	-4,17 (17,835)	
LS MW (SE)	-2,56 (1,602)	-5,64 (1,770)	
95 %-KI	[-5,716; 0,592]	[-9,120; -2,157]	
Veränderung zu Woche 48			
n/N (%)	5/87 (6)	3/72 (4)	LS MD 2,94 [-2,429; 8,307]
MW (SD)	5,00 (31,513)	8,33 (8,333)	
LS MW (SE)	-4,63 (1,789)	-7,57 (2,060)	
95 %-KI	[-8,149; -1,115]	[-11,617; -3,525]	
<b>Baseline ECOG PS: 1</b>			
Baseline			
n/N (%)	76/90 (84)	61/91 (67)	-
MW (SD)	67,98 (23,056)	67,21 (25,724)	
Absolute Werte zum Studienende			
n/N (%)	3/53 (6)	3/37 (8)	-
MW (SD)	91,67 (8,333)	75,00 (0,000)	
Effekt über Studiendauer			
n	76	61	LS MD 5,91 [0,340; 11,488] 0,0378
LS MW (SE)	3,47 (1,869)	-2,45 (2,114)	
95 %-KI	[-0,230; 7,166]	[-6,627; 1,734]	Hedges' g 0,36 [0,019; 0,698]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	51/86 (59)	44/87 (51)	LS MD 3,60 [-2,072; 9,266]
MW (SD)	6,21 (17,547)	3,41 (20,039)	
LS MW (SE)	6,50 (1,910)	2,91 (2,145)	
95 %-KI	[2,729; 10,278]	[-1,332; 7,145]	
Veränderung zu Woche 8/9			
n/N (%)	60/84 (71)	48/78 (62)	LS MD 4,66 [-0,917; 10,243]
MW (SD)	4,03 (22,207)	1,39 (24,392)	
LS MW (SE)	5,11 (1,879)	0,44 (2,110)	
95 %-KI	[1,390; 8,823]	[-3,728; 4,615]	
Veränderung zu Woche 12			
n/N (%)	45/83 (54)	24/74 (32)	LS MD 5,41 [-0,154; 10,973]
MW (SD)	5,00 (19,332)	2,08 (16,892)	
LS MW (SE)	4,13 (1,870)	-1,28 (2,106)	
95 %-KI	[0,430; 7,827]	[-5,447; 2,884]	
Veränderung zu Woche 15/16			
n/N (%)	40/79 (51)	20/72 (28)	LS MD 6,16 [0,571; 11,742]
MW (SD)	1,87 (15,956)	12,92 (18,629)	
LS MW (SE)	3,15 (1,871)	-3,01 (2,121)	
95 %-KI	[-0,550; 6,851]	[-7,199; 1,187]	
Veränderung zu Woche 20/21			
n/N (%)	26/73 (36)	18/63 (29)	LS MD 7,22 [1,540; 12,905]
MW (SD)	0,96 (21,386)	14,81 (20,121)	
LS MW (SE)	1,75 (1,890)	-5,47 (2,172)	
95 %-KI	[-1,985; 5,492]	[-9,760; -1,179]	
Veränderung zu Woche 24			
n/N (%)	26/72 (36)	14/58 (24)	LS MD 7,97 [2,175; 13,763]
MW (SD)	1,60 (21,346)	-1,19 (15,281)	
LS MW (SE)	0,78 (1,916)	-7,19 (2,227)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,012; 4,563]	[-11,590; -2,797]	
Veränderung zu Woche 36			
n/N (%)	31/61 (51)	12/46 (26)	LS MD 10,53 [4,107; 16,951]
MW (SD)	0,81 (17,395)	-4,86 (26,462)	
LS MW (SE)	-2,58 (2,075)	-13,11 (2,523)	
95 %-KI	[-6,669; 1,514]	[-18,073; -8,139]	
Veränderung zu Woche 48			
n/N (%)	3/53 (6)	2/37 (5)	LS MD 13,09 [5,739; 20,438]
MW (SD)	-2,78 (9,623)	-16,67 (11,785)	
LS MW (SE)	-5,93 (2,323)	-19,02 (2,941)	
95 %-KI	[-10,501; -1,360]	[-24,799; -13,239]	
<b>Anzahl vorheriger Therapielinien: 1</b>			
Baseline			
n/N (%)	24/31 (77)	22/29 (76)	-
MW (SD)	75,00 (18,389)	72,35 (23,343)	
Absolute Werte zum Studienende			
n/N (%)	1/22 (5)	0/14 (0)	-
MW (SD)	100,00 (NA)	NA (NA)	
Effekt über Studiendauer			
n	24	22	LS MD 6,42 [-4,838; 17,672] 0,2566  Hedges' g 0,33 [-0,250; 0,915]
LS MW (SE)	0,92 (3,843)	-5,49 (4,077)	
95 %-KI	[-6,832; 8,676]	[-13,715; 2,725]	
Veränderung zu Woche 3/4			
n/N (%)	16/31 (52)	13/29 (45)	LS MD 9,23 [-2,215; 20,681]
MW (SD)	1,04 (15,176)	-1,92 (13,244)	
LS MW (SE)	5,15 (3,913)	-4,08 (4,159)	
95 %-KI	[-2,730; 13,027]	[-12,452; 4,282]	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	20/31 (65)	17/26 (65)	LS MD 8,05 [-3,251; 19,348]
MW (SD)	5,00 (19,384)	-6,37 (26,927)	
LS MW (SE)	3,37 (3,867)	-4,68 (4,088)	
95 %-KI	[-4,426; 11,166]	[-12,918; 3,561]	
Veränderung zu Woche 12			
n/N (%)	14/31 (45)	11/24 (46)	LS MD 7,22 [-4,035; 18,472]
MW (SD)	7,14 (19,844)	-3,03 (15,489)	
LS MW (SE)	2,12 (3,849)	-5,09 (4,070)	
95 %-KI	[-5,640; 9,890]	[-13,300; 3,113]	
Veränderung zu Woche 15/16			
n/N (%)	15/31 (48)	10/22 (45)	LS MD 6,39 [-4,867; 17,645]
MW (SD)	-3,89 (17,499)	-2,50 (12,454)	
LS MW (SE)	0,88 (3,843)	-5,51 (4,078)	
95 %-KI	[-6,874; 8,634]	[-13,730; 2,712]	
Veränderung zu Woche 20/21			
n/N (%)	11/30 (37)	8/22 (36)	LS MD 5,20 [-6,140; 16,547]
MW (SD)	-3,79 (26,184)	-5,21 (6,200)	
LS MW (SE)	-0,90 (3,856)	-6,10 (4,134)	
95 %-KI	[-8,675; 6,877]	[-14,424; 2,220]	
Veränderung zu Woche 24			
n/N (%)	9/30 (30)	11/20 (55)	LS MD 4,37 [-7,088; 15,836]
MW (SD)	-4,63 (21,695)	6,82 (18,936)	
LS MW (SE)	-2,14 (3,879)	-6,52 (4,204)	
95 %-KI	[-9,961; 5,673]	[-14,966; 1,931]	
Veränderung zu Woche 36			
n/N (%)	15/26 (58)	5/18 (28)	LS MD 1,53 [-10,684; 13,742]
MW (SD)	-6,11 (22,596)	-8,33 (31,732)	
LS MW (SE)	-6,41 (4,043)	-7,94 (4,615)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-14,527; 1,702]	[-17,145; 1,262]	
Veränderung zu Woche 48			
n/N (%)	0/22 (0)	0/14 (0)	LS MD -1,32 [-14,748; 12,117]
MW (SD)	NA (NA)	NA (NA)	
LS MW (SE)	-10,68 (4,328)	-9,37 (5,237)	
95 %-KI	[-19,319; -2,043]	[-19,742; 1,011]	
<b>Anzahl vorheriger Therapielinien: 2</b>			
Baseline			
n/N (%)	75/89 (84)	64/83 (77)	-
MW (SD)	70,89 (21,547)	67,84 (25,410)	
Absolute Werte zum Studienende			
n/N (%)	4/59 (7)	2/50 (4)	-
MW (SD)	66,67 (29,659)	75,00 (0,000)	
Effekt über Studiendauer			
n	75	64	LS MD 2,69 [-2,291; 7,667] 0,2876  Hedges' g 0,18 [-0,153; 0,515]
LS MW (SE)	2,32 (1,690)	-0,37 (1,864)	
95 %-KI	[-1,023; 5,663]	[-4,053; 3,316]	
Veränderung zu Woche 3/4			
n/N (%)	53/86 (62)	45/80 (56)	LS MD 1,76 [-3,349; 6,867]
MW (SD)	3,14 (17,695)	5,00 (20,132)	
LS MW (SE)	5,08 (1,739)	3,32 (1,910)	
95 %-KI	[1,644; 8,517]	[-0,452; 7,094]	
Veränderung zu Woche 8/9			
n/N (%)	61/85 (72)	51/77 (66)	LS MD 2,18 [-2,816; 7,172]
MW (SD)	2,32 (19,845)	1,31 (20,908)	
LS MW (SE)	3,84 (1,703)	1,66 (1,862)	
95 %-KI	[0,468; 7,204]	[-2,024; 5,339]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	40/83 (48)	30/75 (40)	LS MD 2,47 [-2,497; 7,440]
MW (SD)	3,12 (19,030)	-1,67 (19,745)	
LS MW (SE)	2,96 (1,691)	0,49 (1,855)	
95 %-KI	[-0,381; 6,310]	[-3,174; 4,161]	
Veränderung zu Woche 15/16			
n/N (%)	41/80 (51)	19/74 (26)	LS MD 2,76 [-2,224; 7,753]
MW (SD)	-0,00 (18,911)	10,09 (26,291)	
LS MW (SE)	2,09 (1,691)	-0,67 (1,870)	
95 %-KI	[-1,251; 5,438]	[-4,367; 3,025]	
Veränderung zu Woche 20/21			
n/N (%)	32/78 (41)	20/68 (29)	LS MD 3,18 [-1,912; 8,278]
MW (SD)	0,78 (21,829)	11,67 (18,016)	
LS MW (SE)	0,85 (1,710)	-2,33 (1,927)	
95 %-KI	[-2,532; 4,229]	[-6,141; 1,472]	
Veränderung zu Woche 24			
n/N (%)	27/74 (36)	13/65 (20)	LS MD 3,48 [-1,745; 8,697]
MW (SD)	0,93 (22,685)	-1,92 (13,244)	
LS MW (SE)	-0,02 (1,736)	-3,50 (1,992)	
95 %-KI	[-3,454; 3,409]	[-7,429; 0,432]	
Veränderung zu Woche 36			
n/N (%)	33/65 (51)	17/58 (29)	LS MD 4,48 [-1,452; 10,414]
MW (SD)	-2,27 (22,173)	-4,41 (16,435)	
LS MW (SE)	-3,01 (1,902)	-7,49 (2,336)	
95 %-KI	[-6,760; 0,740]	[-12,086; -2,896]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	1/50 (2)	LS MD 5,49 [-1,484; 12,456]
MW (SD)	-10,42 (10,486)	-8,33 (NA)	
LS MW (SE)	-6,00 (2,161)	-11,48 (2,811)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-10,249; -1,745]	[-17,004; -5,961]	
<b>Anzahl vorheriger Therapielinien: 3</b>			
Baseline			
n/N (%)	76/98 (78)	71/95 (75)	-
MW (SD)	72,15 (22,712)	71,13 (22,085)	
Absolute Werte zum Studienende			
n/N (%)	5/59 (8)	4/46 (9)	-
MW (SD)	85,00 (14,907)	81,25 (12,500)	
Effekt über Studiendauer			
n	76	71	LS MD 5,32 [0,514; 10,127] 0,0303  Hedges' g 0,36 [0,033; 0,685]
LS MW (SE)	2,65 (1,681)	-2,67 (1,763)	
95 %-KI	[-0,675; 5,974]	[-6,156; 0,814]	
Veränderung zu Woche 3/4			
n/N (%)	50/96 (52)	49/91 (54)	LS MD 3,64 [-1,265; 8,537]
MW (SD)	7,67 (17,238)	1,70 (15,021)	
LS MW (SE)	3,93 (1,718)	0,29 (1,797)	
95 %-KI	[0,532; 7,319]	[-3,260; 3,840]	
Veränderung zu Woche 8/9			
n/N (%)	60/94 (64)	54/85 (64)	LS MD 4,38 [-0,441; 9,205]
MW (SD)	0,42 (19,734)	-2,47 (18,922)	
LS MW (SE)	3,36 (1,690)	-1,02 (1,767)	
95 %-KI	[0,019; 6,701]	[-4,514; 2,470]	
Veränderung zu Woche 12			
n/N (%)	42/91 (46)	28/84 (33)	LS MD 4,90 [0,102; 9,707]
MW (SD)	3,97 (19,148)	-3,27 (16,872)	
LS MW (SE)	2,96 (1,682)	-1,94 (1,760)	
95 %-KI	[-0,360; 6,289]	[-5,419; 1,539]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	38/88 (43)	24/82 (29)	LS MD 5,43 [0,616; 10,238]
MW (SD)	2,85 (18,712)	1,74 (21,420)	
LS MW (SE)	2,57 (1,682)	-2,86 (1,765)	
95 %-KI	[-0,757; 5,894]	[-6,347; 0,630]	
Veränderung zu Woche 20/21			
n/N (%)	23/82 (28)	21/75 (28)	LS MD 6,17 [1,302; 11,046]
MW (SD)	2,90 (14,993)	2,38 (19,569)	
LS MW (SE)	2,00 (1,699)	-4,17 (1,793)	
95 %-KI	[-1,354; 5,361]	[-7,712; -0,629]	
Veränderung zu Woche 24			
n/N (%)	17/80 (21)	13/70 (19)	LS MD 6,70 [1,748; 11,645]
MW (SD)	4,90 (12,520)	-0,64 (15,389)	
LS MW (SE)	1,61 (1,721)	-5,09 (1,826)	
95 %-KI	[-1,792; 5,008]	[-8,693; -1,484]	
Veränderung zu Woche 36			
n/N (%)	33/69 (48)	22/58 (38)	LS MD 8,49 [3,086; 13,889]
MW (SD)	4,29 (17,446)	-3,41 (20,839)	
LS MW (SE)	0,25 (1,859)	-8,24 (2,016)	
95 %-KI	[-3,415; 3,917]	[-12,207; -4,266]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	4/46 (9)	LS MD 10,28 [4,183; 16,376]
MW (SD)	14,58 (29,950)	-0,00 (18,002)	
LS MW (SE)	-1,11 (2,077)	-11,38 (2,299)	
95 %-KI	[-5,192; 2,980]	[-15,905; -6,865]	
<b>Vorherige Verabreichung von Bevacizumab: Ja</b>			
Baseline			
n/N (%)	104/134 (78)	99/132 (75)	-
MW (SD)	73,48 (19,801)	69,11 (24,347)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	3/79 (4)	3/62 (5)	-
MW (SD)	63,89 (29,266)	72,22 (4,811)	
Effekt über Studiendauer			
n	104	99	LS MD 3,21 [-0,874; 7,296] 0,1227  Hedges' g 0,22 [-0,059; 0,493]
LS MW (SE)	0,19 (1,428)	-3,03 (1,499)	
95 %-KI	[-2,631; 3,001]	[-5,982; -0,070]	
Veränderung zu Woche 3/4			
n/N (%)	68/130 (52)	67/127 (53)	LS MD 2,10 [-2,077; 6,277]
MW (SD)	3,06 (13,878)	3,23 (15,688)	
LS MW (SE)	2,86 (1,463)	0,76 (1,532)	
95 %-KI	[-0,025; 5,741]	[-2,260; 3,777]	
Veränderung zu Woche 8/9			
n/N (%)	84/130 (65)	73/119 (61)	LS MD 2,62 [-1,474; 6,714]
MW (SD)	0,30 (17,616)	-1,83 (21,839)	
LS MW (SE)	1,61 (1,436)	-1,01 (1,497)	
95 %-KI	[-1,225; 4,439]	[-3,966; 1,939]	
Veränderung zu Woche 12			
n/N (%)	54/126 (43)	37/114 (32)	LS MD 2,98 [-1,093; 7,062]
MW (SD)	1,85 (19,268)	-0,45 (18,315)	
LS MW (SE)	0,73 (1,428)	-2,25 (1,493)	
95 %-KI	[-2,086; 3,548]	[-5,198; 0,691]	
Veränderung zu Woche 15/16			
n/N (%)	56/122 (46)	31/112 (28)	LS MD 3,35 [-0,748; 7,445]
MW (SD)	-1,64 (15,277)	1,61 (19,886)	
LS MW (SE)	-0,14 (1,429)	-3,49 (1,506)	
95 %-KI	[-2,963; 2,674]	[-6,463; -0,524]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	38/114 (33)	28/103 (27)	LS MD 3,87 [-0,315; 8,052]
MW (SD)	-0,88 (21,816)	6,25 (20,987)	
LS MW (SE)	-1,40 (1,445)	-5,26 (1,553)	
95 %-KI	[-4,246; 1,453]	[-8,324; -2,205]	
Veränderung zu Woche 24			
n/N (%)	29/109 (27)	17/95 (18)	LS MD 4,23 [-0,051; 8,517]
MW (SD)	-1,15 (15,386)	-1,47 (13,253)	
LS MW (SE)	-2,27 (1,467)	-6,51 (1,604)	
95 %-KI	[-5,164; 0,619]	[-9,663; -3,347]	
Veränderung zu Woche 36			
n/N (%)	44/93 (47)	20/79 (25)	LS MD 5,48 [0,637; 10,326]
MW (SD)	-2,65 (17,771)	-7,92 (15,875)	
LS MW (SE)	-5,28 (1,600)	-10,76 (1,873)	
95 %-KI	[-8,423; -2,128]	[-14,437; -7,077]	
Veränderung zu Woche 48			
n/N (%)	3/79 (4)	2/62 (3)	LS MD 6,73 [1,072; 12,387]
MW (SD)	-11,11 (12,729)	-4,17 (5,893)	
LS MW (SE)	-8,28 (1,806)	-15,01 (2,244)	
95 %-KI	[-11,827; -4,731]	[-19,413; -10,604]	
<b>Vorherige Verabreichung von Bevacizumab: Nein</b>			
Baseline			
n/N (%)	71/84 (85)	58/75 (77)	-
MW (SD)	69,84 (23,961)	71,41 (22,356)	
Absolute Werte zum Studienende			
n/N (%)	7/61 (11)	3/48 (6)	-
MW (SD)	85,71 (18,456)	86,11 (9,623)	
Effekt über Studiendauer			
n	71	58	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	4,80 (1,891)	-0,64 (2,100)	LS MD 5,44 [-0,146; 11,034] 0,0562  Hedges' g 0,34 [-0,010; 0,688]
95 %-KI	[1,062; 8,548]	[-4,795; 3,517]	
Veränderung zu Woche 3/4			
n/N (%)	51/83 (61)	40/73 (55)	LS MD 4,88 [-0,843; 10,599]
MW (SD)	7,03 (20,842)	1,67 (19,630)	
LS MW (SE)	6,88 (1,938)	2,01 (2,151)	
95 %-KI	[3,051; 10,716]	[-2,246; 6,258]	
Veränderung zu Woche 8/9			
n/N (%)	57/80 (71)	49/69 (71)	LS MD 5,11 [-0,512; 10,736]
MW (SD)	4,24 (22,279)	-0,85 (19,855)	
LS MW (SE)	6,02 (1,906)	0,91 (2,112)	
95 %-KI	[2,254; 9,796]	[-3,264; 5,091]	
Veränderung zu Woche 12			
n/N (%)	42/79 (53)	32/69 (46)	LS MD 5,28 [-0,316; 10,867]
MW (SD)	6,94 (18,581)	-4,95 (17,047)	
LS MW (SE)	5,42 (1,894)	0,15 (2,100)	
95 %-KI	[1,675; 9,172]	[-4,006; 4,303]	
Veränderung zu Woche 15/16			
n/N (%)	38/77 (49)	22/66 (33)	LS MD 5,44 [-0,150; 11,028]
MW (SD)	3,73 (22,402)	7,20 (25,236)	
LS MW (SE)	4,82 (1,891)	-0,62 (2,100)	
95 %-KI	[1,079; 8,566]	[-4,772; 3,539]	
Veränderung zu Woche 20/21			
n/N (%)	28/76 (37)	21/62 (34)	LS MD 5,67 [0,035; 11,311]
MW (SD)	2,98 (18,316)	3,17 (14,062)	
LS MW (SE)	3,96 (1,904)	-1,71 (2,123)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[0,197; 7,730]	[-5,909; 2,490]	
Veränderung zu Woche 24			
n/N (%)	24/75 (32)	20/60 (33)	LS MD 5,84 [0,129; 11,545]
MW (SD)	4,17 (23,951)	3,33 (17,812)	
LS MW (SE)	3,36 (1,923)	-2,47 (2,154)	
95 %-KI	[-0,442; 7,167]	[-6,733; 1,785]	
Veränderung zu Woche 36			
n/N (%)	37/67 (55)	24/55 (44)	LS MD 6,40 [0,244; 12,552]
MW (SD)	2,48 (23,477)	-1,39 (23,139)	
LS MW (SE)	1,30 (2,055)	-5,10 (2,347)	
95 %-KI	[-2,755; 5,357]	[-9,725; -0,468]	
Veränderung zu Woche 48			
n/N (%)	5/61 (8)	3/48 (6)	LS MD 6,96 [0,090; 13,828]
MW (SD)	10,00 (27,889)	-0,00 (22,048)	
LS MW (SE)	-0,76 (2,271)	-7,72 (2,647)	
95 %-KI	[-5,233; 3,713]	[-12,927; -2,511]	
<b>Letztes Platin-freies Intervall: ≤ 3 Monate</b>			
Baseline			
n/N (%)	67/83 (81)	62/91 (68)	-
MW (SD)	72,76 (20,545)	66,26 (22,044)	
Absolute Werte zum Studienende			
n/N (%)	3/55 (5)	5/39 (13)	-
MW (SD)	77,78 (38,490)	80,00 (11,180)	
Effekt über Studiendauer			
n	67	62	LS MD 5,33 [0,083; 10,568] 0,0465
LS MW (SE)	2,93 (1,811)	-2,39 (1,916)	
95 %-KI	[-0,649; 6,519]	[-6,182; 1,401]	Hedges' g 0,35 [0,006; 0,702]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	49/82 (60)	46/86 (53)	LS MD 3,82 [-1,541; 9,174]
MW (SD)	2,21 (19,153)	2,72 (18,092)	
LS MW (SE)	3,54 (1,857)	-0,28 (1,955)	
95 %-KI	[-0,132; 7,212]	[-4,142; 3,588]	
Veränderung zu Woche 8/9			
n/N (%)	50/81 (62)	45/80 (56)	LS MD 4,51 [-0,742; 9,766]
MW (SD)	-0,33 (17,248)	-0,74 (20,321)	
LS MW (SE)	3,26 (1,820)	-1,25 (1,916)	
95 %-KI	[-0,340; 6,862]	[-5,042; 2,540]	
Veränderung zu Woche 12			
n/N (%)	33/78 (42)	24/78 (31)	LS MD 5,00 [-0,234; 10,232]
MW (SD)	5,05 (21,745)	-1,74 (20,848)	
LS MW (SE)	3,07 (1,810)	-1,93 (1,910)	
95 %-KI	[-0,516; 6,648]	[-5,712; 1,847]	
Veränderung zu Woche 15/16			
n/N (%)	33/76 (43)	14/75 (19)	LS MD 5,49 [0,231; 10,740]
MW (SD)	3,03 (17,532)	6,55 (27,186)	
LS MW (SE)	2,87 (1,813)	-2,61 (1,922)	
95 %-KI	[-0,718; 6,460]	[-6,418; 1,188]	
Veränderung zu Woche 20/21			
n/N (%)	22/72 (31)	14/67 (21)	LS MD 6,18 [0,824; 11,538]
MW (SD)	5,68 (18,073)	5,95 (21,787)	
LS MW (SE)	2,59 (1,842)	-3,59 (1,970)	
95 %-KI	[-1,052; 6,236]	[-7,483; 0,305]	
Veränderung zu Woche 24			
n/N (%)	15/72 (21)	11/62 (18)	LS MD 6,67 [1,189; 12,146]
MW (SD)	5,00 (16,306)	-2,27 (13,990)	
LS MW (SE)	2,40 (1,878)	-4,27 (2,023)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-1,316; 6,109]	[-8,268; -0,274]	
Veränderung zu Woche 36			
n/N (%)	27/63 (43)	17/50 (34)	LS MD 8,34 [2,176; 14,496]
MW (SD)	2,78 (22,169)	-0,98 (22,025)	
LS MW (SE)	1,73 (2,088)	-6,61 (2,313)	
95 %-KI	[-2,389; 5,844]	[-11,163; -2,055]	
Veränderung zu Woche 48			
n/N (%)	2/55 (4)	4/39 (10)	LS MD 10,00 [2,847; 17,163]
MW (SD)	-8,33 (23,570)	4,17 (10,758)	
LS MW (SE)	1,06 (2,404)	-8,95 (2,722)	
95 %-KI	[-3,669; 5,785]	[-14,297; -3,597]	
<b>Letztes Platin-freies Intervall: &gt; 3 Monate</b>			
Baseline			
n/N (%)	108/135 (80)	95/116 (82)	-
MW (SD)	71,53 (22,300)	72,37 (24,349)	
Absolute Werte zum Studienende			
n/N (%)	7/85 (8)	1/71 (1)	-
MW (SD)	79,76 (17,252)	75,00 (NA)	
Effekt über Studiendauer			
n	108	95	LS MD 3,29 [-1,004; 7,588] 0,1323  Hedges' g 0,21 [-0,065; 0,488]
LS MW (SE)	1,62 (1,482)	-1,67 (1,600)	
95 %-KI	[-1,299; 4,548]	[-4,822; 1,486]	
Veränderung zu Woche 3/4			
n/N (%)	70/131 (53)	61/114 (54)	LS MD 2,64 [-1,756; 7,034]
MW (SD)	6,55 (15,664)	2,60 (16,635)	
LS MW (SE)	5,02 (1,517)	2,38 (1,638)	
95 %-KI	[2,029; 8,009]	[-0,848; 5,608]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	91/129 (71)	77/108 (71)	LS MD 2,92 [-1,395; 7,239]
MW (SD)	3,11 (20,848)	-1,84 (21,486)	
LS MW (SE)	3,55 (1,493)	0,63 (1,604)	
95 %-KI	[0,604; 6,492]	[-2,537; 3,789]	
Veränderung zu Woche 12			
n/N (%)	63/127 (50)	45/105 (43)	LS MD 3,12 [-1,174; 7,414]
MW (SD)	3,57 (17,628)	-2,96 (16,104)	
LS MW (SE)	2,52 (1,484)	-0,60 (1,596)	
95 %-KI	[-0,409; 5,446]	[-3,749; 2,546]	
Veränderung zu Woche 15/16			
n/N (%)	61/123 (50)	39/103 (38)	LS MD 3,32 [-0,980; 7,617]
MW (SD)	-0,82 (19,106)	2,99 (20,456)	
LS MW (SE)	1,49 (1,483)	-1,83 (1,601)	
95 %-KI	[-1,435; 4,412]	[-4,986; 1,327]	
Veränderung zu Woche 20/21			
n/N (%)	44/118 (37)	35/98 (36)	LS MD 3,60 [-0,750; 7,953]
MW (SD)	-1,70 (21,157)	4,52 (16,951)	
LS MW (SE)	0,02 (1,492)	-3,58 (1,630)	
95 %-KI	[-2,924; 2,959]	[-6,796; -0,372]	
Veränderung zu Woche 24			
n/N (%)	38/112 (34)	26/93 (28)	LS MD 3,80 [-0,621; 8,220]
MW (SD)	-0,22 (20,911)	2,56 (16,628)	
LS MW (SE)	-1,01 (1,506)	-4,81 (1,665)	
95 %-KI	[-3,981; 1,957]	[-8,092; -1,532]	
Veränderung zu Woche 36			
n/N (%)	54/97 (56)	27/84 (32)	LS MD 4,48 [-0,358; 9,317]
MW (SD)	-1,85 (19,804)	-6,48 (19,106)	
LS MW (SE)	-4,54 (1,603)	-9,02 (1,866)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-7,699; -1,386]	[-12,691; -5,352]	
Veränderung zu Woche 48			
n/N (%)	6/85 (7)	1/71 (1)	LS MD 5,16 [-0,322; 10,640]
MW (SD)	5,56 (26,176)	-25,00 (NA)	
LS MW (SE)	-8,07 (1,763)	-13,23 (2,162)	
95 %-KI	[-11,539; -4,606]	[-17,478; -8,985]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Pegyliertes liposomales Doxorubicin</b>			
Baseline			
n/N (%)	62/80 (78)	56/76 (74)	-
MW (SD)	69,35 (20,511)	75,30 (20,595)	
Absolute Werte zum Studienende			
n/N (%)	3/51 (6)	3/41 (7)	-
MW (SD)	80,56 (26,788)	80,56 (9,623)	
Effekt über Studiendauer			
n	62	56	LS MD 2,48 [-2,935; 7,900] 0,3659  Hedges' g 0,17 [-0,195; 0,529]
LS MW (SE)	0,30 (1,861)	-2,19 (1,984)	
95 %-KI	[-3,392; 3,983]	[-6,115; 1,741]	
Veränderung zu Woche 3/4			
n/N (%)	41/76 (54)	42/74 (57)	LS MD 4,08 [-1,483; 9,652]
MW (SD)	6,71 (15,835)	-0,60 (14,538)	
LS MW (SE)	3,30 (1,925)	-0,78 (2,030)	
95 %-KI	[-0,507; 7,111]	[-4,798; 3,232]	
Veränderung zu Woche 8/9			
n/N (%)	50/76 (66)	42/66 (64)	LS MD 3,39 [-2,056; 8,834]
MW (SD)	1,50 (18,342)	-6,35 (22,301)	
LS MW (SE)	2,00 (1,882)	-1,39 (1,983)	
95 %-KI	[-1,732; 5,723]	[-5,319; 2,533]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	33/75 (44)	22/64 (34)	LS MD 2,90 [-2,510; 8,313]
MW (SD)	5,56 (22,113)	-4,55 (14,935)	
LS MW (SE)	1,08 (1,866)	-1,82 (1,975)	
95 %-KI	[-2,615; 4,778]	[-5,730; 2,090]	
Veränderung zu Woche 15/16			
n/N (%)	34/74 (46)	18/62 (29)	LS MD 2,41 [-3,007; 7,836]
MW (SD)	-2,21 (17,921)	-1,39 (15,978)	
LS MW (SE)	0,17 (1,861)	-2,25 (1,987)	
95 %-KI	[-3,520; 3,855]	[-6,181; 1,687]	
Veränderung zu Woche 20/21			
n/N (%)	27/72 (38)	17/59 (29)	LS MD 1,72 [-3,793; 7,230]
MW (SD)	-1,23 (21,768)	0,00 (12,500)	
LS MW (SE)	-1,14 (1,875)	-2,86 (2,039)	
95 %-KI	[-4,853; 2,575]	[-6,891; 1,176]	
Veränderung zu Woche 24			
n/N (%)	22/69 (32)	16/54 (30)	LS MD 1,23 [-4,393; 6,856]
MW (SD)	1,14 (18,775)	5,21 (17,180)	
LS MW (SE)	-2,05 (1,899)	-3,28 (2,098)	
95 %-KI	[-5,812; 1,706]	[-7,431; 0,862]	
Veränderung zu Woche 36			
n/N (%)	31/60 (52)	15/48 (31)	LS MD -0,44 [-6,732; 5,855]
MW (SD)	-2,42 (21,103)	-3,33 (27,603)	
LS MW (SE)	-5,19 (2,062)	-4,75 (2,421)	
95 %-KI	[-9,258; -1,118]	[-9,518; 0,020]	
Veränderung zu Woche 48			
n/N (%)	2/51 (4)	2/41 (5)	LS MD -2,11 [-9,408; 5,190]
MW (SD)	-4,17 (5,893)	4,17 (17,678)	
LS MW (SE)	-8,32 (2,326)	-6,21 (2,877)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-12,903; -3,741]	[-11,867; -0,560]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Paclitaxel</b>			
Baseline			
n/N (%)	74/88 (84)	69/82 (84)	-
MW (SD)	72,07 (22,131)	64,37 (24,708)	
Absolute Werte zum Studienende			
n/N (%)	1/56 (2)	1/49 (2)	-
MW (SD)	33,33 (NA)	91,67 (NA)	
Effekt über Studiendauer			
n	74	69	LS MD 0,89 [-4,167; 5,955] 0,7274
LS MW (SE)	1,99 (1,746)	1,09 (1,858)	
95 %-KI	[-1,466; 5,439]	[-2,582; 4,766]	Hedges' g 0,06 [-0,270; 0,387]
Veränderung zu Woche 3/4			
n/N (%)	55/87 (63)	47/81 (58)	LS MD -0,46 [-5,647; 4,722]
MW (SD)	2,58 (12,409)	8,51 (18,511)	
LS MW (SE)	4,54 (1,788)	5,00 (1,906)	
95 %-KI	[1,005; 8,071]	[1,235; 8,766]	
Veränderung zu Woche 8/9			
n/N (%)	61/86 (71)	53/79 (67)	LS MD 0,16 [-4,927; 5,240]
MW (SD)	2,46 (20,601)	4,25 (20,905)	
LS MW (SE)	3,37 (1,756)	3,22 (1,865)	
95 %-KI	[-0,098; 6,845]	[-0,469; 6,903]	
Veränderung zu Woche 12			
n/N (%)	42/84 (50)	35/77 (45)	LS MD 0,59 [-4,468; 5,648]
MW (SD)	2,38 (16,285)	-0,48 (21,192)	
LS MW (SE)	2,56 (1,746)	1,97 (1,855)	
95 %-KI	[-0,894; 6,011]	[-1,700; 5,636]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	44/81 (54)	27/76 (36)	LS MD 1,02 [-4,045; 6,092]
MW (SD)	-0,95 (17,070)	9,57 (27,122)	
LS MW (SE)	1,74 (1,747)	0,72 (1,862)	
95 %-KI	[-1,712; 5,198]	[-2,961; 4,401]	
Veränderung zu Woche 20/21			
n/N (%)	28/77 (36)	25/73 (34)	LS MD 1,64 [-3,504; 6,790]
MW (SD)	-1,79 (19,024)	8,67 (22,500)	
LS MW (SE)	0,58 (1,768)	-1,06 (1,900)	
95 %-KI	[-2,915; 4,073]	[-4,818; 2,690]	
Veränderung zu Woche 24			
n/N (%)	21/74 (28)	18/72 (25)	LS MD 2,08 [-3,169; 7,321]
MW (SD)	0,40 (24,221)	-2,31 (15,605)	
LS MW (SE)	-0,24 (1,795)	-2,31 (1,946)	
95 %-KI	[-3,782; 3,309]	[-6,154; 1,529]	
Veränderung zu Woche 36			
n/N (%)	35/64 (55)	21/63 (33)	LS MD 3,56 [-2,257; 9,382]
MW (SD)	-0,48 (18,846)	-3,17 (16,132)	
LS MW (SE)	-3,03 (1,959)	-6,59 (2,202)	
95 %-KI	[-6,892; 0,831]	[-10,928; -2,258]	
Veränderung zu Woche 48			
n/N (%)	1/56 (2)	1/49 (2)	LS MD 5,05 [-1,637; 11,734]
MW (SD)	-25,00 (NA)	8,33 (NA)	
LS MW (SE)	-5,83 (2,214)	-10,87 (2,575)	
95 %-KI	[-10,180; -1,470]	[-15,933; -5,815]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Topotecan</b>			
Baseline			
n/N (%)	39/50 (78)	32/49 (65)	-
MW (SD)	76,07 (22,145)	72,66 (24,063)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	6/33 (18)	2/20 (10)	-
MW (SD)	86,11 (13,608)	70,83 (5,893)	
Effekt über Studiendauer			
n	39	32	LS MD 12,44 [4,682; 20,191] 0,0021  Hedges' g 0,75 [0,268; 1,237]
LS MW (SE)	4,70 (2,599)	-7,73 (2,915)	
95 %-KI	[-0,484; 9,891]	[-13,549; -1,917]	
Veränderung zu Woche 3/4			
n/N (%)	23/50 (46)	18/45 (40)	LS MD 8,72 [0,876; 16,564]
MW (SD)	6,52 (27,173)	-5,09 (14,890)	
LS MW (SE)	5,77 (2,627)	-2,95 (2,956)	
95 %-KI	[0,527; 11,003]	[-8,846; 2,937]	
Veränderung zu Woche 8/9			
n/N (%)	30/48 (62)	27/43 (63)	LS MD 10,31 [2,542; 18,078]
MW (SD)	1,39 (20,422)	-4,94 (16,548)	
LS MW (SE)	5,31 (2,605)	-5,00 (2,921)	
95 %-KI	[0,114; 10,508]	[-10,825; 0,828]	
Veränderung zu Woche 12			
n/N (%)	21/46 (46)	12/42 (29)	LS MD 11,42 [3,675; 19,171]
MW (SD)	5,16 (19,628)	-4,86 (10,334)	
LS MW (SE)	4,99 (2,598)	-6,43 (2,912)	
95 %-KI	[-0,193; 10,179]	[-12,240; -0,620]	
Veränderung zu Woche 15/16			
n/N (%)	16/44 (36)	8/40 (20)	LS MD 12,54 [4,780; 20,292]
MW (SD)	10,42 (21,624)	-3,13 (7,634)	
LS MW (SE)	4,68 (2,599)	-7,86 (2,916)	
95 %-KI	[-0,513; 9,863]	[-13,679; -2,043]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	11/41 (27)	7/33 (21)	LS MD 14,13 [6,310; 21,942]
MW (SD)	12,12 (17,624)	3,57 (9,449)	
LS MW (SE)	4,22 (2,614)	-9,91 (2,945)	
95 %-KI	[-0,995; 9,436]	[-15,776; -4,034]	
Veränderung zu Woche 24			
n/N (%)	10/41 (24)	3/29 (10)	LS MD 15,24 [7,347; 23,131]
MW (SD)	3,33 (10,541)	0,00 (0,000)	
LS MW (SE)	3,90 (2,634)	-11,34 (2,980)	
95 %-KI	[-1,349; 9,155]	[-17,273; -5,399]	
Veränderung zu Woche 36			
n/N (%)	15/36 (42)	8/23 (35)	LS MD 19,06 [10,708; 27,402]
MW (SD)	4,44 (23,960)	-9,38 (14,391)	
LS MW (SE)	2,81 (2,754)	-16,24 (3,190)	
95 %-KI	[-2,664; 8,290]	[-22,574; -9,911]	
Veränderung zu Woche 48			
n/N (%)	5/33 (15)	2/20 (10)	LS MD 22,87 [13,799; 31,944]
MW (SD)	10,00 (27,889)	-12,50 (17,678)	
LS MW (SE)	1,72 (2,950)	-21,15 (3,517)	
95 %-KI	[-4,122; 7,568]	[-28,101; -14,195]	
<p><i>Analysepopulation: ITT</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023</i></p> <p><i>Modell: Veränderung zu Baseline ~ Behandlung + Baseline-Wert * Zeit in Wochen + Behandlung * Zeit in Wochen + zufällige Effekte durch die Patientin</i></p> <p><i>Die Berechnung des LS-MWs erfolgt durch ein MMRM mit dem oben angegebenen Modell. Basierend hierauf werden KI und p-Wert ermittelt. Hedges' g basiert ebenfalls auf den LS-MW und ist somit auf das Modell angepasst.</i></p> <p><i>Es werden ausschließlich gemeinsame Analysezeitpunkte dargestellt.</i></p> <p><i>Ein LS MD und Hedges' g größer als Null bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

## 2.12 EORTC QLQ-C30 physische Funktion

### EORTC QLQ-C30 physische Funktion: Subgruppenanalyse

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
<b>EORTC QLQ-C30 physische Funktion</b>			
<b>Alter: &lt; 65 Jahre</b>			
Baseline			
n/N (%)	95/115 (83)	92/119 (77)	-
MW (SD)	78,55 (19,244)	79,64 (18,969)	
Absolute Werte zum Studienende			
n/N (%)	4/73 (5)	4/64 (6)	-
MW (SD)	76,67 (11,547)	83,33 (22,111)	
Effekt über Studiendauer			
n	95	92	LS MD 8,79 [4,484; 13,101] 0,0001  Hedges' g 0,59 [0,294; 0,880]
LS MW (SE)	-1,33 (1,504)	-10,13 (1,584)	
95 %-KI	[-4,301; 1,635]	[-13,249; -7,002]	
Veränderung zu Woche 3/4			
n/N (%)	61/113 (54)	61/115 (53)	LS MD 5,75 [0,995; 10,505]
MW (SD)	1,86 (11,098)	-4,48 (17,627)	
LS MW (SE)	-0,70 (1,672)	-6,45 (1,744)	
95 %-KI	[-3,994; 2,591]	[-9,884; -3,019]	
Veränderung zu Woche 8/9			
n/N (%)	76/112 (68)	72/108 (67)	LS MD 7,09 [2,680; 11,498]
MW (SD)	-2,57 (16,685)	-10,65 (19,658)	
LS MW (SE)	-0,98 (1,554)	-8,07 (1,609)	
95 %-KI	[-4,044; 2,085]	[-11,240; -4,897]	
Veränderung zu Woche 12			
n/N (%)	47/110 (43)	40/105 (38)	
MW (SD)	-1,04 (20,144)	-8,33 (14,539)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-1,17 (1,511)	-9,20 (1,573)	LS MD 8,03 [3,723; 12,330]
95 %-KI	[-4,157; 1,809]	[-12,303; -6,097]	
Veränderung zu Woche 15/16			
n/N (%)	55/107 (51)	33/102 (32)	LS MD 8,96 [4,643; 13,284]
MW (SD)	-0,65 (21,119)	-7,07 (16,828)	
LS MW (SE)	-1,37 (1,505)	-10,33 (1,591)	
95 %-KI	[-4,340; 1,603]	[-13,469; -7,194]	
Veränderung zu Woche 20/21			
n/N (%)	37/101 (37)	30/96 (31)	LS MD 10,30 [5,750; 14,854]
MW (SD)	-2,22 (18,076)	-8,00 (15,202)	
LS MW (SE)	-1,65 (1,560)	-11,95 (1,703)	
95 %-KI	[-4,723; 1,430]	[-15,304; -8,593]	
Veränderung zu Woche 24			
n/N (%)	25/99 (25)	19/91 (21)	LS MD 11,24 [6,395; 16,083]
MW (SD)	0,27 (19,387)	-8,77 (16,637)	
LS MW (SE)	-1,84 (1,639)	-13,08 (1,834)	
95 %-KI	[-5,071; 1,389]	[-16,690; -9,470]	
Veränderung zu Woche 36			
n/N (%)	42/86 (49)	28/79 (35)	LS MD 14,45 [8,044; 20,860]
MW (SD)	-0,32 (17,543)	-12,62 (20,475)	
LS MW (SE)	-2,51 (2,099)	-16,96 (2,496)	
95 %-KI	[-6,632; 1,617]	[-21,863; -12,057]	
Veränderung zu Woche 48			
n/N (%)	4/73 (5)	3/64 (5)	LS MD 17,67 [9,214; 26,116]
MW (SD)	0,00 (22,443)	-4,44 (16,777)	
LS MW (SE)	-3,17 (2,727)	-20,84 (3,327)	
95 %-KI	[-8,531; 2,181]	[-27,373; -14,306]	
<b>Alter: ≥ 65 Jahre</b>			
Baseline			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	83/103 (81)	67/88 (76)	-
MW (SD)	75,45 (21,266)	78,91 (21,637)	
Absolute Werte zum Studienende			
n/N (%)	6/67 (9)	2/46 (4)	-
MW (SD)	74,44 (21,671)	86,67 (0,000)	
Effekt über Studiendauer			
n	83	67	LS MD 5,73 [1,318; 10,133] 0,0113  Hedges' g 0,42 [0,095; 0,746]
LS MW (SE)	-0,60 (1,466)	-6,32 (1,680)	
95 %-KI	[-3,498; 2,300]	[-9,643; -3,006]	
Veränderung zu Woche 3/4			
n/N (%)	62/100 (62)	49/85 (58)	LS MD 4,70 [-0,081; 9,476]
MW (SD)	-0,65 (16,063)	-4,04 (12,576)	
LS MW (SE)	0,16 (1,600)	-4,54 (1,819)	
95 %-KI	[-2,994; 3,318]	[-8,122; -0,949]	
Veränderung zu Woche 8/9			
n/N (%)	71/98 (72)	55/80 (69)	LS MD 5,16 [0,678; 9,635]
MW (SD)	0,95 (16,900)	-4,61 (15,389)	
LS MW (SE)	-0,18 (1,503)	-5,33 (1,696)	
95 %-KI	[-3,148; 2,792]	[-8,683; -1,985]	
Veränderung zu Woche 12			
n/N (%)	51/95 (54)	32/78 (41)	LS MD 5,48 [1,082; 9,873]
MW (SD)	1,13 (14,896)	-11,81 (21,176)	
LS MW (SE)	-0,42 (1,470)	-5,89 (1,667)	
95 %-KI	[-3,322; 2,492]	[-9,186; -2,599]	
Veränderung zu Woche 15/16			
n/N (%)	41/92 (45)	22/76 (29)	
MW (SD)	1,30 (15,579)	-8,18 (18,162)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-0,65 (1,468)	-6,45 (1,689)	LS MD 5,80 [1,375; 10,222]
95 %-KI	[-3,556; 2,250]	[-9,788; -3,115]	
Veränderung zu Woche 20/21			
n/N (%)	31/89 (35)	21/69 (30)	LS MD 6,26 [1,605; 10,908]
MW (SD)	4,52 (14,235)	-5,08 (17,372)	
LS MW (SE)	-0,99 (1,519)	-7,25 (1,804)	
95 %-KI	[-3,993; 2,007]	[-10,808; -3,691]	
Veränderung zu Woche 24			
n/N (%)	30/85 (35)	19/64 (30)	LS MD 6,58 [1,648; 11,507]
MW (SD)	1,78 (19,647)	-4,68 (12,281)	
LS MW (SE)	-1,23 (1,589)	-7,81 (1,935)	
95 %-KI	[-4,365; 1,904]	[-11,620; -3,997]	
Veränderung zu Woche 36			
n/N (%)	40/74 (54)	20/55 (36)	LS MD 7,68 [1,271; 14,084]
MW (SD)	-2,54 (17,172)	-9,11 (16,072)	
LS MW (SE)	-2,05 (1,992)	-9,72 (2,591)	
95 %-KI	[-5,963; 1,871]	[-14,816; -4,631]	
Veränderung zu Woche 48			
n/N (%)	4/67 (6)	2/46 (4)	LS MD 8,78 [0,432; 17,124]
MW (SD)	-3,33 (11,547)	-3,33 (4,714)	
LS MW (SE)	-2,86 (2,548)	-11,64 (3,419)	
95 %-KI	[-7,867; 2,145]	[-18,356; -4,923]	
<b>Region: USA</b>			
Baseline			
n/N (%)	49/65 (75)	34/51 (67)	-
MW (SD)	75,83 (24,035)	77,45 (16,331)	
Absolute Werte zum Studienende			
n/N (%)	2/39 (5)	3/27 (11)	-
MW (SD)	73,33 (0,000)	75,56 (19,245)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Effekt über Studiendauer			
n	49	34	LS MD 7,36 [2,511; 12,216] 0,0034  Hedges' g 0,67 [0,218; 1,118]
LS MW (SE)	0,91 (1,551)	-6,45 (1,889)	
95 %-KI	[-2,180; 4,002]	[-10,212; -2,694]	
Veränderung zu Woche 3/4			
n/N (%)	34/64 (53)	21/49 (43)	LS MD 5,93 [0,480; 11,374]
MW (SD)	2,84 (12,990)	-2,22 (11,022)	
LS MW (SE)	0,96 (1,738)	-4,96 (2,144)	
95 %-KI	[-2,479; 4,405]	[-9,209; -0,720]	
Veränderung zu Woche 8/9			
n/N (%)	42/62 (68)	30/46 (65)	LS MD 6,58 [1,571; 11,584]
MW (SD)	1,48 (18,217)	-6,22 (12,121)	
LS MW (SE)	0,94 (1,601)	-5,64 (1,957)	
95 %-KI	[-2,243; 4,122]	[-9,525; -1,751]	
Veränderung zu Woche 12			
n/N (%)	26/59 (44)	16/45 (36)	LS MD 7,03 [2,169; 11,896]
MW (SD)	2,22 (16,012)	-10,00 (18,053)	
LS MW (SE)	0,92 (1,555)	-6,11 (1,894)	
95 %-KI	[-2,175; 4,021]	[-9,879; -2,341]	
Veränderung zu Woche 15/16			
n/N (%)	21/56 (38)	11/44 (25)	LS MD 7,49 [2,618; 12,357]
MW (SD)	-1,59 (16,180)	-10,91 (13,751)	
LS MW (SE)	0,91 (1,556)	-6,58 (1,895)	
95 %-KI	[-2,194; 4,006]	[-10,353; -2,809]	
Veränderung zu Woche 20/21			
n/N (%)	13/54 (24)	9/40 (22)	
MW (SD)	-1,03 (11,815)	-9,63 (13,789)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	0,88 (1,636)	-7,26 (2,006)	LS MD 8,14 [3,006; 13,269]
95 %-KI	[-2,369; 4,134]	[-11,237; -3,273]	
Veränderung zu Woche 24			
n/N (%)	9/53 (17)	6/38 (16)	LS MD 8,59 [3,117; 14,068]
MW (SD)	0,74 (13,517)	-13,33 (16,330)	
LS MW (SE)	0,87 (1,741)	-7,73 (2,150)	
95 %-KI	[-2,586; 4,318]	[-11,985; -3,469]	
Veränderung zu Woche 36			
n/N (%)	22/43 (51)	10/33 (30)	LS MD 10,15 [2,804; 17,501]
MW (SD)	-0,61 (14,388)	-2,67 (9,532)	
LS MW (SE)	0,81 (2,314)	-9,34 (2,921)	
95 %-KI	[-3,753; 5,371]	[-15,101; -3,586]	
Veränderung zu Woche 48			
n/N (%)	2/39 (5)	3/27 (11)	LS MD 11,71 [1,916; 21,509]
MW (SD)	0,00 (9,428)	-4,44 (3,849)	
LS MW (SE)	0,75 (3,064)	-10,96 (3,915)	
95 %-KI	[-5,281; 6,785]	[-18,669; -3,253]	
<b>Region: Rest der Welt</b>			
Baseline			
n/N (%)	129/153 (84)	125/156 (80)	-
MW (SD)	77,59 (18,642)	79,84 (21,005)	
Absolute Werte zum Studienende			
n/N (%)	8/101 (8)	3/83 (4)	-
MW (SD)	75,83 (19,821)	93,33 (11,547)	
Effekt über Studiendauer			
n	129	125	LS MD 7,60 [3,808; 11,396] 0,0001  Hedges' g
LS MW (SE)	-1,70 (1,323)	-9,30 (1,398)	
95 %-KI	[-4,309; 0,903]	[-12,058; -6,551]	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
			0,49 [0,245; 0,744]
Veränderung zu Woche 3/4			
n/N (%)	89/149 (60)	89/151 (59)	LS MD 5,07 [0,949; 9,197]
MW (SD)	-0,26 (14,108)	-4,77 (16,411)	
LS MW (SE)	-0,75 (1,452)	-5,83 (1,512)	
95 %-KI	[-3,611; 2,102]	[-8,800; -2,854]	
Veränderung zu Woche 8/9			
n/N (%)	105/148 (71)	97/142 (68)	LS MD 6,19 [2,329; 10,043]
MW (SD)	-1,81 (16,230)	-8,59 (19,625)	
LS MW (SE)	-1,17 (1,362)	-7,36 (1,407)	
95 %-KI	[-3,853; 1,509]	[-10,128; -4,587]	
Veränderung zu Woche 12			
n/N (%)	72/146 (49)	56/138 (41)	LS MD 6,96 [3,183; 10,747]
MW (SD)	-0,68 (18,117)	-9,84 (17,822)	
LS MW (SE)	-1,46 (1,329)	-8,43 (1,384)	
95 %-KI	[-4,082; 1,154]	[-11,155; -5,702]	
Veränderung zu Woche 15/16			
n/N (%)	75/143 (52)	44/134 (33)	LS MD 7,74 [3,938; 11,550]
MW (SD)	0,68 (19,646)	-6,67 (18,015)	
LS MW (SE)	-1,76 (1,324)	-9,50 (1,405)	
95 %-KI	[-4,364; 0,853]	[-12,267; -6,733]	
Veränderung zu Woche 20/21			
n/N (%)	55/136 (40)	42/125 (34)	LS MD 8,86 [4,851; 12,863]
MW (SD)	1,29 (17,678)	-6,19 (16,554)	
LS MW (SE)	-2,17 (1,365)	-11,03 (1,507)	
95 %-KI	[-4,861; 0,516]	[-13,995; -8,065]	
Veränderung zu Woche 24			
n/N (%)	46/131 (35)	32/117 (27)	
MW (SD)	1,16 (20,430)	-5,49 (14,156)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-2,46 (1,426)	-12,10 (1,622)	LS MD 9,64 [5,386; 13,886]
95 %-KI	[-5,271; 0,341]	[-15,289; -8,914]	
Veränderung zu Woche 36			
n/N (%)	60/117 (51)	38/101 (38)	LS MD 12,31 [6,762; 17,853]
MW (SD)	-1,69 (18,344)	-13,39 (19,893)	
LS MW (SE)	-3,47 (1,783)	-15,77 (2,188)	
95 %-KI	[-6,968; 0,036]	[-20,068; -11,479]	
Veränderung zu Woche 48			
n/N (%)	6/101 (6)	2/83 (2)	LS MD 14,98 [7,739; 22,218]
MW (SD)	-2,22 (19,168)	-3,33 (23,570)	
LS MW (SE)	-4,47 (2,282)	-19,45 (2,896)	
95 %-KI	[-8,946; 0,011]	[-25,130; -13,762]	
<b>Stadium bei der Diagnose: I-III</b>			
Baseline			
n/N (%)	113/141 (80)	112/144 (78)	-
MW (SD)	78,80 (20,062)	79,64 (20,047)	
Absolute Werte zum Studienende			
n/N (%)	6/91 (7)	4/76 (5)	-
MW (SD)	68,89 (17,722)	76,67 (15,870)	
Effekt über Studiendauer			
n	113	112	LS MD 6,68 [2,870; 10,493] 0,0007
LS MW (SE)	-2,54 (1,340)	-9,22 (1,395)	
95 %-KI	[-5,182; 0,102]	[-11,970; -6,473]	Hedges' g 0,46 [0,194; 0,724]
Veränderung zu Woche 3/4			
n/N (%)	76/137 (55)	79/138 (57)	LS MD 4,36 [0,201; 8,513]
MW (SD)	0,39 (15,553)	-4,89 (15,124)	
LS MW (SE)	-1,24 (1,473)	-5,60 (1,515)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-4,140; 1,657]	[-8,579; -2,618]	
Veränderung zu Woche 8/9			
n/N (%)	95/136 (70)	89/129 (69)	LS MD 5,38 [1,484; 9,267]
MW (SD)	-3,11 (16,910)	-7,72 (16,481)	
LS MW (SE)	-1,81 (1,380)	-7,19 (1,414)	
95 %-KI	[-4,529; 0,909]	[-9,971; -4,401]	
Veränderung zu Woche 12			
n/N (%)	62/133 (47)	49/128 (38)	LS MD 6,09 [2,279; 9,898]
MW (SD)	-0,07 (18,549)	-9,07 (16,171)	
LS MW (SE)	-2,21 (1,347)	-8,30 (1,387)	
95 %-KI	[-4,863; 0,446]	[-11,031; -5,564]	
Veränderung zu Woche 15/16			
n/N (%)	63/130 (48)	35/125 (28)	LS MD 6,80 [2,982; 10,622]
MW (SD)	-2,68 (18,164)	-9,33 (14,207)	
LS MW (SE)	-2,61 (1,341)	-9,41 (1,400)	
95 %-KI	[-5,251; 0,037]	[-12,166; -6,651]	
Veränderung zu Woche 20/21			
n/N (%)	46/123 (37)	34/116 (29)	LS MD 7,82 [3,829; 11,812]
MW (SD)	0,24 (18,128)	-7,65 (18,286)	
LS MW (SE)	-3,18 (1,383)	-11,00 (1,483)	
95 %-KI	[-5,900; -0,451]	[-13,915; -8,078]	
Veränderung zu Woche 24			
n/N (%)	35/121 (29)	27/109 (25)	LS MD 8,53 [4,322; 12,745]
MW (SD)	-1,71 (21,593)	-7,49 (15,324)	
LS MW (SE)	-3,57 (1,444)	-12,11 (1,580)	
95 %-KI	[-6,417; -0,730]	[-15,216; -8,999]	
Veränderung zu Woche 36			
n/N (%)	53/105 (50)	36/92 (39)	
MW (SD)	-4,28 (18,215)	-13,95 (19,652)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-4,94 (1,807)	-15,92 (2,086)	LS MD 10,98 [5,560; 16,397]
95 %-KI	[-8,490; -1,388]	[-20,015; -11,821]	
Veränderung zu Woche 48			
n/N (%)	5/91 (5)	4/76 (5)	LS MD 13,42 [6,393; 20,454]
MW (SD)	-8,00 (14,453)	-8,33 (8,389)	
LS MW (SE)	-6,30 (2,314)	-19,73 (2,737)	
95 %-KI	[-10,848; -1,760]	[-25,100; -14,355]	
<b>Stadium bei der Diagnose: IV</b>			
Baseline			
n/N (%)	60/72 (83)	45/60 (75)	-
MW (SD)	73,44 (20,739)	78,52 (20,345)	
Absolute Werte zum Studienende			
n/N (%)	4/46 (9)	2/33 (6)	-
MW (SD)	85,00 (13,744)	100,00 (0,000)	
Effekt über Studiendauer			
n	60	45	LS MD 9,18 [3,636; 14,733] 0,0014
LS MW (SE)	2,31 (1,801)	-6,88 (2,134)	
95 %-KI	[-1,269; 5,884]	[-11,108; -2,646]	Hedges' g 0,65 [0,250; 1,043]
Veränderung zu Woche 3/4			
n/N (%)	42/71 (59)	29/59 (49)	LS MD 8,42 [2,349; 14,500]
MW (SD)	1,83 (9,717)	-1,99 (16,580)	
LS MW (SE)	2,07 (1,987)	-6,36 (2,344)	
95 %-KI	[-1,861; 5,996]	[-10,987; -1,726]	
Veränderung zu Woche 8/9			
n/N (%)	47/69 (68)	36/56 (64)	LS MD 8,77 [3,144; 14,388]
MW (SD)	4,40 (16,346)	-9,63 (21,935)	
LS MW (SE)	2,18 (1,853)	-6,59 (2,145)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-1,498; 5,849]	[-10,839; -2,342]	
Veränderung zu Woche 12			
n/N (%)	31/67 (46)	22/52 (42)	LS MD 9,01 [3,493; 14,517]
MW (SD)	1,29 (16,186)	-12,73 (20,769)	
LS MW (SE)	2,25 (1,807)	-6,75 (2,105)	
95 %-KI	[-1,336; 5,838]	[-10,929; -2,580]	
Veränderung zu Woche 15/16			
n/N (%)	30/64 (47)	18/50 (36)	LS MD 9,24 [3,661; 14,828]
MW (SD)	5,56 (20,197)	-3,33 (17,896)	
LS MW (SE)	2,33 (1,805)	-6,92 (2,154)	
95 %-KI	[-1,257; 5,909]	[-11,188; -2,648]	
Veränderung zu Woche 20/21			
n/N (%)	19/62 (31)	16/46 (35)	LS MD 9,59 [3,599; 15,573]
MW (SD)	1,75 (13,670)	-5,83 (10,292)	
LS MW (SE)	2,43 (1,876)	-7,15 (2,366)	
95 %-KI	[-1,285; 6,153]	[-11,829; -2,475]	
Veränderung zu Woche 24			
n/N (%)	18/59 (31)	10/44 (23)	LS MD 9,83 [3,375; 16,276]
MW (SD)	7,04 (14,183)	-3,33 (12,669)	
LS MW (SE)	2,51 (1,974)	-7,32 (2,594)	
95 %-KI	[-1,396; 6,415]	[-12,433; -2,198]	
Veränderung zu Woche 36			
n/N (%)	28/52 (54)	11/41 (27)	LS MD 10,65 [1,858; 19,433]
MW (SD)	3,99 (14,546)	-1,82 (12,681)	
LS MW (SE)	2,77 (2,527)	-7,88 (3,671)	
95 %-KI	[-2,210; 7,746]	[-15,099; -0,656]	
Veränderung zu Woche 48			
n/N (%)	3/46 (7)	1/33 (3)	
MW (SD)	8,89 (16,777)	13,33 (NA)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	3,03 (3,278)	-8,44 (4,967)	LS MD 11,47 [-0,259; 23,189]
95 %-KI	[-3,421; 9,473]	[-18,207; 1,329]	
<b>BRCA Status: Positiv</b>			
Baseline			
n/N (%)	25/27 (93)	23/35 (66)	-
MW (SD)	76,62 (23,519)	75,94 (23,246)	
Absolute Werte zum Studienende			
n/N (%)	1/19 (5)	0/15 (0)	-
MW (SD)	73,33 (NA)	NA (NA)	
Effekt über Studiendauer			
n	25	23	LS MD 11,34 [2,055; 20,621] 0,0178  Hedges' g 0,70 [0,115; 1,284]
LS MW (SE)	-2,75 (3,123)	-14,09 (3,397)	
95 %-KI	[-9,055; 3,549]	[-20,922; -7,260]	
Veränderung zu Woche 3/4			
n/N (%)	16/27 (59)	18/35 (51)	LS MD 5,28 [-4,694; 15,253]
MW (SD)	-1,39 (14,832)	-8,89 (22,052)	
LS MW (SE)	-3,79 (3,445)	-9,07 (3,618)	
95 %-KI	[-10,682; 3,093]	[-16,302; -1,846]	
Veränderung zu Woche 8/9			
n/N (%)	21/26 (81)	20/30 (67)	LS MD 8,27 [-1,035; 17,581]
MW (SD)	-2,96 (15,077)	-8,33 (22,045)	
LS MW (SE)	-3,28 (3,210)	-11,55 (3,339)	
95 %-KI	[-9,736; 3,176]	[-18,270; -4,836]	
Veränderung zu Woche 12			
n/N (%)	15/26 (58)	11/30 (37)	LS MD 10,37 [1,151; 19,585]
MW (SD)	-2,37 (11,713)	-19,19 (25,556)	
LS MW (SE)	-2,92 (3,133)	-13,29 (3,340)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-9,238; 3,398]	[-20,012; -6,564]	
Veränderung zu Woche 15/16			
n/N (%)	11/26 (42)	8/29 (28)	LS MD 12,46 [3,020; 21,906]
MW (SD)	-2,63 (14,258)	-7,50 (15,301)	
LS MW (SE)	-2,56 (3,133)	-15,02 (3,506)	
95 %-KI	[-8,881; 3,762]	[-22,056; -7,990]	
Veränderung zu Woche 20/21			
n/N (%)	10/25 (40)	4/25 (16)	LS MD 15,46 [5,179; 25,734]
MW (SD)	2,00 (21,094)	-6,67 (10,887)	
LS MW (SE)	-2,05 (3,269)	-17,50 (3,985)	
95 %-KI	[-8,615; 4,524]	[-25,436; -9,568]	
Veränderung zu Woche 24			
n/N (%)	8/25 (32)	4/24 (17)	LS MD 17,55 [6,385; 28,718]
MW (SD)	4,17 (11,785)	-7,22 (12,620)	
LS MW (SE)	-1,69 (3,448)	-19,24 (4,445)	
95 %-KI	[-8,588; 5,218]	[-28,054; -10,419]	
Veränderung zu Woche 36			
n/N (%)	9/21 (43)	5/20 (25)	LS MD 24,74 [9,290; 40,181]
MW (SD)	-1,48 (8,012)	-21,78 (19,839)	
LS MW (SE)	-0,45 (4,449)	-25,19 (6,452)	
95 %-KI	[-9,266; 8,365]	[-37,933; -12,438]	
Veränderung zu Woche 48			
n/N (%)	1/19 (5)	0/15 (0)	LS MD 31,92 [11,242; 52,596]
MW (SD)	-6,67 (NA)	NA (NA)	
LS MW (SE)	0,78 (5,791)	-31,13 (8,762)	
95 %-KI	[-10,657; 12,226]	[-48,445; -13,824]	
<b>BRCA Status: Negativ/Unbekannt</b>			
Baseline			
n/N (%)	153/191 (80)	136/172 (79)	-

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	77,18 (19,709)	79,90 (19,525)	
Absolute Werte zum Studienende			
n/N (%)	9/121 (7)	6/95 (6)	-
MW (SD)	75,56 (18,559)	84,44 (17,213)	
Effekt über Studiendauer			
n	153	136	LS MD 6,87 [3,624; 10,120] < 0,0001  Hedges' g 0,49 [0,256; 0,725]
LS MW (SE)	-0,79 (1,111)	-7,66 (1,218)	
95 %-KI	[-2,974; 1,402]	[-10,055; -5,260]	
Veränderung zu Woche 3/4			
n/N (%)	107/186 (58)	92/165 (56)	LS MD 5,10 [1,534; 8,675]
MW (SD)	0,89 (13,719)	-3,38 (13,874)	
LS MW (SE)	0,21 (1,226)	-4,89 (1,339)	
95 %-KI	[-2,197; 2,625]	[-7,522; -2,260]	
Veränderung zu Woche 8/9			
n/N (%)	126/184 (68)	107/158 (68)	LS MD 5,87 [2,552; 9,197]
MW (SD)	-0,52 (17,129)	-7,98 (17,410)	
LS MW (SE)	-0,22 (1,145)	-6,10 (1,240)	
95 %-KI	[-2,475; 2,031]	[-8,536; -3,657]	
Veränderung zu Woche 12			
n/N (%)	83/179 (46)	61/153 (40)	LS MD 6,41 [3,168; 9,659]
MW (SD)	0,54 (18,428)	-8,20 (15,653)	
LS MW (SE)	-0,53 (1,116)	-6,94 (1,212)	
95 %-KI	[-2,724; 1,670]	[-9,327; -4,555]	
Veränderung zu Woche 15/16			
n/N (%)	85/173 (49)	47/149 (32)	LS MD 6,95 [3,698; 10,208]
MW (SD)	0,55 (19,442)	-7,52 (17,672)	
LS MW (SE)	-0,83 (1,112)	-7,78 (1,222)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,022; 1,358]	[-10,190; -5,380]	
Veränderung zu Woche 20/21			
n/N (%)	58/165 (35)	47/140 (34)	LS MD 7,72 [4,307; 11,139]
MW (SD)	0,65 (15,998)	-6,81 (16,477)	
LS MW (SE)	-1,27 (1,151)	-8,99 (1,298)	
95 %-KI	[-3,534; 0,998]	[-11,544; -6,438]	
Veränderung zu Woche 24			
n/N (%)	47/159 (30)	34/131 (26)	LS MD 8,26 [4,641; 11,883]
MW (SD)	0,57 (20,422)	-6,67 (14,952)	
LS MW (SE)	-1,57 (1,207)	-9,83 (1,390)	
95 %-KI	[-3,947; 0,801]	[-12,566; -7,104]	
Veränderung zu Woche 36			
n/N (%)	73/139 (53)	43/114 (38)	LS MD 10,11 [5,376; 14,843]
MW (SD)	-1,39 (18,145)	-9,92 (18,366)	
LS MW (SE)	-2,62 (1,531)	-12,73 (1,861)	
95 %-KI	[-5,625; 0,387]	[-16,382; -9,075]	
Veränderung zu Woche 48			
n/N (%)	7/121 (6)	5/95 (5)	LS MD 11,96 [5,758; 18,158]
MW (SD)	-0,95 (17,817)	-4,00 (12,111)	
LS MW (SE)	-3,67 (1,977)	-15,62 (2,464)	
95 %-KI	[-7,544; 0,214]	[-20,458; -10,788]	
<b>Baseline ECOG PS: 0</b>			
Baseline			
n/N (%)	102/128 (80)	97/113 (86)	-
MW (SD)	83,20 (17,266)	85,91 (12,906)	
Absolute Werte zum Studienende			
n/N (%)	7/87 (8)	3/72 (4)	-
MW (SD)	73,33 (12,766)	80,00 (24,037)	
Effekt über Studiendauer			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n	102	97	LS MD 7,19 [3,341; 11,034] 0,0003  Hedges' g 0,52 [0,239; 0,804]
LS MW (SE)	-2,34 (1,340)	-9,53 (1,414)	
95 %-KI	[-4,985; 0,302]	[-12,316; -6,741]	
Veränderung zu Woche 3/4			
n/N (%)	72/127 (57)	64/111 (58)	LS MD 6,16 [1,923; 10,388]
MW (SD)	-0,99 (14,113)	-6,22 (16,569)	
LS MW (SE)	-1,37 (1,476)	-7,52 (1,561)	
95 %-KI	[-4,274; 1,537]	[-10,596; -4,452]	
Veränderung zu Woche 8/9			
n/N (%)	86/126 (68)	76/108 (70)	LS MD 6,60 [2,658; 10,545]
MW (SD)	-0,90 (14,175)	-9,65 (16,308)	
LS MW (SE)	-1,79 (1,381)	-8,39 (1,444)	
95 %-KI	[-4,513; 0,934]	[-11,237; -5,546]	
Veränderung zu Woche 12			
n/N (%)	53/122 (43)	46/108 (43)	LS MD 6,91 [3,065; 10,764]
MW (SD)	-1,38 (16,813)	-11,30 (17,826)	
LS MW (SE)	-2,08 (1,347)	-9,00 (1,409)	
95 %-KI	[-4,741; 0,573]	[-11,777; -6,220]	
Veränderung zu Woche 15/16			
n/N (%)	55/120 (46)	35/105 (33)	LS MD 7,23 [3,374; 11,079]
MW (SD)	-4,28 (16,069)	-10,48 (16,353)	
LS MW (SE)	-2,38 (1,341)	-9,61 (1,417)	
95 %-KI	[-5,024; 0,266]	[-12,400; -6,811]	
Veränderung zu Woche 20/21			
n/N (%)	41/117 (35)	32/101 (32)	LS MD 7,67 [3,650; 11,696]
MW (SD)	-1,79 (15,636)	-10,00 (16,242)	
LS MW (SE)	-2,80 (1,381)	-10,47 (1,500)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-5,523; -0,076]	[-13,428; -7,518]	
Veränderung zu Woche 24			
n/N (%)	28/112 (25)	22/96 (23)	LS MD 7,99 [3,737; 12,234]
MW (SD)	-2,14 (15,294)	-9,09 (14,482)	
LS MW (SE)	-3,09 (1,442)	-11,08 (1,602)	
95 %-KI	[-5,935; -0,253]	[-14,233; -7,926]	
Veränderung zu Woche 36			
n/N (%)	51/99 (52)	35/87 (40)	LS MD 9,06 [3,556; 14,557]
MW (SD)	-4,05 (15,554)	-8,57 (18,405)	
LS MW (SE)	-4,10 (1,804)	-13,16 (2,139)	
95 %-KI	[-7,650; -0,558]	[-17,362; -8,961]	
Veränderung zu Woche 48			
n/N (%)	5/87 (6)	3/72 (4)	LS MD 10,13 [2,951; 17,305]
MW (SD)	-9,33 (12,111)	2,22 (10,184)	
LS MW (SE)	-5,11 (2,312)	-15,24 (2,829)	
95 %-KI	[-9,654; -0,576]	[-20,797; -9,688]	
<b>Baseline ECOG PS: 1</b>			
Baseline			
n/N (%)	76/90 (84)	61/91 (67)	-
MW (SD)	68,92 (21,080)	69,62 (24,359)	
Absolute Werte zum Studienende			
n/N (%)	3/53 (6)	3/37 (8)	-
MW (SD)	80,00 (29,059)	88,89 (10,184)	
Effekt über Studiendauer			
n	76	61	LS MD 8,57 [3,379; 13,770] 0,0014
LS MW (SE)	0,90 (1,711)	-7,67 (1,995)	
95 %-KI	[-2,487; 4,288]	[-11,619; -3,730]	Hedges' g 0,56 [0,217; 0,904]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	51/86 (59)	45/87 (52)	LS MD 4,17 [-1,456; 9,791]
MW (SD)	2,83 (13,224)	-1,63 (13,792)	
LS MW (SE)	1,26 (1,886)	-2,91 (2,140)	
95 %-KI	[-2,460; 4,982]	[-7,127; 1,314]	
Veränderung zu Woche 8/9			
n/N (%)	61/84 (73)	50/78 (64)	LS MD 6,19 [0,941; 11,436]
MW (SD)	-0,84 (20,103)	-5,60 (20,663)	
LS MW (SE)	1,10 (1,758)	-5,09 (1,993)	
95 %-KI	[-2,380; 4,572]	[-9,031; -1,154]	
Veränderung zu Woche 12			
n/N (%)	45/83 (54)	25/74 (34)	LS MD 7,60 [2,439; 12,766]
MW (SD)	1,83 (18,418)	-8,18 (17,506)	
LS MW (SE)	0,98 (1,716)	-6,62 (1,970)	
95 %-KI	[-2,415; 4,376]	[-10,519; -2,726]	
Veränderung zu Woche 15/16			
n/N (%)	41/79 (52)	20/72 (28)	LS MD 9,02 [3,783; 14,251]
MW (SD)	6,18 (20,837)	-2,33 (17,872)	
LS MW (SE)	0,86 (1,716)	-8,15 (2,017)	
95 %-KI	[-2,532; 4,261]	[-12,140; -4,166]	
Veränderung zu Woche 20/21			
n/N (%)	27/73 (37)	18/63 (29)	LS MD 11,04 [5,446; 16,629]
MW (SD)	4,86 (17,660)	-3,33 (12,154)	
LS MW (SE)	0,70 (1,790)	-10,34 (2,195)	
95 %-KI	[-2,839; 4,237]	[-14,668; -6,008]	
Veränderung zu Woche 24			
n/N (%)	27/72 (38)	15/58 (26)	LS MD 12,45 [6,454; 18,449]
MW (SD)	4,44 (22,646)	-3,70 (14,994)	
LS MW (SE)	0,58 (1,888)	-11,87 (2,383)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,143; 4,309]	[-16,563; -7,174]	
Veränderung zu Woche 36			
n/N (%)	31/61 (51)	13/46 (28)	LS MD 17,30 [9,260; 25,342]
MW (SD)	2,96 (19,301)	-18,12 (18,231)	
LS MW (SE)	0,19 (2,433)	-17,11 (3,276)	
95 %-KI	[-4,601; 4,973]	[-23,553; -10,676]	
Veränderung zu Woche 48			
n/N (%)	3/53 (6)	2/37 (5)	LS MD 22,15 [11,525; 32,774]
MW (SD)	11,11 (16,777)	-13,33 (9,428)	
LS MW (SE)	-0,21 (3,165)	-22,36 (4,363)	
95 %-KI	[-6,431; 6,010]	[-30,934; -13,787]	
<b>Anzahl vorheriger Therapielinien: 1</b>			
Baseline			
n/N (%)	24/31 (77)	23/29 (79)	-
MW (SD)	72,78 (23,584)	81,45 (15,822)	
Absolute Werte zum Studienende			
n/N (%)	1/22 (5)	0/14 (0)	-
MW (SD)	60,00 (NA)	NA (NA)	
Effekt über Studiendauer			
n	24	23	LS MD 7,12 [-2,459; 16,702] 0,1412
LS MW (SE)	-0,67 (3,266)	-7,79 (3,388)	
95 %-KI	[-7,265; 5,930]	[-14,611; -0,967]	Hedges' g 0,43 [-0,145; 1,014]
Veränderung zu Woche 3/4			
n/N (%)	16/31 (52)	15/29 (52)	LS MD 4,28 [-6,293; 14,852]
MW (SD)	-0,42 (10,174)	-2,22 (11,996)	
LS MW (SE)	2,00 (3,644)	-2,28 (3,775)	
95 %-KI	[-5,287; 9,282]	[-9,812; 5,249]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	20/31 (65)	18/26 (69)	LS MD 5,47 [-4,377; 15,327]
MW (SD)	1,33 (15,835)	-8,89 (21,933)	
LS MW (SE)	0,88 (3,406)	-4,60 (3,462)	
95 %-KI	[-5,972; 7,725]	[-11,549; 2,351]	
Veränderung zu Woche 12			
n/N (%)	14/31 (45)	12/24 (50)	LS MD 6,31 [-3,293; 15,917]
MW (SD)	6,67 (16,119)	-6,11 (15,429)	
LS MW (SE)	0,09 (3,305)	-6,22 (3,369)	
95 %-KI	[-6,577; 6,759]	[-13,004; 0,562]	
Veränderung zu Woche 15/16			
n/N (%)	15/31 (48)	11/22 (50)	LS MD 7,15 [-2,435; 16,733]
MW (SD)	3,11 (19,333)	-9,09 (20,281)	
LS MW (SE)	-0,69 (3,265)	-7,84 (3,390)	
95 %-KI	[-7,291; 5,903]	[-14,669; -1,016]	
Veränderung zu Woche 20/21			
n/N (%)	11/30 (37)	9/22 (41)	LS MD 8,34 [-1,598; 18,288]
MW (SD)	1,82 (9,929)	-5,93 (18,392)	
LS MW (SE)	-1,81 (3,317)	-10,16 (3,614)	
95 %-KI	[-8,504; 4,874]	[-17,403; -2,916]	
Veränderung zu Woche 24			
n/N (%)	9/30 (30)	11/20 (55)	LS MD 9,18 [-1,269; 19,632]
MW (SD)	-8,15 (17,568)	-3,64 (18,466)	
LS MW (SE)	-2,60 (3,426)	-11,78 (3,887)	
95 %-KI	[-9,486; 4,286]	[-19,539; -4,024]	
Veränderung zu Woche 36			
n/N (%)	15/26 (58)	6/18 (33)	LS MD 12,05 [-1,368; 25,472]
MW (SD)	-7,11 (21,302)	-11,11 (31,175)	
LS MW (SE)	-5,29 (4,168)	-17,34 (5,299)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-13,567; 2,985]	[-27,824; -6,862]	
Veränderung zu Woche 48			
n/N (%)	0/22 (0)	0/14 (0)	LS MD 14,92 [-2,592; 32,435]
MW (SD)	NA (NA)	NA (NA)	
LS MW (SE)	-7,98 (5,277)	-22,90 (7,089)	
95 %-KI	[-18,408; 2,443]	[-36,898; -8,910]	
<b>Anzahl vorheriger Therapielinien: 2</b>			
Baseline			
n/N (%)	76/89 (85)	65/83 (78)	-
MW (SD)	77,11 (17,599)	77,95 (23,568)	
Absolute Werte zum Studienende			
n/N (%)	4/59 (7)	2/50 (4)	-
MW (SD)	63,33 (11,547)	93,33 (9,428)	
Effekt über Studiendauer			
n	76	65	LS MD 6,50 [1,711; 11,289] 0,0082  Hedges' g 0,45 [0,117; 0,788]
LS MW (SE)	-0,71 (1,597)	-7,21 (1,820)	
95 %-KI	[-3,872; 2,451]	[-10,808; -3,613]	
Veränderung zu Woche 3/4			
n/N (%)	54/86 (63)	46/80 (57)	LS MD 4,37 [-0,912; 9,651]
MW (SD)	0,97 (13,579)	-2,32 (14,553)	
LS MW (SE)	0,11 (1,782)	-4,26 (2,000)	
95 %-KI	[-3,405; 3,623]	[-8,204; -0,318]	
Veränderung zu Woche 8/9			
n/N (%)	64/85 (75)	53/77 (69)	LS MD 5,33 [0,457; 10,210]
MW (SD)	-0,35 (16,235)	-6,42 (20,463)	
LS MW (SE)	-0,26 (1,650)	-5,60 (1,835)	
95 %-KI	[-3,523; 3,000]	[-9,220; -1,971]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	40/83 (48)	31/75 (41)	LS MD 6,01 [1,240; 10,777]
MW (SD)	-2,83 (17,338)	-10,97 (20,838)	
LS MW (SE)	-0,52 (1,604)	-6,53 (1,800)	
95 %-KI	[-3,696; 2,653]	[-10,088; -2,971]	
Veränderung zu Woche 15/16			
n/N (%)	41/80 (51)	20/74 (27)	LS MD 6,68 [1,866; 11,501]
MW (SD)	-0,49 (23,352)	-4,67 (18,992)	
LS MW (SE)	-0,78 (1,601)	-7,46 (1,837)	
95 %-KI	[-3,948; 2,387]	[-11,094; -3,834]	
Veränderung zu Woche 20/21			
n/N (%)	32/78 (41)	21/68 (31)	LS MD 7,65 [2,500; 12,795]
MW (SD)	0,83 (19,874)	-5,71 (15,533)	
LS MW (SE)	-1,15 (1,668)	-8,80 (2,005)	
95 %-KI	[-4,449; 2,146]	[-12,753; -4,844]	
Veränderung zu Woche 24			
n/N (%)	27/74 (36)	13/65 (20)	LS MD 8,32 [2,786; 13,859]
MW (SD)	2,47 (20,351)	-5,64 (10,834)	
LS MW (SE)	-1,41 (1,762)	-9,73 (2,188)	
95 %-KI	[-4,889; 2,067]	[-14,043; -5,423]	
Veränderung zu Woche 36			
n/N (%)	33/65 (51)	19/58 (33)	LS MD 10,64 [3,114; 18,158]
MW (SD)	-2,88 (18,082)	-11,58 (18,304)	
LS MW (SE)	-2,30 (2,291)	-12,94 (3,067)	
95 %-KI	[-6,806; 2,205]	[-18,964; -6,909]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	1/50 (2)	LS MD 12,95 [2,917; 22,983]
MW (SD)	-13,33 (9,428)	-6,67 (NA)	
LS MW (SE)	-3,19 (3,000)	-16,14 (4,134)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-9,086; 2,706]	[-24,263; -8,016]	
<b>Anzahl vorheriger Therapielinien: 3</b>			
Baseline			
n/N (%)	78/98 (80)	71/95 (75)	-
MW (SD)	78,43 (21,537)	79,91 (17,871)	
Absolute Werte zum Studienende			
n/N (%)	5/59 (8)	4/46 (9)	-
MW (SD)	88,00 (13,663)	80,00 (19,626)	
Effekt über Studiendauer			
n	78	71	LS MD 8,79 [4,156; 13,432] 0,0003  Hedges' g 0,61 [0,282; 0,940]
LS MW (SE)	-1,35 (1,607)	-10,14 (1,714)	
95 %-KI	[-4,523; 1,832]	[-13,526; -6,753]	
Veränderung zu Woche 3/4			
n/N (%)	53/96 (55)	49/91 (54)	LS MD 6,81 [1,857; 11,770]
MW (SD)	0,52 (15,173)	-6,76 (17,171)	
LS MW (SE)	-1,11 (1,727)	-7,92 (1,832)	
95 %-KI	[-4,513; 2,300]	[-11,533; -4,308]	
Veränderung zu Woche 8/9			
n/N (%)	63/94 (67)	56/85 (66)	LS MD 7,69 [2,989; 12,389]
MW (SD)	-2,11 (17,847)	-9,29 (14,252)	
LS MW (SE)	-1,21 (1,638)	-8,90 (1,732)	
95 %-KI	[-4,448; 2,024]	[-12,322; -5,481]	
Veränderung zu Woche 12			
n/N (%)	44/91 (48)	29/84 (35)	LS MD 8,30 [3,674; 12,930]
MW (SD)	0,66 (17,923)	-10,27 (15,240)	
LS MW (SE)	-1,29 (1,609)	-9,59 (1,706)	
95 %-KI	[-4,467; 1,895]	[-12,960; -6,216]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	40/88 (45)	24/82 (29)	LS MD 8,91 [4,266; 13,564]
MW (SD)	-0,22 (13,092)	-9,17 (14,421)	
LS MW (SE)	-1,36 (1,610)	-10,27 (1,719)	
95 %-KI	[-4,543; 1,822]	[-13,672; -6,878]	
Veränderung zu Woche 20/21			
n/N (%)	25/82 (30)	21/75 (28)	LS MD 9,79 [4,953; 14,628]
MW (SD)	0,44 (14,948)	-8,25 (16,180)	
LS MW (SE)	-1,47 (1,661)	-11,26 (1,803)	
95 %-KI	[-4,747; 1,816]	[-14,814; -7,698]	
Veränderung zu Woche 24			
n/N (%)	19/80 (24)	14/70 (20)	LS MD 10,40 [5,333; 15,474]
MW (SD)	3,51 (18,374)	-10,16 (14,552)	
LS MW (SE)	-1,54 (1,730)	-11,94 (1,902)	
95 %-KI	[-4,953; 1,874]	[-15,692; -8,193]	
Veränderung zu Woche 36			
n/N (%)	34/69 (49)	23/58 (40)	LS MD 12,50 [6,153; 18,857]
MW (SD)	2,55 (13,831)	-10,82 (15,775)	
LS MW (SE)	-1,79 (2,125)	-14,30 (2,426)	
95 %-KI	[-5,973; 2,388]	[-19,067; -9,528]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	4/46 (9)	LS MD 14,61 [6,517; 22,696]
MW (SD)	10,00 (13,878)	-3,33 (13,878)	
LS MW (SE)	-2,05 (2,676)	-16,65 (3,116)	
95 %-KI	[-7,304; 3,212]	[-22,775; -10,530]	
<b>Vorherige Verabreichung von Bevacizumab: Ja</b>			
Baseline			
n/N (%)	106/134 (79)	100/132 (76)	-
MW (SD)	78,39 (19,825)	78,53 (21,411)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	3/79 (4)	3/62 (5)	-
MW (SD)	62,22 (13,878)	80,00 (24,037)	
Effekt über Studiendauer			
n	106	100	LS MD 6,63 [2,796; 10,468] 0,0008  Hedges' g 0,47 [0,197; 0,751]
LS MW (SE)	-2,14 (1,322)	-8,77 (1,429)	
95 %-KI	[-4,745; 0,471]	[-11,587; -5,952]	
Veränderung zu Woche 3/4			
n/N (%)	70/130 (54)	69/127 (54)	LS MD 4,90 [0,683; 9,119]
MW (SD)	-0,97 (14,234)	-4,15 (15,042)	
LS MW (SE)	-1,49 (1,468)	-6,39 (1,564)	
95 %-KI	[-4,376; 1,403]	[-9,464; -3,311]	
Veränderung zu Woche 8/9			
n/N (%)	87/130 (67)	77/119 (65)	LS MD 5,71 [1,813; 9,603]
MW (SD)	-1,88 (15,638)	-7,97 (18,001)	
LS MW (SE)	-1,79 (1,362)	-7,50 (1,434)	
95 %-KI	[-4,475; 0,895]	[-10,324; -4,673]	
Veränderung zu Woche 12			
n/N (%)	55/126 (44)	38/114 (33)	LS MD 6,27 [2,456; 10,091]
MW (SD)	-2,95 (19,316)	-7,02 (14,116)	
LS MW (SE)	-2,00 (1,327)	-8,28 (1,412)	
95 %-KI	[-4,619; 0,614]	[-11,060; -5,493]	
Veränderung zu Woche 15/16			
n/N (%)	59/122 (48)	32/112 (29)	LS MD 6,84 [2,968; 10,710]
MW (SD)	-0,94 (18,326)	-7,29 (18,187)	
LS MW (SE)	-2,22 (1,326)	-9,05 (1,450)	
95 %-KI	[-4,830; 0,400]	[-11,912; -6,196]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	40/114 (35)	28/103 (27)	LS MD 7,65 [3,483; 11,810]
MW (SD)	-2,39 (18,168)	-4,29 (17,612)	
LS MW (SE)	-2,52 (1,384)	-10,16 (1,600)	
95 %-KI	[-5,247; 0,210]	[-13,313; -7,016]	
Veränderung zu Woche 24			
n/N (%)	30/109 (28)	17/95 (18)	LS MD 8,21 [3,715; 12,708]
MW (SD)	0,22 (14,167)	-7,45 (14,885)	
LS MW (SE)	-2,73 (1,463)	-10,94 (1,757)	
95 %-KI	[-5,613; 0,151]	[-14,398; -7,487]	
Veränderung zu Woche 36			
n/N (%)	46/93 (49)	22/79 (28)	LS MD 10,15 [3,993; 16,306]
MW (SD)	-1,20 (14,676)	-9,39 (16,797)	
LS MW (SE)	-3,46 (1,904)	-13,61 (2,492)	
95 %-KI	[-7,199; 0,280]	[-18,503; -8,715]	
Veränderung zu Woche 48			
n/N (%)	3/79 (4)	2/62 (3)	LS MD 12,09 [3,860; 20,315]
MW (SD)	-13,33 (11,547)	-6,67 (0,000)	
LS MW (SE)	-4,19 (2,491)	-16,28 (3,371)	
95 %-KI	[-9,080; 0,703]	[-22,894; -9,657]	
<b>Vorherige Verabreichung von Bevacizumab: Nein</b>			
Baseline			
n/N (%)	72/84 (86)	59/75 (79)	-
MW (SD)	75,22 (20,768)	80,68 (17,669)	
Absolute Werte zum Studienende			
n/N (%)	7/61 (11)	3/48 (6)	-
MW (SD)	80,95 (16,523)	88,89 (10,184)	
Effekt über Studiendauer			
n	72	59	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	0,69 (1,731)	-8,15 (1,941)	LS MD 8,84 [3,675; 14,004] 0,0009  Hedges' g 0,59 [0,242; 0,946]
95 %-KI	[-2,739; 4,114]	[-11,993; -4,312]	
Veränderung zu Woche 3/4			
n/N (%)	53/83 (64)	41/73 (56)	LS MD 6,01 [0,372; 11,653]
MW (SD)	2,66 (13,115)	-4,50 (16,469)	
LS MW (SE)	1,49 (1,896)	-4,53 (2,126)	
95 %-KI	[-2,256; 5,229]	[-8,720; -0,331]	
Veränderung zu Woche 8/9			
n/N (%)	60/80 (75)	50/69 (72)	LS MD 7,19 [1,888; 12,484]
MW (SD)	0,59 (18,447)	-8,13 (18,482)	
LS MW (SE)	1,16 (1,783)	-6,03 (1,989)	
95 %-KI	[-2,370; 4,680]	[-9,962; -2,100]	
Veränderung zu Woche 12			
n/N (%)	43/79 (54)	34/69 (49)	LS MD 8,01 [2,830; 13,185]
MW (SD)	3,98 (14,283)	-13,07 (20,837)	
LS MW (SE)	0,92 (1,740)	-7,08 (1,942)	
95 %-KI	[-2,521; 4,367]	[-10,927; -3,242]	
Veränderung zu Woche 15/16			
n/N (%)	37/77 (48)	23/66 (35)	LS MD 8,83 [3,665; 13,993]
MW (SD)	1,98 (19,868)	-7,83 (16,162)	
LS MW (SE)	0,69 (1,731)	-8,14 (1,941)	
95 %-KI	[-2,736; 4,117]	[-11,978; -4,298]	
Veränderung zu Woche 20/21			
n/N (%)	28/76 (37)	23/62 (37)	LS MD 10,00 [4,674; 15,331]
MW (SD)	5,48 (13,216)	-9,86 (13,614)	
LS MW (SE)	0,36 (1,776)	-9,64 (2,016)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,153; 3,871]	[-13,627; -5,659]	
Veränderung zu Woche 24			
n/N (%)	25/75 (33)	21/60 (35)	LS MD 10,82 [5,260; 16,388]
MW (SD)	2,13 (24,474)	-6,14 (14,655)	
LS MW (SE)	0,13 (1,845)	-10,70 (2,118)	
95 %-KI	[-3,519; 3,773]	[-14,877; -6,517]	
Veränderung zu Woche 36			
n/N (%)	36/67 (54)	26/55 (47)	LS MD 13,64 [6,685; 20,596]
MW (SD)	-1,67 (20,370)	-12,65 (20,316)	
LS MW (SE)	-0,67 (2,272)	-14,31 (2,695)	
95 %-KI	[-5,141; 3,803]	[-19,611; -9,008]	
Veränderung zu Woche 48			
n/N (%)	5/61 (8)	3/48 (6)	LS MD 16,46 [7,555; 25,358]
MW (SD)	5,33 (15,916)	-2,22 (16,777)	
LS MW (SE)	-1,47 (2,881)	-17,92 (3,480)	
95 %-KI	[-7,127; 4,196]	[-24,760; -11,084]	
<b>Letztes Platin-freies Intervall: ≤ 3 Monate</b>			
Baseline			
n/N (%)	68/83 (82)	62/91 (68)	-
MW (SD)	81,08 (16,596)	77,20 (20,576)	
Absolute Werte zum Studienende			
n/N (%)	3/55 (5)	5/39 (13)	-
MW (SD)	86,67 (17,638)	85,33 (19,090)	
Effekt über Studiendauer			
n	68	62	LS MD 10,06 [4,654; 15,468] 0,0003
LS MW (SE)	-1,95 (1,847)	-12,01 (2,011)	
95 %-KI	[-5,604; 1,710]	[-15,986; -8,029]	Hedges' g 0,64 [0,291; 0,998]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	50/82 (61)	46/86 (53)	LS MD 8,90 [3,133; 14,670]
MW (SD)	-1,40 (16,164)	-7,49 (18,506)	
LS MW (SE)	-1,91 (1,990)	-10,81 (2,134)	
95 %-KI	[-5,837; 2,021]	[-15,022; -6,596]	
Veränderung zu Woche 8/9			
n/N (%)	52/81 (64)	46/80 (57)	LS MD 9,43 [3,970; 14,894]
MW (SD)	-2,18 (13,766)	-10,29 (19,460)	
LS MW (SE)	-1,93 (1,878)	-11,36 (2,020)	
95 %-KI	[-5,641; 1,790]	[-15,353; -7,363]	
Veränderung zu Woche 12			
n/N (%)	33/78 (42)	25/78 (32)	LS MD 9,80 [4,416; 15,191]
MW (SD)	-3,64 (17,645)	-14,58 (19,980)	
LS MW (SE)	-1,94 (1,846)	-11,74 (1,998)	
95 %-KI	[-5,593; 1,716]	[-15,694; -7,789]	
Veränderung zu Woche 15/16			
n/N (%)	35/76 (46)	14/75 (19)	LS MD 10,17 [4,741; 15,609]
MW (SD)	0,51 (20,332)	-11,43 (15,782)	
LS MW (SE)	-1,95 (1,854)	-12,13 (2,025)	
95 %-KI	[-5,621; 1,719]	[-16,130; -8,121]	
Veränderung zu Woche 20/21			
n/N (%)	22/72 (31)	14/67 (21)	LS MD 10,71 [5,003; 16,408]
MW (SD)	-3,03 (17,545)	-10,95 (18,966)	
LS MW (SE)	-1,97 (1,933)	-12,67 (2,144)	
95 %-KI	[-5,790; 1,853]	[-16,909; -8,440]	
Veränderung zu Woche 24			
n/N (%)	16/72 (22)	12/62 (19)	LS MD 11,08 [5,059; 17,095]
MW (SD)	2,50 (18,679)	-6,30 (11,676)	
LS MW (SE)	-1,98 (2,032)	-13,06 (2,277)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-5,993; 2,030]	[-17,550; -8,567]	
Veränderung zu Woche 36			
n/N (%)	28/63 (44)	18/50 (36)	LS MD 12,35 [4,666; 20,035]
MW (SD)	0,24 (14,905)	-10,12 (17,879)	
LS MW (SE)	-2,02 (2,570)	-14,37 (2,951)	
95 %-KI	[-7,081; 3,033]	[-20,181; -8,569]	
Veränderung zu Woche 48			
n/N (%)	2/55 (4)	4/39 (10)	LS MD 13,62 [3,739; 23,509]
MW (SD)	0,00 (37,712)	-0,00 (9,428)	
LS MW (SE)	-2,07 (3,292)	-15,69 (3,817)	
95 %-KI	[-8,539; 4,404]	[-23,194; -8,189]	
<b>Letztes Platin-freies Intervall: &gt; 3 Monate</b>			
Baseline			
n/N (%)	110/135 (81)	97/116 (84)	-
MW (SD)	74,65 (21,869)	80,69 (19,732)	
Absolute Werte zum Studienende			
n/N (%)	7/85 (8)	1/71 (1)	-
MW (SD)	70,48 (16,265)	80,00 (NA)	
Effekt über Studiendauer			
n	110	97	LS MD 6,10 [2,363; 9,833] 0,0015
LS MW (SE)	-0,42 (1,269)	-6,51 (1,397)	
95 %-KI	[-2,919; 2,086]	[-9,268; -3,760]	Hedges' g 0,45 [0,173; 0,726]
Veränderung zu Woche 3/4			
n/N (%)	73/131 (56)	64/114 (56)	LS MD 2,88 [-1,299; 7,069]
MW (SD)	1,96 (11,893)	-1,98 (12,609)	
LS MW (SE)	0,70 (1,424)	-2,18 (1,568)	
95 %-KI	[-2,099; 3,505]	[-5,266; 0,903]	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	95/129 (74)	81/108 (75)	LS MD 4,28 [0,435; 8,131]
MW (SD)	-0,16 (18,314)	-6,75 (17,304)	
LS MW (SE)	0,22 (1,319)	-4,07 (1,429)	
95 %-KI	[-2,384; 2,816]	[-6,882; -1,252]	
Veränderung zu Woche 12			
n/N (%)	65/127 (51)	47/105 (45)	LS MD 5,26 [1,524; 9,000]
MW (SD)	1,98 (17,330)	-7,38 (16,106)	
LS MW (SE)	-0,12 (1,279)	-5,39 (1,389)	
95 %-KI	[-2,648; 2,398]	[-8,126; -2,648]	
Veränderung zu Woche 15/16			
n/N (%)	61/123 (50)	41/103 (40)	LS MD 6,24 [2,498; 9,984]
MW (SD)	-0,00 (18,176)	-6,18 (17,663)	
LS MW (SE)	-0,47 (1,269)	-6,71 (1,402)	
95 %-KI	[-2,969; 2,037]	[-9,471; -3,943]	
Veränderung zu Woche 20/21			
n/N (%)	46/118 (39)	37/98 (38)	LS MD 7,64 [3,695; 11,584]
MW (SD)	2,71 (16,092)	-5,23 (14,752)	
LS MW (SE)	-0,95 (1,308)	-8,59 (1,508)	
95 %-KI	[-3,531; 1,625]	[-11,562; -5,623]	
Veränderung zu Woche 24			
n/N (%)	39/112 (35)	26/93 (28)	LS MD 8,62 [4,412; 12,825]
MW (SD)	0,51 (19,846)	-6,92 (15,942)	
LS MW (SE)	-1,29 (1,370)	-9,91 (1,634)	
95 %-KI	[-3,992; 1,404]	[-13,127; -6,698]	
Veränderung zu Woche 36			
n/N (%)	54/97 (56)	30/84 (36)	LS MD 11,97 [6,345; 17,604]
MW (SD)	-2,25 (18,483)	-11,78 (19,392)	
LS MW (SE)	-2,46 (1,744)	-14,44 (2,270)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-5,890; 0,963]	[-18,895; -9,981]	
Veränderung zu Woche 48			
n/N (%)	6/85 (7)	1/71 (1)	LS MD 15,33 [7,846; 22,815]
MW (SD)	-2,22 (10,037)	-20,00 (NA)	
LS MW (SE)	-3,63 (2,266)	-18,96 (3,062)	
95 %-KI	[-8,081; 0,816]	[-24,974; -12,953]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Pegyliertes liposomales Doxorubicin</b>			
Baseline			
n/N (%)	63/80 (79)	57/76 (75)	-
MW (SD)	77,50 (18,955)	81,29 (18,748)	
Absolute Werte zum Studienende			
n/N (%)	3/51 (6)	3/41 (7)	-
MW (SD)	66,67 (6,667)	91,11 (7,698)	
Effekt über Studiendauer			
n	63	57	LS MD 4,46 [-0,111; 9,024] 0,0557  Hedges' g 0,35 [-0,008; 0,714]
LS MW (SE)	-2,60 (1,546)	-7,06 (1,704)	
95 %-KI	[-5,670; 0,461]	[-10,434; -3,687]	
Veränderung zu Woche 3/4			
n/N (%)	43/76 (57)	43/74 (58)	LS MD 2,92 [-2,248; 8,097]
MW (SD)	1,42 (10,678)	-2,79 (10,614)	
LS MW (SE)	-0,75 (1,788)	-3,68 (1,912)	
95 %-KI	[-4,281; 2,777]	[-7,447; 0,094]	
Veränderung zu Woche 8/9			
n/N (%)	53/76 (70)	44/66 (67)	LS MD 3,60 [-1,108; 8,304]
MW (SD)	-2,98 (14,637)	-5,91 (16,780)	
LS MW (SE)	-1,57 (1,627)	-5,16 (1,730)	
95 %-KI	[-4,786; 1,652]	[-8,586; -1,744]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	34/75 (45)	23/64 (36)	LS MD 4,07 [-0,492; 8,632]
MW (SD)	-1,24 (16,855)	-9,57 (17,271)	
LS MW (SE)	-2,14 (1,563)	-6,21 (1,685)	
95 %-KI	[-5,235; 0,961]	[-9,543; -2,871]	
Veränderung zu Woche 15/16			
n/N (%)	34/74 (46)	19/62 (31)	LS MD 4,54 [-0,042; 9,125]
MW (SD)	-3,14 (17,153)	-10,88 (18,620)	
LS MW (SE)	-2,71 (1,547)	-7,25 (1,715)	
95 %-KI	[-5,774; 0,359]	[-10,643; -3,854]	
Veränderung zu Woche 20/21			
n/N (%)	27/72 (38)	18/59 (31)	LS MD 5,22 [0,321; 10,109]
MW (SD)	0,74 (11,596)	-11,11 (15,509)	
LS MW (SE)	-3,52 (1,606)	-8,74 (1,879)	
95 %-KI	[-6,702; -0,342]	[-12,448; -5,027]	
Veränderung zu Woche 24			
n/N (%)	22/69 (32)	16/54 (30)	LS MD 5,69 [0,406; 10,968]
MW (SD)	-1,21 (17,893)	-4,58 (15,534)	
LS MW (SE)	-4,09 (1,701)	-9,78 (2,062)	
95 %-KI	[-7,454; -0,730]	[-13,845; -5,713]	
Veränderung zu Woche 36			
n/N (%)	30/60 (50)	16/48 (33)	LS MD 7,30 [0,001; 14,607]
MW (SD)	-6,28 (17,197)	-12,92 (25,701)	
LS MW (SE)	-6,05 (2,261)	-13,35 (2,943)	
95 %-KI	[-10,497; -1,598]	[-19,140; -7,563]	
Veränderung zu Woche 48			
n/N (%)	2/51 (4)	2/41 (5)	LS MD 8,92 [-0,942; 18,785]
MW (SD)	-10,00 (4,714)	-3,33 (4,714)	
LS MW (SE)	-8,00 (3,018)	-16,92 (4,010)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-13,934; -2,071]	[-24,805; -9,042]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Paclitaxel</b>			
Baseline			
n/N (%)	76/88 (86)	70/82 (85)	-
MW (SD)	76,96 (19,955)	75,71 (22,358)	
Absolute Werte zum Studienende			
n/N (%)	1/56 (2)	1/49 (2)	-
MW (SD)	66,67 (NA)	100,00 (NA)	
Effekt über Studiendauer			
n	76	70	LS MD 6,90 [2,195; 11,598] 0,0043  Hedges' g 0,48 [0,149; 0,808]
LS MW (SE)	-1,58 (1,620)	-8,48 (1,742)	
95 %-KI	[-4,789; 1,619]	[-11,924; -5,038]	
Veränderung zu Woche 3/4			
n/N (%)	56/87 (64)	49/81 (60)	LS MD 4,58 [-0,612; 9,773]
MW (SD)	-0,50 (15,088)	-3,36 (15,073)	
LS MW (SE)	-1,44 (1,792)	-6,02 (1,930)	
95 %-KI	[-4,978; 2,090]	[-9,827; -2,222]	
Veränderung zu Woche 8/9			
n/N (%)	64/86 (74)	56/79 (71)	LS MD 5,63 [0,816; 10,437]
MW (SD)	-2,46 (17,748)	-7,62 (19,172)	
LS MW (SE)	-1,51 (1,665)	-7,13 (1,777)	
95 %-KI	[-4,798; 1,783]	[-10,643; -3,625]	
Veränderung zu Woche 12			
n/N (%)	43/84 (51)	37/77 (48)	LS MD 6,36 [1,662; 11,056]
MW (SD)	-1,76 (17,582)	-12,01 (19,720)	
LS MW (SE)	-1,55 (1,624)	-7,91 (1,735)	
95 %-KI	[-4,763; 1,659]	[-11,340; -4,481]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	46/81 (57)	28/76 (37)	LS MD 7,09 [2,370; 11,812]
MW (SD)	0,24 (20,689)	-5,95 (18,355)	
LS MW (SE)	-1,60 (1,624)	-8,69 (1,753)	
95 %-KI	[-4,809; 1,616]	[-12,151; -5,224]	
Veränderung zu Woche 20/21			
n/N (%)	30/77 (39)	26/73 (36)	LS MD 8,14 [3,150; 13,124]
MW (SD)	-2,74 (19,796)	-4,87 (17,845)	
LS MW (SE)	-1,66 (1,698)	-9,80 (1,875)	
95 %-KI	[-5,014; 1,694]	[-13,496; -6,098]	
Veränderung zu Woche 24			
n/N (%)	22/74 (30)	19/72 (26)	LS MD 8,87 [3,551; 14,187]
MW (SD)	-1,82 (20,695)	-9,59 (14,667)	
LS MW (SE)	-1,70 (1,796)	-10,57 (2,019)	
95 %-KI	[-5,247; 1,837]	[-14,551; -6,596]	
Veränderung zu Woche 36			
n/N (%)	37/64 (58)	24/63 (38)	LS MD 11,38 [4,303; 18,455]
MW (SD)	-0,90 (17,081)	-9,26 (15,321)	
LS MW (SE)	-1,86 (2,335)	-13,24 (2,750)	
95 %-KI	[-6,449; 2,733]	[-18,641; -7,833]	
Veränderung zu Woche 48			
n/N (%)	1/56 (2)	1/49 (2)	LS MD 13,89 [4,532; 23,246]
MW (SD)	-26,67 (NA)	13,33 (NA)	
LS MW (SE)	-2,01 (3,053)	-15,90 (3,670)	
95 %-KI	[-8,008; 3,987]	[-23,109; -8,691]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Topotecan</b>			
Baseline			
n/N (%)	39/50 (78)	32/49 (65)	-
MW (SD)	76,75 (23,037)	83,75 (15,789)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	6/33 (18)	2/20 (10)	-
MW (SD)	81,11 (20,834)	66,67 (18,856)	
Effekt über Studiendauer			
n	39	32	LS MD 15,80 [7,327; 24,277] 0,0004  Hedges' g 0,89 [0,394; 1,376]
LS MW (SE)	2,79 (2,820)	-13,01 (3,131)	
95 %-KI	[-2,842; 8,419]	[-19,257; -6,770]	
Veränderung zu Woche 3/4			
n/N (%)	24/50 (48)	18/45 (40)	LS MD 12,49 [3,748; 21,234]
MW (SD)	1,67 (16,001)	-10,37 (24,007)	
LS MW (SE)	3,15 (2,909)	-9,34 (3,246)	
95 %-KI	[-2,641; 8,948]	[-15,795; -2,879]	
Veränderung zu Woche 8/9			
n/N (%)	30/48 (62)	27/43 (63)	LS MD 13,91 [5,406; 22,413]
MW (SD)	6,22 (17,058)	-12,35 (17,898)	
LS MW (SE)	3,00 (2,839)	-10,91 (3,141)	
95 %-KI	[-2,668; 8,662]	[-17,173; -4,650]	
Veränderung zu Woche 12			
n/N (%)	21/46 (46)	12/42 (29)	LS MD 14,90 [6,455; 23,349]
MW (SD)	6,03 (18,124)	-3,89 (10,429)	
LS MW (SE)	2,89 (2,818)	-12,01 (3,117)	
95 %-KI	[-2,739; 8,515]	[-18,231; -5,797]	
Veränderung zu Woche 15/16			
n/N (%)	16/44 (36)	8/40 (20)	LS MD 15,89 [7,412; 24,377]
MW (SD)	7,08 (15,864)	-5,00 (6,901)	
LS MW (SE)	2,78 (2,822)	-13,12 (3,135)	
95 %-KI	[-2,855; 8,412]	[-19,366; -6,867]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	11/41 (27)	7/33 (21)	LS MD 17,31 [8,620; 26,005]
MW (SD)	10,91 (14,988)	-2,86 (6,506)	
LS MW (SE)	2,62 (2,867)	-14,69 (3,230)	
95 %-KI	[-3,096; 8,340]	[-21,121; -8,261]	
Veränderung zu Woche 24			
n/N (%)	11/41 (27)	3/29 (10)	LS MD 18,31 [9,360; 27,251]
MW (SD)	11,52 (17,408)	0,00 (0,000)	
LS MW (SE)	2,51 (2,927)	-15,79 (3,344)	
95 %-KI	[-3,317; 8,342]	[-22,437; -9,149]	
Veränderung zu Woche 36			
n/N (%)	15/36 (42)	8/23 (35)	LS MD 21,71 [11,330; 32,089]
MW (SD)	7,11 (15,423)	-13,33 (11,269)	
LS MW (SE)	2,14 (3,282)	-19,57 (3,964)	
95 %-KI	[-4,367; 8,641]	[-27,408; -11,736]	
Veränderung zu Woche 48			
n/N (%)	5/33 (15)	2/20 (10)	LS MD 25,11 [12,664; 37,561]
MW (SD)	6,67 (14,142)	-13,33 (9,428)	
LS MW (SE)	1,76 (3,816)	-23,35 (4,829)	
95 %-KI	[-5,775; 9,298]	[-32,876; -13,827]	
<p><i>Analysepopulation: ITT</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023</i></p> <p><i>Modell: Veränderung zu Baseline ~ Behandlung + Baseline-Wert * Zeit in Wochen + Behandlung * Zeit in Wochen + zufällige Effekte durch die Patientin</i></p> <p><i>Die Berechnung des LS-MWs erfolgt durch ein MMRM mit dem oben angegebenen Modell. Basierend hierauf werden KI und p-Wert ermittelt. Hedges' g basiert ebenfalls auf den LS-MW und ist somit auf das Modell angepasst.</i></p> <p><i>Es werden ausschließlich gemeinsame Analysezeitpunkte dargestellt.</i></p> <p><i>Ein LS MD und Hedges' g größer als Null bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

## 2.13 EORTC QLQ-C30 Rollenfunktion

### EORTC QLQ-C30 Rollenfunktion: Subgruppenanalyse

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
<b>EORTC QLQ-C30 Rollenfunktion</b>			
<b>Alter: &lt; 65 Jahre</b>			
Baseline			
n/N (%)	95/115 (83)	92/119 (77)	-
MW (SD)	76,84 (25,299)	73,91 (26,647)	
Absolute Werte zum Studienende			
n/N (%)	4/73 (5)	4/64 (6)	-
MW (SD)	62,50 (28,464)	91,67 (16,667)	
Effekt über Studiendauer			
n	95	92	LS MD 6,83 [1,517; 12,149] 0,0121
LS MW (SE)	-5,69 (1,838)	-12,52 (1,968)	
95 %-KI	[-9,316; -2,056]	[-16,403; -8,635]	Hedges' g 0,37 [0,081; 0,659]
Veränderung zu Woche 3/4			
n/N (%)	60/113 (53)	61/115 (53)	LS MD 5,02 [-1,154; 11,203]
MW (SD)	-1,11 (19,855)	-3,83 (25,165)	
LS MW (SE)	-4,15 (2,159)	-9,18 (2,280)	
95 %-KI	[-8,400; 0,096]	[-13,661; -4,692]	
Veränderung zu Woche 8/9			
n/N (%)	76/112 (68)	72/108 (67)	LS MD 5,82 [0,283; 11,356]
MW (SD)	-4,39 (26,299)	-13,19 (24,536)	
LS MW (SE)	-4,83 (1,940)	-10,65 (2,031)	
95 %-KI	[-8,651; -1,002]	[-14,647; -6,643]	
Veränderung zu Woche 12			
n/N (%)	48/110 (44)	40/105 (38)	
MW (SD)	-7,29 (26,162)	-12,08 (21,677)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-5,30 (1,857)	-11,67 (1,957)	LS MD 6,38 [1,052; 11,700]
95 %-KI	[-8,963; -1,634]	[-15,535; -7,812]	
Veränderung zu Woche 15/16			
n/N (%)	55/107 (51)	33/102 (32)	LS MD 6,93 [1,597; 12,267]
MW (SD)	-5,15 (26,425)	-11,11 (26,571)	
LS MW (SE)	-5,77 (1,841)	-12,70 (1,979)	
95 %-KI	[-9,404; -2,136]	[-16,607; -8,797]	
Veränderung zu Woche 20/21			
n/N (%)	37/101 (37)	30/96 (31)	LS MD 7,73 [1,999; 13,455]
MW (SD)	-13,51 (26,597)	-9,44 (28,258)	
LS MW (SE)	-6,44 (1,936)	-14,17 (2,167)	
95 %-KI	[-10,263; -2,626]	[-18,441; -9,902]	
Veränderung zu Woche 24			
n/N (%)	25/99 (25)	19/91 (21)	LS MD 8,28 [2,054; 14,513]
MW (SD)	-7,33 (25,495)	-7,89 (25,073)	
LS MW (SE)	-6,92 (2,076)	-15,20 (2,388)	
95 %-KI	[-11,007; -2,826]	[-19,898; -10,501]	
Veränderung zu Woche 36			
n/N (%)	42/86 (49)	28/79 (35)	LS MD 10,19 [1,360; 19,022]
MW (SD)	-6,35 (27,038)	-16,67 (30,429)	
LS MW (SE)	-8,53 (2,862)	-18,73 (3,466)	
95 %-KI	[-14,158; -2,912]	[-25,534; -11,917]	
Veränderung zu Woche 48			
n/N (%)	4/73 (5)	3/64 (5)	LS MD 12,10 [0,014; 24,183]
MW (SD)	-12,50 (15,957)	11,11 (19,245)	
LS MW (SE)	-10,15 (3,884)	-22,25 (4,772)	
95 %-KI	[-17,781; -2,526]	[-31,623; -12,881]	
<b>Alter: ≥ 65 Jahre</b>			
Baseline			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	81/103 (79)	66/88 (75)	-
MW (SD)	71,19 (27,514)	78,28 (25,649)	
Absolute Werte zum Studienende			
n/N (%)	6/67 (9)	2/46 (4)	-
MW (SD)	72,22 (25,092)	83,33 (23,570)	
Effekt über Studiendauer			
n	81	66	LS MD 9,01 [3,055; 14,964] 0,0033  Hedges' g 0,50 [0,167; 0,827]
LS MW (SE)	-0,06 (1,968)	-9,07 (2,272)	
95 %-KI	[-3,955; 3,832]	[-13,560; -4,583]	
Veränderung zu Woche 3/4			
n/N (%)	60/100 (60)	49/85 (58)	LS MD 9,76 [3,090; 16,425]
MW (SD)	1,67 (22,064)	-7,48 (16,337)	
LS MW (SE)	1,63 (2,234)	-8,12 (2,531)	
95 %-KI	[-2,770; 6,039]	[-13,110; -3,137]	
Veränderung zu Woche 8/9			
n/N (%)	69/98 (70)	54/80 (68)	LS MD 9,42 [3,328; 15,519]
MW (SD)	0,48 (23,391)	-7,72 (24,382)	
LS MW (SE)	0,88 (2,046)	-8,55 (2,299)	
95 %-KI	[-3,166; 4,919]	[-13,085; -4,009]	
Veränderung zu Woche 12			
n/N (%)	50/95 (53)	31/78 (40)	LS MD 9,19 [3,256; 15,123]
MW (SD)	4,67 (24,290)	-17,20 (24,901)	
LS MW (SE)	0,35 (1,979)	-8,84 (2,245)	
95 %-KI	[-3,568; 4,261]	[-13,280; -4,406]	
Veränderung zu Woche 15/16			
n/N (%)	41/92 (45)	22/76 (29)	
MW (SD)	3,25 (25,609)	-10,61 (31,094)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-0,18 (1,972)	-9,14 (2,291)	LS MD 8,96 [2,970; 14,941]
95 %-KI	[-4,085; 3,717]	[-13,665; -4,614]	
Veränderung zu Woche 20/21			
n/N (%)	30/89 (34)	21/69 (30)	LS MD 8,62 [2,203; 15,039]
MW (SD)	5,00 (21,059)	-7,94 (19,450)	
LS MW (SE)	-0,94 (2,065)	-9,56 (2,514)	
95 %-KI	[-5,021; 3,137]	[-14,521; -4,605]	
Veränderung zu Woche 24			
n/N (%)	29/85 (34)	19/64 (30)	LS MD 8,39 [1,451; 15,323]
MW (SD)	-0,57 (29,708)	-5,26 (18,470)	
LS MW (SE)	-1,47 (2,195)	-9,86 (2,760)	
95 %-KI	[-5,803; 2,858]	[-15,294; -4,425]	
Veränderung zu Woche 36			
n/N (%)	39/74 (53)	19/55 (35)	LS MD 7,58 [-1,996; 17,165]
MW (SD)	-2,56 (23,427)	-9,65 (24,417)	
LS MW (SE)	-3,29 (2,923)	-10,88 (3,932)	
95 %-KI	[-9,039; 2,457]	[-18,603; -3,149]	
Veränderung zu Woche 48			
n/N (%)	4/67 (6)	2/46 (4)	LS MD 6,78 [-6,118; 19,682]
MW (SD)	-8,33 (21,517)	-8,33 (11,785)	
LS MW (SE)	-5,11 (3,886)	-11,89 (5,346)	
95 %-KI	[-12,745; 2,525]	[-22,394; -1,390]	
<b>Region: USA</b>			
Baseline			
n/N (%)	49/65 (75)	33/51 (65)	-
MW (SD)	72,45 (27,544)	80,30 (22,994)	
Absolute Werte zum Studienende			
n/N (%)	2/39 (5)	3/27 (11)	-
MW (SD)	83,33 (23,570)	77,78 (19,245)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Effekt über Studiendauer			
n	49	33	LS MD 10,59 [3,036; 18,148] 0,0066  Hedges' g 0,62 [0,173; 1,077]
LS MW (SE)	-2,93 (2,396)	-13,52 (2,929)	
95 %-KI	[-7,705; 1,845]	[-19,353; -7,690]	
Veränderung zu Woche 3/4			
n/N (%)	33/64 (52)	21/49 (43)	LS MD 8,71 [0,230; 17,186]
MW (SD)	-3,03 (16,902)	-9,52 (19,416)	
LS MW (SE)	-3,22 (2,705)	-11,93 (3,302)	
95 %-KI	[-8,577; 2,138]	[-18,464; -5,390]	
Veränderung zu Woche 8/9			
n/N (%)	42/62 (68)	30/46 (65)	LS MD 9,57 [1,787; 17,345]
MW (SD)	1,19 (20,951)	-14,44 (22,630)	
LS MW (SE)	-3,09 (2,482)	-12,65 (3,011)	
95 %-KI	[-8,022; 1,848]	[-18,636; -6,671]	
Veränderung zu Woche 12			
n/N (%)	26/59 (44)	16/45 (36)	LS MD 10,17 [2,605; 17,729]
MW (SD)	-0,00 (21,602)	-18,75 (29,107)	
LS MW (SE)	-3,00 (2,406)	-13,16 (2,925)	
95 %-KI	[-7,788; 1,798]	[-18,984; -7,340]	
Veränderung zu Woche 15/16			
n/N (%)	21/56 (38)	11/44 (25)	LS MD 10,77 [3,179; 18,357]
MW (SD)	-2,38 (21,913)	-9,09 (31,941)	
LS MW (SE)	-2,90 (2,402)	-13,67 (2,947)	
95 %-KI	[-7,691; 1,886]	[-19,536; -7,805]	
Veränderung zu Woche 20/21			
n/N (%)	13/54 (24)	9/40 (22)	
MW (SD)	-5,13 (20,844)	-11,11 (23,570)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-2,77 (2,525)	-14,40 (3,159)	LS MD 11,63 [3,583; 19,668]
95 %-KI	[-7,790; 2,248]	[-20,666; -8,127]	
Veränderung zu Woche 24			
n/N (%)	9/53 (17)	6/38 (16)	LS MD 12,23 [3,609; 20,844]
MW (SD)	-0,00 (16,667)	-11,11 (22,771)	
LS MW (SE)	-2,68 (2,689)	-14,90 (3,415)	
95 %-KI	[-8,010; 2,654]	[-21,665; -8,145]	
Veränderung zu Woche 36			
n/N (%)	22/43 (51)	9/33 (27)	LS MD 14,29 [2,598; 25,974]
MW (SD)	-3,03 (20,979)	-16,67 (32,275)	
LS MW (SE)	-2,36 (3,591)	-16,65 (4,721)	
95 %-KI	[-9,440; 4,717]	[-25,950; -7,346]	
Veränderung zu Woche 48			
n/N (%)	2/39 (5)	3/27 (11)	LS MD 16,35 [0,698; 31,993]
MW (SD)	8,33 (11,785)	-5,56 (9,623)	
LS MW (SE)	-2,05 (4,772)	-18,39 (6,358)	
95 %-KI	[-11,441; 7,351]	[-30,910; -5,871]	
<b>Region: Rest der Welt</b>			
Baseline			
n/N (%)	127/153 (83)	125/156 (80)	-
MW (SD)	74,93 (26,047)	74,53 (26,989)	
Absolute Werte zum Studienende			
n/N (%)	8/101 (8)	3/83 (4)	-
MW (SD)	64,58 (25,877)	100,00 (0,000)	
Effekt über Studiendauer			
n	127	125	LS MD 7,32 [2,665; 11,977] 0,0022  Hedges' g
LS MW (SE)	-3,17 (1,614)	-10,49 (1,728)	
95 %-KI	[-6,347; 0,016]	[-13,888; -7,085]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
			0,39 [0,140; 0,638]
Veränderung zu Woche 3/4			
n/N (%)	87/149 (58)	89/151 (59)	LS MD 6,87 [1,535; 12,209]
MW (SD)	1,53 (22,249)	-4,49 (22,157)	
LS MW (SE)	-0,78 (1,876)	-7,65 (1,965)	
95 %-KI	[-4,466; 2,910]	[-11,512; -3,789]	
Veränderung zu Woche 8/9			
n/N (%)	103/148 (70)	96/142 (68)	LS MD 7,07 [2,256; 11,882]
MW (SD)	-3,40 (26,441)	-9,72 (25,092)	
LS MW (SE)	-1,83 (1,697)	-8,90 (1,761)	
95 %-KI	[-5,168; 1,515]	[-12,362; -5,429]	
Veränderung zu Woche 12			
n/N (%)	72/146 (49)	55/138 (40)	LS MD 7,21 [2,558; 11,856]
MW (SD)	-1,62 (27,287)	-13,03 (21,201)	
LS MW (SE)	-2,56 (1,630)	-9,77 (1,709)	
95 %-KI	[-5,771; 0,651]	[-13,132; -6,403]	
Veränderung zu Woche 15/16			
n/N (%)	75/143 (52)	44/134 (33)	LS MD 7,35 [2,671; 12,019]
MW (SD)	-1,33 (27,504)	-11,36 (27,556)	
LS MW (SE)	-3,29 (1,616)	-10,64 (1,739)	
95 %-KI	[-6,479; -0,109]	[-14,063; -7,216]	
Veränderung zu Woche 20/21			
n/N (%)	54/136 (40)	42/125 (34)	LS MD 7,54 [2,516; 12,569]
MW (SD)	-5,25 (27,054)	-8,33 (25,303)	
LS MW (SE)	-4,34 (1,693)	-11,88 (1,915)	
95 %-KI	[-7,675; -1,009]	[-15,652; -8,117]	
Veränderung zu Woche 24			
n/N (%)	45/131 (34)	32/117 (27)	
MW (SD)	-4,44 (29,602)	-5,73 (21,837)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-5,08 (1,806)	-12,76 (2,114)	LS MD 7,68 [2,218; 13,143]
95 %-KI	[-8,630; -1,522]	[-16,911; -8,602]	
Veränderung zu Woche 36			
n/N (%)	59/117 (50)	38/101 (38)	LS MD 8,15 [0,461; 15,847]
MW (SD)	-5,08 (26,848)	-13,16 (27,443)	
LS MW (SE)	-7,59 (2,451)	-15,75 (3,064)	
95 %-KI	[-12,404; -2,780]	[-21,760; -9,731]	
Veränderung zu Woche 48			
n/N (%)	6/101 (6)	2/83 (2)	LS MD 8,63 [-1,847; 19,102]
MW (SD)	-16,67 (14,907)	16,67 (23,570)	
LS MW (SE)	-10,11 (3,300)	-18,74 (4,204)	
95 %-KI	[-16,584; -3,632]	[-26,987; -10,483]	
<b>Stadium bei der Diagnose: I-III</b>			
Baseline			
n/N (%)	111/141 (79)	111/144 (77)	-
MW (SD)	77,18 (25,219)	75,68 (26,187)	
Absolute Werte zum Studienende			
n/N (%)	6/91 (7)	4/76 (5)	-
MW (SD)	69,44 (26,701)	83,33 (19,245)	
Effekt über Studiendauer			
n	111	111	LS MD 8,02 [3,066; 12,978] 0,0016
LS MW (SE)	-4,60 (1,731)	-12,62 (1,826)	
95 %-KI	[-8,010; -1,184]	[-16,217; -9,021]	Hedges' g 0,43 [0,160; 0,693]
Veränderung zu Woche 3/4			
n/N (%)	74/137 (54)	79/138 (57)	LS MD 6,27 [0,628; 11,920]
MW (SD)	1,13 (20,334)	-6,54 (21,420)	
LS MW (SE)	-2,14 (2,000)	-8,42 (2,062)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,077; 1,790]	[-12,472; -4,363]	
Veränderung zu Woche 8/9			
n/N (%)	93/136 (68)	88/129 (68)	LS MD 7,04 [1,915; 12,167]
MW (SD)	-5,56 (23,356)	-9,47 (23,812)	
LS MW (SE)	-3,22 (1,815)	-10,26 (1,867)	
95 %-KI	[-6,796; 0,357]	[-13,936; -6,584]	
Veränderung zu Woche 12			
n/N (%)	62/133 (47)	48/128 (38)	LS MD 7,58 [2,620; 12,536]
MW (SD)	-2,15 (27,902)	-15,97 (23,560)	
LS MW (SE)	-3,97 (1,746)	-11,55 (1,813)	
95 %-KI	[-7,415; -0,530]	[-15,123; -7,978]	
Veränderung zu Woche 15/16			
n/N (%)	63/130 (48)	35/125 (28)	LS MD 8,11 [3,143; 13,086]
MW (SD)	-5,03 (28,182)	-14,29 (25,928)	
LS MW (SE)	-4,73 (1,732)	-12,84 (1,835)	
95 %-KI	[-8,143; -1,309]	[-16,456; -9,224]	
Veränderung zu Woche 20/21			
n/N (%)	45/123 (37)	34/116 (29)	LS MD 8,88 [3,583; 14,179]
MW (SD)	-6,67 (24,464)	-12,75 (25,969)	
LS MW (SE)	-5,80 (1,812)	-14,68 (1,992)	
95 %-KI	[-9,373; -2,231]	[-18,604; -10,762]	
Veränderung zu Woche 24			
n/N (%)	34/121 (28)	27/109 (25)	LS MD 9,42 [3,704; 15,132]
MW (SD)	-8,33 (28,795)	-8,02 (25,474)	
LS MW (SE)	-6,56 (1,931)	-15,97 (2,174)	
95 %-KI	[-10,356; -2,755]	[-20,249; -11,697]	
Veränderung zu Woche 36			
n/N (%)	52/105 (50)	35/92 (38)	
MW (SD)	-7,69 (25,451)	-19,05 (29,744)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-9,14 (2,603)	-20,40 (3,074)	LS MD 11,26 [3,361; 19,155]
95 %-KI	[-14,250; -4,026]	[-26,432; -14,360]	
Veränderung zu Woche 48			
n/N (%)	5/91 (5)	4/76 (5)	LS MD 13,10 [2,429; 23,767]
MW (SD)	-13,33 (21,731)	-4,17 (8,333)	
LS MW (SE)	-11,72 (3,491)	-24,82 (4,178)	
95 %-KI	[-18,574; -4,868]	[-33,020; -16,618]	
<b>Stadium bei der Diagnose: IV</b>			
Baseline			
n/N (%)	60/72 (83)	45/60 (75)	-
MW (SD)	68,61 (27,972)	75,93 (26,722)	
Absolute Werte zum Studienende			
n/N (%)	4/46 (9)	2/33 (6)	-
MW (SD)	66,67 (27,217)	100,00 (0,000)	
Effekt über Studiendauer			
n	60	45	LS MD 6,83 [-0,122; 13,785] 0,0541
LS MW (SE)	-0,60 (2,247)	-7,43 (2,679)	
95 %-KI	[-5,065; 3,861]	[-12,746; -2,121]	Hedges' g 0,38 [-0,006; 0,774]
Veränderung zu Woche 3/4			
n/N (%)	41/71 (58)	29/59 (49)	LS MD 9,74 [1,856; 17,627]
MW (SD)	-0,41 (21,886)	-1,72 (22,425)	
LS MW (SE)	-0,31 (2,569)	-10,06 (3,052)	
95 %-KI	[-5,389; 4,761]	[-16,078; -4,032]	
Veränderung zu Woche 8/9			
n/N (%)	47/69 (68)	36/56 (64)	LS MD 8,44 [1,318; 15,556]
MW (SD)	4,26 (27,686)	-15,74 (25,493)	
LS MW (SE)	-0,44 (2,342)	-8,88 (2,718)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-5,084; 4,198]	[-14,263; -3,497]	
Veränderung zu Woche 12			
n/N (%)	31/67 (46)	22/52 (42)	LS MD 7,52 [0,613; 14,435]
MW (SD)	2,15 (20,066)	-12,12 (21,932)	
LS MW (SE)	-0,53 (2,261)	-8,06 (2,641)	
95 %-KI	[-5,021; 3,954]	[-13,296; -2,819]	
Veränderung zu Woche 15/16			
n/N (%)	30/64 (47)	18/50 (36)	LS MD 6,61 [-0,391; 13,613]
MW (SD)	5,00 (21,950)	-4,63 (26,695)	
LS MW (SE)	-0,62 (2,252)	-7,23 (2,708)	
95 %-KI	[-5,096; 3,849]	[-12,604; -1,866]	
Veränderung zu Woche 20/21			
n/N (%)	19/62 (31)	16/46 (35)	LS MD 5,31 [-2,316; 12,930]
MW (SD)	-3,51 (29,700)	-2,08 (20,972)	
LS MW (SE)	-0,75 (2,365)	-6,06 (3,030)	
95 %-KI	[-5,442; 3,936]	[-12,048; -0,071]	
Veränderung zu Woche 24			
n/N (%)	18/59 (31)	10/44 (23)	LS MD 4,39 [-3,950; 12,737]
MW (SD)	2,78 (25,082)	-1,67 (5,270)	
LS MW (SE)	-0,84 (2,523)	-5,24 (3,377)	
95 %-KI	[-5,835; 4,149]	[-11,899; 1,425]	
Veränderung zu Woche 36			
n/N (%)	28/52 (54)	11/41 (27)	LS MD 1,26 [-10,640; 13,167]
MW (SD)	1,19 (24,816)	1,52 (15,731)	
LS MW (SE)	-1,15 (3,400)	-2,42 (4,989)	
95 %-KI	[-7,847; 5,541]	[-12,231; 7,398]	
Veränderung zu Woche 48			
n/N (%)	3/46 (7)	1/33 (3)	
MW (SD)	-5,56 (9,623)	33,33 (NA)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-1,46 (4,549)	0,40 (6,887)	LS MD -1,87 [-18,127; 14,394]
95 %-KI	[-10,409; 7,484]	[-13,140; 13,947]	
<b>BRCA Status: Positiv</b>			
Baseline			
n/N (%)	25/27 (93)	23/35 (66)	-
MW (SD)	72,67 (27,165)	76,09 (30,078)	
Absolute Werte zum Studienende			
n/N (%)	1/19 (5)	0/15 (0)	-
MW (SD)	33,33 (NA)	NA (NA)	
Effekt über Studiendauer			
n	25	23	LS MD 10,85 [1,676; 20,025] 0,0216  Hedges' g 0,68 [0,097; 1,265]
LS MW (SE)	-2,04 (2,998)	-12,89 (3,417)	
95 %-KI	[-8,109; 4,035]	[-19,767; -6,007]	
Veränderung zu Woche 3/4			
n/N (%)	16/27 (59)	18/35 (51)	LS MD 12,09 [1,391; 22,786]
MW (SD)	0,00 (18,257)	-10,19 (23,666)	
LS MW (SE)	-2,44 (3,672)	-14,52 (3,932)	
95 %-KI	[-9,743; 4,872]	[-22,336; -6,712]	
Veränderung zu Woche 8/9			
n/N (%)	21/26 (81)	19/30 (63)	LS MD 11,49 [2,178; 20,799]
MW (SD)	-0,00 (19,720)	-15,79 (28,040)	
LS MW (SE)	-2,24 (3,210)	-13,73 (3,346)	
95 %-KI	[-8,689; 4,205]	[-20,450; -7,012]	
Veränderung zu Woche 12			
n/N (%)	15/26 (58)	11/30 (37)	LS MD 11,07 [2,013; 20,124]
MW (SD)	-6,67 (25,820)	-10,61 (22,697)	
LS MW (SE)	-2,11 (3,033)	-13,18 (3,306)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-8,238; 4,024]	[-19,841; -6,509]	
Veränderung zu Woche 15/16			
n/N (%)	12/26 (46)	8/29 (28)	LS MD 10,65 [1,216; 20,080]
MW (SD)	-1,39 (22,983)	-10,42 (26,633)	
LS MW (SE)	-1,97 (3,002)	-12,62 (3,593)	
95 %-KI	[-8,055; 4,111]	[-19,833; -5,407]	
Veränderung zu Woche 20/21			
n/N (%)	10/25 (40)	4/25 (16)	LS MD 10,05 [-0,882; 20,979]
MW (SD)	1,67 (19,954)	-12,50 (15,957)	
LS MW (SE)	-1,78 (3,215)	-11,83 (4,430)	
95 %-KI	[-8,255; 4,699]	[-20,639; -3,014]	
Veränderung zu Woche 24			
n/N (%)	8/25 (32)	4/24 (17)	LS MD 9,63 [-2,852; 22,108]
MW (SD)	6,25 (19,796)	0,00 (0,000)	
LS MW (SE)	-1,64 (3,519)	-11,27 (5,201)	
95 %-KI	[-8,686; 5,400]	[-21,579; -0,962]	
Veränderung zu Woche 36			
n/N (%)	10/21 (48)	5/20 (25)	LS MD 8,19 [-11,174; 27,549]
MW (SD)	1,67 (12,298)	-6,67 (14,907)	
LS MW (SE)	-1,18 (5,135)	-9,37 (8,337)	
95 %-KI	[-11,339; 8,981]	[-25,838; 7,105]	
Veränderung zu Woche 48			
n/N (%)	1/19 (5)	0/15 (0)	LS MD 6,75 [-20,459; 33,953]
MW (SD)	-16,67 (NA)	NA (NA)	
LS MW (SE)	-0,71 (7,152)	-7,46 (11,761)	
95 %-KI	[-14,843; 13,413]	[-30,692; 15,769]	
<b>BRCA Status: Negativ/Unbekannt</b>			
Baseline			
n/N (%)	151/191 (79)	135/172 (78)	-

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	74,50 (26,374)	75,68 (25,656)	
Absolute Werte zum Studienende			
n/N (%)	9/121 (7)	6/95 (6)	-
MW (SD)	72,22 (23,570)	88,89 (17,213)	
Effekt über Studiendauer			
n	151	135	LS MD 7,16 [2,801; 11,516] 0,0014  Hedges' g 0,38 [0,148; 0,617]
LS MW (SE)	-3,42 (1,487)	-10,58 (1,642)	
95 %-KI	[-6,352; -0,494]	[-13,814; -7,350]	
Veränderung zu Woche 3/4			
n/N (%)	104/186 (56)	92/165 (56)	LS MD 6,04 [1,078; 10,999]
MW (SD)	0,32 (21,409)	-4,53 (21,270)	
LS MW (SE)	-1,45 (1,706)	-7,49 (1,864)	
95 %-KI	[-4,803; 1,903]	[-11,151; -3,826]	
Veränderung zu Woche 8/9			
n/N (%)	124/184 (67)	107/158 (68)	LS MD 6,53 [2,023; 11,033]
MW (SD)	-2,42 (25,828)	-9,97 (23,886)	
LS MW (SE)	-2,31 (1,554)	-8,84 (1,685)	
95 %-KI	[-5,369; 0,746]	[-12,154; -5,525]	
Veränderung zu Woche 12			
n/N (%)	83/179 (46)	60/153 (39)	LS MD 6,87 [2,512; 11,228]
MW (SD)	-0,20 (25,832)	-15,00 (23,309)	
LS MW (SE)	-2,92 (1,498)	-9,79 (1,633)	
95 %-KI	[-5,864; 0,034]	[-13,000; -6,571]	
Veränderung zu Woche 15/16			
n/N (%)	84/173 (49)	47/149 (32)	LS MD 7,21 [2,843; 11,583]
MW (SD)	-1,59 (26,839)	-10,99 (28,716)	
LS MW (SE)	-3,52 (1,489)	-10,73 (1,649)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,451; -0,586]	[-13,977; -7,485]	
Veränderung zu Woche 20/21			
n/N (%)	57/165 (35)	47/140 (34)	LS MD 7,70 [3,045; 12,360]
MW (SD)	-6,43 (26,680)	-8,51 (25,507)	
LS MW (SE)	-4,38 (1,560)	-12,08 (1,785)	
95 %-KI	[-7,450; -1,311]	[-15,592; -8,573]	
Veränderung zu Woche 24			
n/N (%)	46/159 (29)	34/131 (26)	LS MD 8,04 [3,022; 13,067]
MW (SD)	-5,43 (28,772)	-7,35 (22,915)	
LS MW (SE)	-4,98 (1,661)	-13,03 (1,945)	
95 %-KI	[-8,250; -1,717]	[-16,851; -9,205]	
Veränderung zu Woche 36			
n/N (%)	71/139 (51)	42/114 (37)	LS MD 9,22 [2,283; 16,155]
MW (SD)	-5,40 (26,544)	-14,68 (29,264)	
LS MW (SE)	-7,05 (2,231)	-16,27 (2,746)	
95 %-KI	[-11,431; -2,672]	[-21,661; -10,880]	
Veränderung zu Woche 48			
n/N (%)	7/121 (6)	5/95 (5)	LS MD 10,39 [1,027; 19,760]
MW (SD)	-9,52 (18,898)	3,33 (18,257)	
LS MW (SE)	-9,12 (2,983)	-19,51 (3,734)	
95 %-KI	[-14,974; -3,266]	[-26,841; -12,186]	
<b>Baseline ECOG PS: 0</b>			
Baseline			
n/N (%)	101/128 (79)	96/113 (85)	-
MW (SD)	81,19 (23,293)	82,47 (20,430)	
Absolute Werte zum Studienende			
n/N (%)	7/87 (8)	3/72 (4)	-
MW (SD)	64,29 (20,250)	77,78 (19,245)	
Effekt über Studiendauer			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n	101	96	LS MD 6,32 [1,463; 11,176] 0,0110  Hedges' g 0,36 [0,083; 0,646]
LS MW (SE)	-5,26 (1,681)	-11,58 (1,800)	
95 %-KI	[-8,580; -1,944]	[-15,131; -8,032]	
Veränderung zu Woche 3/4			
n/N (%)	70/127 (55)	64/111 (58)	LS MD 4,92 [-0,694; 10,534]
MW (SD)	-2,62 (18,309)	-5,73 (20,188)	
LS MW (SE)	-4,20 (1,951)	-9,12 (2,083)	
95 %-KI	[-8,043; -0,364]	[-13,220; -5,027]	
Veränderung zu Woche 8/9			
n/N (%)	85/126 (67)	75/108 (69)	LS MD 5,53 [0,469; 10,581]
MW (SD)	-3,53 (23,301)	-11,11 (21,805)	
LS MW (SE)	-4,66 (1,769)	-10,19 (1,861)	
95 %-KI	[-8,147; -1,175]	[-13,852; -6,521]	
Veränderung zu Woche 12			
n/N (%)	53/122 (43)	46/108 (43)	LS MD 5,95 [1,082; 10,816]
MW (SD)	-2,52 (26,834)	-15,94 (21,647)	
LS MW (SE)	-4,98 (1,698)	-10,93 (1,792)	
95 %-KI	[-8,332; -1,631]	[-14,464; -7,396]	
Veränderung zu Woche 15/16			
n/N (%)	55/120 (46)	35/105 (33)	LS MD 6,37 [1,505; 11,240]
MW (SD)	-5,76 (26,101)	-15,24 (26,621)	
LS MW (SE)	-5,30 (1,682)	-11,67 (1,806)	
95 %-KI	[-8,622; -1,981]	[-15,236; -8,112]	
Veränderung zu Woche 20/21			
n/N (%)	40/117 (34)	32/101 (32)	LS MD 6,98 [1,786; 12,168]
MW (SD)	-8,75 (22,954)	-11,98 (27,512)	
LS MW (SE)	-5,76 (1,756)	-12,74 (1,963)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-9,223; -2,296]	[-16,603; -8,871]	
Veränderung zu Woche 24			
n/N (%)	27/112 (24)	22/96 (23)	LS MD 7,40 [1,787; 13,015]
MW (SD)	-9,88 (22,768)	-7,58 (23,975)	
LS MW (SE)	-6,08 (1,869)	-13,48 (2,152)	
95 %-KI	[-9,762; -2,398]	[-17,715; -9,247]	
Veränderung zu Woche 36			
n/N (%)	51/99 (52)	34/87 (39)	LS MD 8,85 [1,004; 16,702]
MW (SD)	-4,58 (22,871)	-10,78 (29,268)	
LS MW (SE)	-7,18 (2,519)	-16,03 (3,094)	
95 %-KI	[-12,128; -2,230]	[-22,107; -9,956]	
Veränderung zu Woche 48			
n/N (%)	5/87 (6)	3/72 (4)	LS MD 10,30 [-0,376; 20,986]
MW (SD)	-10,00 (19,003)	5,56 (25,459)	
LS MW (SE)	-8,28 (3,382)	-18,58 (4,246)	
95 %-KI	[-14,918; -1,637]	[-26,920; -10,246]	
<b>Baseline ECOG PS: 1</b>			
Baseline			
n/N (%)	75/90 (83)	61/91 (67)	-
MW (SD)	64,89 (27,615)	66,39 (29,735)	
Absolute Werte zum Studienende			
n/N (%)	3/53 (6)	3/37 (8)	-
MW (SD)	77,78 (38,490)	100,00 (0,000)	
Effekt über Studiendauer			
n	75	61	LS MD 10,54 [3,710; 17,364] 0,0027
LS MW (SE)	-0,51 (2,240)	-11,04 (2,629)	
95 %-KI	[-4,942; 3,931]	[-16,241; -5,844]	Hedges' g 0,53 [0,182; 0,870]



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	50/86 (58)	45/87 (52)	LS MD 9,68 [2,034; 17,327]
MW (SD)	4,33 (23,764)	-5,19 (24,053)	
LS MW (SE)	1,96 (2,570)	-7,72 (2,907)	
95 %-KI	[-3,111; 7,022]	[-13,455; -1,995]	
Veränderung zu Woche 8/9			
n/N (%)	60/84 (71)	50/78 (64)	LS MD 10,07 [3,119; 17,028]
MW (SD)	0,00 (27,274)	-10,67 (28,524)	
LS MW (SE)	0,83 (2,333)	-9,25 (2,639)	
95 %-KI	[-3,785; 5,439]	[-14,460; -4,033]	
Veränderung zu Woche 12			
n/N (%)	45/83 (54)	24/74 (32)	LS MD 10,35 [3,566; 17,131]
MW (SD)	0,37 (24,743)	-13,19 (24,563)	
LS MW (SE)	0,04 (2,251)	-10,31 (2,591)	
95 %-KI	[-4,420; 4,493]	[-15,435; -5,189]	
Veränderung zu Woche 15/16			
n/N (%)	41/79 (52)	20/72 (28)	LS MD 10,62 [3,733; 17,515]
MW (SD)	4,07 (25,761)	-3,33 (29,912)	
LS MW (SE)	-0,75 (2,248)	-11,38 (2,666)	
95 %-KI	[-5,204; 3,698]	[-16,647; -6,107]	
Veränderung zu Woche 20/21			
n/N (%)	27/73 (37)	18/63 (29)	LS MD 11,02 [3,514; 18,520]
MW (SD)	-0,00 (29,235)	-5,56 (17,150)	
LS MW (SE)	-1,88 (2,378)	-12,90 (2,967)	
95 %-KI	[-6,583; 2,819]	[-18,750; -7,047]	
Veränderung zu Woche 24			
n/N (%)	27/72 (38)	15/58 (26)	LS MD 11,29 [3,096; 19,489]
MW (SD)	2,47 (31,250)	-6,67 (18,687)	
LS MW (SE)	-2,67 (2,552)	-13,96 (3,283)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-7,709; 2,365]	[-20,430; -7,498]	
Veränderung zu Woche 36			
n/N (%)	30/61 (49)	13/46 (28)	LS MD 12,24 [0,644; 23,827]
MW (SD)	-4,44 (29,339)	-21,79 (23,945)	
LS MW (SE)	-5,38 (3,491)	-17,62 (4,742)	
95 %-KI	[-12,246; 1,485]	[-26,937; -8,296]	
Veränderung zu Woche 48			
n/N (%)	3/53 (6)	2/37 (5)	LS MD 13,18 [-2,564; 28,922]
MW (SD)	-11,11 (19,245)	0,00 (0,000)	
LS MW (SE)	-8,09 (4,700)	-21,27 (6,468)	
95 %-KI	[-17,325; 1,147]	[-33,978; -8,558]	
<b>Anzahl vorheriger Therapielinien: 1</b>			
Baseline			
n/N (%)	23/31 (74)	23/29 (79)	-
MW (SD)	69,57 (35,764)	80,43 (19,235)	
Absolute Werte zum Studienende			
n/N (%)	1/22 (5)	0/14 (0)	-
MW (SD)	66,67 (NA)	NA (NA)	
Effekt über Studiendauer			
n	23	23	LS MD 3,93 [-7,324; 15,181] 0,4845
LS MW (SE)	-4,23 (3,843)	-8,16 (4,002)	
95 %-KI	[-12,015; 3,549]	[-16,235; -0,088]	Hedges' g 0,21 [-0,374; 0,785]
Veränderung zu Woche 3/4			
n/N (%)	15/31 (48)	15/29 (52)	LS MD 2,96 [-10,384; 16,300]
MW (SD)	0,00 (27,458)	1,11 (14,729)	
LS MW (SE)	-0,30 (4,630)	-3,25 (4,810)	
95 %-KI	[-9,520; 8,929]	[-12,818; 6,311]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	19/31 (61)	18/26 (69)	LS MD 3,37 [-8,512; 15,245]
MW (SD)	-0,00 (18,426)	-10,19 (34,838)	
LS MW (SE)	-1,95 (4,138)	-5,32 (4,198)	
95 %-KI	[-10,263; 6,356]	[-13,735; 3,094]	
Veränderung zu Woche 12			
n/N (%)	14/31 (45)	12/24 (50)	LS MD 3,65 [-7,689; 14,994]
MW (SD)	8,33 (22,408)	-9,72 (26,071)	
LS MW (SE)	-3,11 (3,925)	-6,77 (3,992)	
95 %-KI	[-11,040; 4,812]	[-14,812; 1,278]	
Veränderung zu Woche 15/16			
n/N (%)	15/31 (48)	11/22 (50)	LS MD 3,94 [-7,319; 15,196]
MW (SD)	1,11 (29,859)	-6,06 (25,025)	
LS MW (SE)	-4,28 (3,842)	-8,21 (4,006)	
95 %-KI	[-12,056; 3,506]	[-16,295; -0,132]	
Veränderung zu Woche 20/21			
n/N (%)	11/30 (37)	9/22 (41)	LS MD 4,35 [-7,577; 16,271]
MW (SD)	-10,61 (25,025)	-1,85 (17,568)	
LS MW (SE)	-5,93 (3,964)	-10,28 (4,396)	
95 %-KI	[-13,932; 2,065]	[-19,095; -1,466]	
Veränderung zu Woche 24			
n/N (%)	9/30 (30)	11/20 (55)	LS MD 4,63 [-8,253; 17,518]
MW (SD)	-14,81 (30,556)	-4,55 (25,918)	
LS MW (SE)	-7,09 (4,205)	-11,73 (4,877)	
95 %-KI	[-15,531; 1,343]	[-21,456; -1,998]	
Veränderung zu Woche 36			
n/N (%)	14/26 (54)	6/18 (33)	LS MD 5,61 [-12,632; 23,858]
MW (SD)	-10,71 (26,640)	-13,89 (32,347)	
LS MW (SE)	-11,07 (5,709)	-16,69 (7,261)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-22,374; 0,225]	[-31,045; -2,329]	
Veränderung zu Woche 48			
n/N (%)	0/22 (0)	0/14 (0)	LS MD 6,59 [-18,555; 31,741]
MW (SD)	NA (NA)	NA (NA)	
LS MW (SE)	-15,05 (7,755)	-21,65 (10,136)	
95 %-KI	[-30,362; 0,254]	[-41,659; -1,635]	
<b>Anzahl vorheriger Therapielinien: 2</b>			
Baseline			
n/N (%)	76/89 (85)	64/83 (77)	-
MW (SD)	73,03 (24,939)	72,66 (28,540)	
Absolute Werte zum Studienende			
n/N (%)	4/59 (7)	2/50 (4)	-
MW (SD)	45,83 (15,957)	100,00 (0,000)	
Effekt über Studiendauer			
n	76	64	LS MD 7,25 [0,993; 13,508] 0,0235  Hedges' g 0,39 [0,053; 0,725]
LS MW (SE)	-2,43 (2,057)	-9,68 (2,405)	
95 %-KI	[-6,504; 1,641]	[-14,435; -4,929]	
Veränderung zu Woche 3/4			
n/N (%)	53/86 (62)	46/80 (57)	LS MD 5,46 [-1,635; 12,554]
MW (SD)	0,31 (23,454)	-2,90 (22,582)	
LS MW (SE)	-0,18 (2,381)	-5,64 (2,703)	
95 %-KI	[-4,871; 4,514]	[-10,961; -0,314]	
Veränderung zu Woche 8/9			
n/N (%)	64/85 (75)	52/77 (68)	LS MD 6,27 [-0,133; 12,668]
MW (SD)	1,30 (26,776)	-7,69 (22,008)	
LS MW (SE)	-1,20 (2,156)	-7,46 (2,420)	
95 %-KI	[-5,455; 3,065]	[-12,243; -2,683]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	40/83 (48)	30/75 (40)	LS MD 6,83 [0,616; 13,051]
MW (SD)	-3,33 (24,807)	-16,67 (23,570)	
LS MW (SE)	-1,91 (2,073)	-8,74 (2,364)	
95 %-KI	[-6,009; 2,195]	[-13,414; -4,066]	
Veränderung zu Woche 15/16			
n/N (%)	42/80 (52)	20/74 (27)	LS MD 7,40 [1,091; 13,707]
MW (SD)	-3,17 (30,408)	-11,67 (30,156)	
LS MW (SE)	-2,62 (2,061)	-10,02 (2,435)	
95 %-KI	[-6,698; 1,461]	[-14,831; -5,205]	
Veränderung zu Woche 20/21			
n/N (%)	32/78 (41)	21/68 (31)	LS MD 8,21 [1,322; 15,093]
MW (SD)	-4,69 (26,517)	-11,11 (24,343)	
LS MW (SE)	-3,64 (2,166)	-11,84 (2,735)	
95 %-KI	[-7,918; 0,647]	[-17,236; -6,450]	
Veränderung zu Woche 24			
n/N (%)	27/74 (36)	13/65 (20)	LS MD 8,77 [1,224; 16,323]
MW (SD)	-0,00 (28,495)	-8,97 (12,938)	
LS MW (SE)	-4,35 (2,317)	-13,12 (3,051)	
95 %-KI	[-8,920; 0,226]	[-19,128; -7,113]	
Veränderung zu Woche 36			
n/N (%)	34/65 (52)	18/58 (31)	LS MD 10,71 [-0,086; 21,513]
MW (SD)	-4,41 (24,724)	-16,67 (28,583)	
LS MW (SE)	-6,79 (3,155)	-17,50 (4,497)	
95 %-KI	[-12,992; -0,582]	[-26,337; -8,664]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	1/50 (2)	LS MD 12,65 [-2,105; 27,411]
MW (SD)	-25,00 (9,623)	0,00 (NA)	
LS MW (SE)	-9,23 (4,250)	-21,88 (6,190)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-17,579; -0,876]	[-34,043; -9,718]	
<b>Anzahl vorheriger Therapielinien: 3</b>			
Baseline			
n/N (%)	77/98 (79)	71/95 (75)	-
MW (SD)	76,84 (24,655)	77,00 (26,029)	
Absolute Werte zum Studienende			
n/N (%)	5/59 (8)	4/46 (9)	-
MW (SD)	86,67 (18,257)	83,33 (19,245)	
Effekt über Studiendauer			
n	77	71	LS MD 10,21 [4,374; 16,041] 0,0007  Hedges' g 0,57 [0,237; 0,895]
LS MW (SE)	-3,35 (2,015)	-13,56 (2,164)	
95 %-KI	[-7,340; 0,633]	[-17,839; -9,284]	
Veränderung zu Woche 3/4			
n/N (%)	52/96 (54)	49/91 (54)	LS MD 9,28 [2,720; 15,835]
MW (SD)	0,32 (15,996)	-9,86 (22,026)	
LS MW (SE)	-3,32 (2,283)	-12,60 (2,431)	
95 %-KI	[-7,824; 1,177]	[-17,390; -7,811]	
Veränderung zu Woche 8/9			
n/N (%)	62/94 (66)	56/85 (66)	LS MD 9,69 [3,686; 15,692]
MW (SD)	-6,18 (24,561)	-13,99 (22,869)	
LS MW (SE)	-3,34 (2,089)	-13,03 (2,218)	
95 %-KI	[-7,464; 0,790]	[-17,406; -8,646]	
Veränderung zu Woche 12			
n/N (%)	44/91 (48)	29/84 (35)	LS MD 9,98 [4,147; 15,808]
MW (SD)	-2,27 (27,513)	-13,79 (21,853)	
LS MW (SE)	-3,35 (2,023)	-13,32 (2,157)	
95 %-KI	[-7,346; 0,653]	[-17,586; -9,062]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	39/88 (44)	24/82 (29)	LS MD 10,27 [4,412; 16,120]
MW (SD)	-0,85 (19,849)	-12,50 (28,763)	
LS MW (SE)	-3,36 (2,020)	-13,62 (2,174)	
95 %-KI	[-7,352; 0,640]	[-17,919; -9,324]	
Veränderung zu Woche 20/21			
n/N (%)	24/82 (29)	21/75 (28)	LS MD 10,68 [4,458; 16,897]
MW (SD)	-3,47 (25,997)	-9,52 (28,172)	
LS MW (SE)	-3,37 (2,127)	-14,05 (2,333)	
95 %-KI	[-7,572; 0,833]	[-18,650; -9,444]	
Veränderung zu Woche 24			
n/N (%)	18/80 (22)	14/70 (20)	LS MD 10,97 [4,288; 17,644]
MW (SD)	-3,70 (25,280)	-5,95 (25,826)	
LS MW (SE)	-3,38 (2,271)	-14,34 (2,522)	
95 %-KI	[-7,859; 1,101]	[-19,315; -9,374]	
Veränderung zu Woche 36			
n/N (%)	33/69 (48)	23/58 (40)	LS MD 11,95 [2,855; 21,054]
MW (SD)	-2,02 (25,603)	-11,59 (27,723)	
LS MW (SE)	-3,41 (3,055)	-15,37 (3,486)	
95 %-KI	[-9,418; 2,596]	[-22,218; -8,513]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	4/46 (9)	LS MD 12,94 [0,744; 25,142]
MW (SD)	4,17 (8,333)	4,17 (20,972)	
LS MW (SE)	-3,44 (4,076)	-16,39 (4,693)	
95 %-KI	[-11,452; 4,566]	[-25,608; -7,165]	
<b>Vorherige Verabreichung von Bevacizumab: Ja</b>			
Baseline			
n/N (%)	104/134 (78)	100/132 (76)	-
MW (SD)	75,00 (23,798)	74,33 (28,071)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	3/79 (4)	3/62 (5)	-
MW (SD)	61,11 (34,694)	88,89 (19,245)	
Effekt über Studiendauer			
n	104	100	LS MD 7,05 [2,031; 12,067] 0,0061  Hedges' g 0,39 [0,110; 0,664]
LS MW (SE)	-4,35 (1,722)	-11,39 (1,876)	
95 %-KI	[-7,744; -0,948]	[-15,093; -7,697]	
Veränderung zu Woche 3/4			
n/N (%)	67/130 (52)	69/127 (54)	LS MD 6,13 [0,338; 11,914]
MW (SD)	0,25 (17,285)	-7,25 (22,593)	
LS MW (SE)	-2,47 (2,016)	-8,60 (2,147)	
95 %-KI	[-6,438; 1,493]	[-12,821; -4,376]	
Veränderung zu Woche 8/9			
n/N (%)	85/130 (65)	77/119 (65)	LS MD 6,56 [1,395; 11,718]
MW (SD)	-3,53 (24,813)	-10,82 (25,329)	
LS MW (SE)	-3,35 (1,807)	-9,90 (1,899)	
95 %-KI	[-6,909; 0,215]	[-13,645; -6,163]	
Veränderung zu Woche 12			
n/N (%)	55/126 (44)	37/114 (32)	LS MD 6,86 [1,864; 11,853]
MW (SD)	-3,94 (27,771)	-12,16 (21,390)	
LS MW (SE)	-3,96 (1,733)	-10,82 (1,849)	
95 %-KI	[-7,379; -0,539]	[-14,463; -7,172]	
Veränderung zu Woche 15/16			
n/N (%)	58/122 (48)	32/112 (29)	LS MD 7,16 [2,082; 12,238]
MW (SD)	-1,44 (25,608)	-10,94 (28,275)	
LS MW (SE)	-4,57 (1,728)	-11,73 (1,912)	
95 %-KI	[-7,981; -1,161]	[-15,499; -7,963]	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	39/114 (34)	28/103 (27)	LS MD 7,59 [1,988; 13,194]
MW (SD)	-5,98 (26,070)	-3,57 (22,842)	
LS MW (SE)	-5,45 (1,838)	-13,04 (2,175)	
95 %-KI	[-9,068; -1,822]	[-17,316; -8,756]	
Veränderung zu Woche 24			
n/N (%)	29/109 (27)	17/95 (18)	LS MD 7,89 [1,694; 14,091]
MW (SD)	-6,90 (20,662)	-11,76 (24,127)	
LS MW (SE)	-6,06 (1,987)	-13,95 (2,449)	
95 %-KI	[-9,969; -2,145]	[-18,764; -9,135]	
Veränderung zu Woche 36			
n/N (%)	44/93 (47)	22/79 (28)	LS MD 8,93 [-0,133; 17,987]
MW (SD)	-5,30 (24,318)	-16,67 (28,637)	
LS MW (SE)	-8,16 (2,784)	-17,08 (3,683)	
95 %-KI	[-13,623; -2,688]	[-24,314; -9,850]	
Veränderung zu Woche 48			
n/N (%)	3/79 (4)	2/62 (3)	LS MD 9,96 [-2,529; 22,451]
MW (SD)	-16,67 (28,868)	0,00 (0,000)	
LS MW (SE)	-10,25 (3,795)	-20,21 (5,110)	
95 %-KI	[-17,705; -2,801]	[-30,249; -10,180]	
<b>Vorherige Verabreichung von Bevacizumab: Nein</b>			
Baseline			
n/N (%)	72/84 (86)	58/75 (77)	-
MW (SD)	73,15 (29,939)	78,16 (22,772)	
Absolute Werte zum Studienende			
n/N (%)	7/61 (11)	3/48 (6)	-
MW (SD)	71,43 (23,002)	88,89 (19,245)	
Effekt über Studiendauer			
n	72	58	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-1,61 (2,162)	-10,43 (2,459)	LS MD 8,82 [2,338; 15,303] 0,0081
95 %-KI	[-5,894; 2,671]	[-15,298; -5,566]	
Veränderung zu Woche 3/4			
n/N (%)	53/83 (64)	41/73 (56)	LS MD 7,73 [0,418; 15,034]
MW (SD)	0,31 (24,998)	-2,44 (19,917)	
LS MW (SE)	-0,25 (2,457)	-7,98 (2,775)	
95 %-KI	[-5,100; 4,591]	[-13,452; -2,510]	
Veränderung zu Woche 8/9			
n/N (%)	60/80 (75)	49/69 (71)	LS MD 8,18 [1,462; 14,899]
MW (SD)	0,00 (25,304)	-10,88 (23,460)	
LS MW (SE)	-0,82 (2,258)	-9,00 (2,540)	
95 %-KI	[-5,282; 3,646]	[-14,018; -3,979]	
Veränderung zu Woche 12			
n/N (%)	43/79 (54)	34/69 (49)	LS MD 8,50 [1,991; 15,006]
MW (SD)	2,33 (22,882)	-16,67 (24,958)	
LS MW (SE)	-1,21 (2,181)	-9,71 (2,460)	
95 %-KI	[-5,530; 3,106]	[-14,578; -4,843]	
Veränderung zu Woche 15/16			
n/N (%)	38/77 (49)	23/66 (35)	LS MD 8,82 [2,335; 15,298]
MW (SD)	-1,75 (27,615)	-10,87 (28,696)	
LS MW (SE)	-1,61 (2,162)	-10,42 (2,458)	
95 %-KI	[-5,888; 2,676]	[-15,288; -5,558]	
Veränderung zu Woche 20/21			
n/N (%)	28/76 (37)	23/62 (37)	LS MD 9,27 [2,506; 16,036]
MW (SD)	-4,17 (25,909)	-15,22 (26,070)	
LS MW (SE)	-2,17 (2,237)	-11,44 (2,590)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,595; 2,256]	[-16,558; -6,322]	
Veränderung zu Woche 24			
n/N (%)	25/75 (33)	21/60 (35)	LS MD 9,59 [2,421; 16,757]
MW (SD)	-0,00 (34,359)	-2,38 (19,211)	
LS MW (SE)	-2,56 (2,356)	-12,15 (2,765)	
95 %-KI	[-7,216; 2,089]	[-17,608; -6,696]	
Veränderung zu Woche 36			
n/N (%)	37/67 (55)	25/55 (45)	LS MD 10,68 [1,215; 20,143]
MW (SD)	-3,60 (26,683)	-11,33 (27,938)	
LS MW (SE)	-3,91 (3,062)	-14,59 (3,718)	
95 %-KI	[-9,938; 2,108]	[-21,905; -7,283]	
Veränderung zu Woche 48			
n/N (%)	5/61 (8)	3/48 (6)	LS MD 11,77 [-0,770; 24,309]
MW (SD)	-6,67 (9,129)	5,56 (25,459)	
LS MW (SE)	-5,27 (4,029)	-17,04 (4,959)	
95 %-KI	[-13,183; 2,651]	[-26,779; -7,292]	
<b>Letztes Platin-freies Intervall: ≤ 3 Monate</b>			
Baseline			
n/N (%)	68/83 (82)	62/91 (68)	-
MW (SD)	77,94 (22,936)	72,31 (28,140)	
Absolute Werte zum Studienende			
n/N (%)	3/55 (5)	5/39 (13)	-
MW (SD)	72,22 (25,459)	86,67 (18,257)	
Effekt über Studiendauer			
n	68	62	LS MD 10,15 [4,237; 16,072] 0,0009
LS MW (SE)	-2,47 (1,992)	-12,62 (2,226)	
95 %-KI	[-6,413; 1,483]	[-17,026; -8,213]	Hedges' g 0,60 [0,243; 0,947]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	49/82 (60)	46/86 (53)	LS MD 9,42 [2,534; 16,302]
MW (SD)	0,34 (17,176)	-5,43 (22,786)	
LS MW (SE)	-2,76 (2,359)	-12,18 (2,565)	
95 %-KI	[-7,415; 1,887]	[-17,236; -7,128]	
Veränderung zu Woche 8/9			
n/N (%)	52/81 (64)	45/80 (56)	LS MD 9,75 [3,623; 15,885]
MW (SD)	-5,77 (23,076)	-12,96 (27,036)	
LS MW (SE)	-2,63 (2,087)	-12,38 (2,288)	
95 %-KI	[-6,755; 1,500]	[-16,902; -7,861]	
Veränderung zu Woche 12			
n/N (%)	33/78 (42)	25/78 (32)	LS MD 9,99 [4,082; 15,895]
MW (SD)	-1,01 (24,274)	-14,67 (26,926)	
LS MW (SE)	-2,53 (1,997)	-12,52 (2,213)	
95 %-KI	[-6,490; 1,425]	[-16,900; -8,142]	
Veränderung zu Woche 15/16			
n/N (%)	35/76 (46)	14/75 (19)	LS MD 10,22 [4,260; 16,187]
MW (SD)	-1,43 (25,040)	-13,10 (32,803)	
LS MW (SE)	-2,44 (2,004)	-12,66 (2,248)	
95 %-KI	[-6,409; 1,535]	[-17,111; -8,211]	
Veränderung zu Woche 20/21			
n/N (%)	22/72 (31)	14/67 (21)	LS MD 10,56 [4,049; 17,070]
MW (SD)	-8,33 (19,754)	-11,90 (28,063)	
LS MW (SE)	-2,30 (2,177)	-12,86 (2,478)	
95 %-KI	[-6,606; 2,004]	[-17,755; -7,966]	
Veränderung zu Woche 24			
n/N (%)	16/72 (22)	12/62 (19)	LS MD 10,79 [3,632; 17,957]
MW (SD)	1,04 (23,936)	-5,56 (21,711)	
LS MW (SE)	-2,21 (2,393)	-13,00 (2,738)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,927; 2,516]	[-18,401; -7,599]	
Veränderung zu Woche 36			
n/N (%)	28/63 (44)	18/50 (36)	LS MD 11,60 [1,206; 21,995]
MW (SD)	-1,79 (20,457)	-10,19 (25,654)	
LS MW (SE)	-1,88 (3,478)	-13,48 (3,990)	
95 %-KI	[-8,718; 4,961]	[-21,327; -5,631]	
Veränderung zu Woche 48			
n/N (%)	2/55 (4)	4/39 (10)	LS MD 12,41 [-1,925; 26,738]
MW (SD)	-16,67 (23,570)	4,17 (20,972)	
LS MW (SE)	-1,55 (4,807)	-13,96 (5,492)	
95 %-KI	[-11,000; 7,897]	[-24,755; -3,161]	
<b>Letztes Platin-freies Intervall: &gt; 3 Monate</b>			
Baseline			
n/N (%)	108/135 (80)	96/116 (83)	-
MW (SD)	71,91 (28,245)	77,95 (24,838)	
Absolute Werte zum Studienende			
n/N (%)	7/85 (8)	1/71 (1)	-
MW (SD)	66,67 (27,217)	100,00 (NA)	
Effekt über Studiendauer			
n	108	96	LS MD 6,24 [0,966; 11,509] 0,0206  Hedges' g 0,33 [0,051; 0,604]
LS MW (SE)	-3,60 (1,793)	-9,83 (1,976)	
95 %-KI	[-7,136; -0,059]	[-13,730; -5,939]	
Veränderung zu Woche 3/4			
n/N (%)	71/131 (54)	64/114 (56)	LS MD 4,77 [-1,229; 10,770]
MW (SD)	0,23 (23,315)	-5,47 (21,010)	
LS MW (SE)	-0,90 (2,050)	-5,67 (2,249)	
95 %-KI	[-4,937; 3,132]	[-10,096; -1,251]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	93/129 (72)	81/108 (75)	LS MD 5,41 [-0,042; 10,862]
MW (SD)	0,00 (25,890)	-9,67 (23,104)	
LS MW (SE)	-2,08 (1,879)	-7,49 (2,023)	
95 %-KI	[-5,780; 1,625]	[-11,474; -3,501]	
Veränderung zu Woche 12			
n/N (%)	65/127 (51)	46/105 (44)	LS MD 5,86 [0,583; 11,131]
MW (SD)	-1,28 (26,730)	-14,13 (21,072)	
LS MW (SE)	-2,90 (1,812)	-8,76 (1,961)	
95 %-KI	[-6,473; 0,674]	[-12,622; -4,892]	
Veränderung zu Woche 15/16			
n/N (%)	61/123 (50)	41/103 (40)	LS MD 6,30 [1,019; 11,591]
MW (SD)	-1,64 (27,166)	-10,16 (26,843)	
LS MW (SE)	-3,72 (1,794)	-10,03 (1,985)	
95 %-KI	[-7,262; -0,182]	[-13,940; -6,113]	
Veränderung zu Woche 20/21			
n/N (%)	45/118 (38)	37/98 (38)	LS MD 6,94 [1,319; 12,569]
MW (SD)	-3,70 (28,402)	-7,66 (23,764)	
LS MW (SE)	-4,90 (1,857)	-11,84 (2,164)	
95 %-KI	[-8,558; -1,235]	[-16,101; -7,580]	
Veränderung zu Woche 24			
n/N (%)	38/112 (34)	26/93 (28)	LS MD 7,39 [1,333; 13,450]
MW (SD)	-5,70 (29,326)	-7,05 (22,198)	
LS MW (SE)	-5,72 (1,958)	-13,11 (2,372)	
95 %-KI	[-9,576; -1,862]	[-17,775; -8,445]	
Veränderung zu Woche 36			
n/N (%)	53/97 (55)	29/84 (35)	LS MD 8,93 [0,576; 17,275]
MW (SD)	-5,97 (27,560)	-16,09 (29,708)	
LS MW (SE)	-8,54 (2,561)	-17,46 (3,391)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-13,568; -3,507]	[-24,122; -10,805]	
Veränderung zu Woche 48			
n/N (%)	6/85 (7)	1/71 (1)	LS MD 10,46 [-0,809; 21,728]
MW (SD)	-8,33 (17,480)	0,00 (NA)	
LS MW (SE)	-11,36 (3,384)	-21,82 (4,633)	
95 %-KI	[-18,000; -4,714]	[-30,912; -12,721]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Pegyliertes liposomales Doxorubicin</b>			
Baseline			
n/N (%)	62/80 (78)	57/76 (75)	-
MW (SD)	75,27 (25,915)	81,58 (20,090)	
Absolute Werte zum Studienende			
n/N (%)	3/51 (6)	3/41 (7)	-
MW (SD)	55,56 (19,245)	88,89 (19,245)	
Effekt über Studiendauer			
n	62	57	LS MD 6,81 [0,434; 13,183] 0,0365  Hedges' g 0,39 [0,025; 0,751]
LS MW (SE)	-6,28 (2,148)	-13,08 (2,384)	
95 %-KI	[-10,539; -2,014]	[-17,806; -8,364]	
Veränderung zu Woche 3/4			
n/N (%)	42/76 (55)	43/74 (58)	LS MD 5,84 [-1,665; 13,347]
MW (SD)	-0,00 (18,033)	-6,59 (16,322)	
LS MW (SE)	-3,48 (2,596)	-9,32 (2,774)	
95 %-KI	[-8,595; 1,643]	[-14,785; -3,850]	
Veränderung zu Woche 8/9			
n/N (%)	52/76 (68)	43/66 (65)	LS MD 6,26 [-0,393; 12,921]
MW (SD)	-4,17 (23,074)	-11,63 (26,361)	
LS MW (SE)	-4,70 (2,302)	-10,96 (2,446)	
95 %-KI	[-9,255; -0,147]	[-15,799; -6,131]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	34/75 (45)	23/64 (36)	LS MD 6,56 [0,182; 12,938]
MW (SD)	-5,39 (24,177)	-19,57 (21,703)	
LS MW (SE)	-5,56 (2,183)	-12,12 (2,357)	
95 %-KI	[-9,885; -1,231]	[-16,784; -7,453]	
Veränderung zu Woche 15/16			
n/N (%)	35/74 (47)	19/62 (31)	LS MD 6,86 [0,459; 13,254]
MW (SD)	-7,62 (26,918)	-20,18 (28,642)	
LS MW (SE)	-6,42 (2,149)	-13,27 (2,400)	
95 %-KI	[-10,679; -2,152]	[-18,024; -8,519]	
Veränderung zu Woche 20/21			
n/N (%)	27/72 (38)	18/59 (31)	LS MD 7,28 [0,349; 14,209]
MW (SD)	-9,26 (20,325)	-15,74 (24,570)	
LS MW (SE)	-7,64 (2,253)	-14,92 (2,676)	
95 %-KI	[-12,103; -3,177]	[-20,205; -9,634]	
Veränderung zu Woche 24			
n/N (%)	22/69 (32)	16/54 (30)	LS MD 7,58 [-0,024; 15,175]
MW (SD)	-8,33 (26,100)	-3,13 (22,948)	
LS MW (SE)	-8,50 (2,422)	-16,07 (2,985)	
95 %-KI	[-13,285; -3,709]	[-21,959; -10,186]	
Veränderung zu Woche 36			
n/N (%)	30/60 (50)	16/48 (33)	LS MD 8,59 [-2,419; 19,601]
MW (SD)	-8,89 (27,589)	-19,79 (34,544)	
LS MW (SE)	-11,44 (3,395)	-20,03 (4,443)	
95 %-KI	[-18,115; -4,758]	[-28,765; -11,289]	
Veränderung zu Woche 48			
n/N (%)	2/51 (4)	2/41 (5)	LS MD 9,61 [-5,608; 24,820]
MW (SD)	-16,67 (0,000)	-8,33 (11,785)	
LS MW (SE)	-14,38 (4,662)	-23,98 (6,168)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-23,540; -5,211]	[-36,107; -11,856]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Paclitaxel</b>			
Baseline			
n/N (%)	75/88 (85)	70/82 (85)	-
MW (SD)	71,78 (27,259)	70,95 (31,043)	
Absolute Werte zum Studienende			
n/N (%)	1/56 (2)	1/49 (2)	-
MW (SD)	50,00 (NA)	100,00 (NA)	
Effekt über Studiendauer			
n	75	70	LS MD 7,86 [1,848; 13,870] 0,0108  Hedges' g 0,43 [0,098; 0,757]
LS MW (SE)	-1,66 (2,072)	-9,52 (2,230)	
95 %-KI	[-5,758; 2,440]	[-13,926; -5,110]	
Veränderung zu Woche 3/4			
n/N (%)	55/87 (63)	49/81 (60)	LS MD 7,41 [0,491; 14,332]
MW (SD)	1,82 (23,717)	-3,06 (25,836)	
LS MW (SE)	0,14 (2,390)	-7,27 (2,580)	
95 %-KI	[-4,565; 4,854]	[-12,347; -2,187]	
Veränderung zu Woche 8/9			
n/N (%)	63/86 (73)	56/79 (71)	LS MD 7,61 [1,384; 13,843]
MW (SD)	0,79 (28,149)	-9,23 (23,338)	
LS MW (SE)	-0,67 (2,161)	-8,28 (2,303)	
95 %-KI	[-4,939; 3,597]	[-12,832; -3,738]	
Veränderung zu Woche 12			
n/N (%)	43/84 (51)	36/77 (47)	LS MD 7,76 [1,742; 13,768]
MW (SD)	-0,78 (27,925)	-13,89 (25,355)	
LS MW (SE)	-1,24 (2,081)	-9,00 (2,222)	
95 %-KI	[-5,359; 2,875]	[-13,390; -4,605]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	45/81 (56)	28/76 (37)	LS MD 7,90 [1,853; 13,941]
MW (SD)	2,22 (28,114)	-6,55 (30,205)	
LS MW (SE)	-1,81 (2,079)	-9,71 (2,247)	
95 %-KI	[-5,926; 2,299]	[-14,151; -5,269]	
Veränderung zu Woche 20/21			
n/N (%)	29/77 (38)	26/73 (36)	LS MD 8,10 [1,596; 14,602]
MW (SD)	-7,47 (28,026)	-9,62 (24,117)	
LS MW (SE)	-2,63 (2,206)	-10,73 (2,455)	
95 %-KI	[-6,986; 1,729]	[-15,571; -5,885]	
Veränderung zu Woche 24			
n/N (%)	21/74 (28)	19/72 (26)	LS MD 8,24 [1,168; 15,314]
MW (SD)	-4,76 (29,881)	-10,53 (22,368)	
LS MW (SE)	-3,20 (2,375)	-11,44 (2,700)	
95 %-KI	[-7,884; 1,485]	[-16,759; -6,122]	
Veränderung zu Woche 36			
n/N (%)	36/64 (56)	24/63 (38)	LS MD 8,73 [-1,271; 18,724]
MW (SD)	-3,70 (21,496)	-11,81 (25,763)	
LS MW (SE)	-5,16 (3,282)	-13,88 (3,902)	
95 %-KI	[-11,608; 1,293]	[-21,552; -6,215]	
Veränderung zu Woche 48			
n/N (%)	1/56 (2)	1/49 (2)	LS MD 9,21 [-4,433; 22,856]
MW (SD)	-33,33 (NA)	33,33 (NA)	
LS MW (SE)	-7,12 (4,439)	-16,33 (5,362)	
95 %-KI	[-15,837; 1,606]	[-26,861; -5,792]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Topotecan</b>			
Baseline			
n/N (%)	39/50 (78)	31/49 (63)	-
MW (SD)	77,35 (25,788)	75,81 (22,705)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	6/33 (18)	2/20 (10)	-
MW (SD)	77,78 (27,217)	83,33 (23,570)	
Effekt über Studiendauer			
n	39	31	LS MD 11,00 [1,496; 20,503] 0,0240  Hedges' g 0,55 [0,070; 1,031]
LS MW (SE)	-1,13 (3,115)	-12,13 (3,619)	
95 %-KI	[-7,356; 5,094]	[-19,348; -4,914]	
Veränderung zu Woche 3/4			
n/N (%)	23/50 (46)	18/45 (40)	LS MD 8,77 [-1,277; 18,812]
MW (SD)	-2,90 (19,235)	-9,26 (20,787)	
LS MW (SE)	-1,57 (3,324)	-10,34 (3,824)	
95 %-KI	[-8,187; 5,037]	[-17,942; -2,743]	
Veränderung zu Woche 8/9			
n/N (%)	30/48 (62)	27/43 (63)	LS MD 9,73 [0,163; 19,298]
MW (SD)	-4,44 (20,960)	-12,96 (24,605)	
LS MW (SE)	-1,38 (3,167)	-11,11 (3,621)	
95 %-KI	[-7,703; 4,935]	[-18,332; -3,896]	
Veränderung zu Woche 12			
n/N (%)	21/46 (46)	12/42 (29)	LS MD 10,40 [0,953; 19,856]
MW (SD)	4,76 (23,654)	-5,56 (16,412)	
LS MW (SE)	-1,25 (3,116)	-11,65 (3,581)	
95 %-KI	[-7,476; 4,977]	[-18,798; -4,509]	
Veränderung zu Woche 15/16			
n/N (%)	16/44 (36)	8/40 (20)	LS MD 11,08 [1,557; 20,600]
MW (SD)	1,04 (16,632)	-4,17 (11,785)	
LS MW (SE)	-1,12 (3,118)	-12,19 (3,629)	
95 %-KI	[-7,346; 5,115]	[-19,430; -4,958]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	11/41 (27)	7/33 (21)	LS MD 12,04 [2,106; 21,976]
MW (SD)	10,61 (28,159)	11,90 (18,545)	
LS MW (SE)	-0,92 (3,209)	-12,97 (3,843)	
95 %-KI	[-7,325; 5,477]	[-20,606; -5,324]	
Veränderung zu Woche 24			
n/N (%)	11/41 (27)	3/29 (10)	LS MD 12,72 [2,289; 23,142]
MW (SD)	7,58 (26,208)	0,00 (0,000)	
LS MW (SE)	-0,79 (3,331)	-13,51 (4,081)	
95 %-KI	[-7,421; 5,841]	[-21,601; -5,410]	
Veränderung zu Woche 36			
n/N (%)	15/36 (42)	7/23 (30)	LS MD 15,03 [1,949; 28,104]
MW (SD)	2,22 (28,776)	-7,14 (18,898)	
LS MW (SE)	-0,33 (4,038)	-15,36 (5,288)	
95 %-KI	[-8,316; 7,655]	[-25,793; -4,921]	
Veränderung zu Woche 48			
n/N (%)	5/33 (15)	2/20 (10)	LS MD 17,34 [0,688; 33,986]
MW (SD)	-3,33 (18,257)	0,00 (0,000)	
LS MW (SE)	0,13 (5,034)	-17,21 (6,836)	
95 %-KI	[-9,800; 10,058]	[-30,684; -3,733]	
<p><i>Analysepopulation: ITT</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023</i></p> <p><i>Modell: Veränderung zu Baseline ~ Behandlung + Baseline-Wert * Zeit in Wochen + Behandlung * Zeit in Wochen + zufällige Effekte durch die Patientin</i></p> <p><i>Die Berechnung des LS-MWs erfolgt durch ein MMRM mit dem oben angegebenen Modell. Basierend hierauf werden KI und p-Wert ermittelt. Hedges' g basiert ebenfalls auf den LS-MW und ist somit auf das Modell angepasst.</i></p> <p><i>Es werden ausschließlich gemeinsame Analysezeitpunkte dargestellt.</i></p> <p><i>Ein LS MD und Hedges' g größer als Null bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

## 2.14 EORTC QLQ-C30 soziale Funktion

### EORTC QLQ-C30 soziale Funktion: Subgruppenanalyse

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
<b>EORTC QLQ-C30 soziale Funktion</b>			
<b>Alter: &lt; 65 Jahre</b>			
Baseline			
n/N (%)	94/115 (82)	92/119 (77)	-
MW (SD)	70,92 (26,089)	71,01 (28,695)	
Absolute Werte zum Studienende			
n/N (%)	4/73 (5)	4/64 (6)	-
MW (SD)	79,17 (15,957)	79,17 (15,957)	
Effekt über Studiendauer			
n	94	92	LS MD 6,46 [0,603; 12,314] 0,0308  Hedges' g 0,32 [0,029; 0,607]
LS MW (SE)	-0,28 (2,070)	-6,74 (2,127)	
95 %-KI	[-4,370; 3,802]	[-10,938; -2,548]	
Veränderung zu Woche 3/4			
n/N (%)	60/113 (53)	61/115 (53)	LS MD 1,95 [-4,202; 8,098]
MW (SD)	2,50 (17,037)	0,27 (26,439)	
LS MW (SE)	0,88 (2,183)	-1,07 (2,232)	
95 %-KI	[-3,423; 5,183]	[-5,465; 3,329]	
Veränderung zu Woche 8/9			
n/N (%)	75/112 (67)	72/108 (67)	LS MD 3,93 [-1,977; 9,846]
MW (SD)	2,00 (29,378)	-7,64 (27,964)	
LS MW (SE)	0,37 (2,102)	-3,57 (2,138)	
95 %-KI	[-3,779; 4,513]	[-7,785; 0,650]	
Veränderung zu Woche 12			
n/N (%)	48/110 (44)	40/105 (38)	
MW (SD)	0,00 (33,333)	-5,42 (20,109)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	0,01 (2,074)	-5,32 (2,117)	LS MD 5,33 [-0,520; 11,171]
95 %-KI	[-4,085; 4,101]	[-9,493; -1,142]	
Veränderung zu Woche 15/16			
n/N (%)	55/107 (51)	33/102 (32)	LS MD 6,72 [0,850; 12,582]
MW (SD)	-3,03 (26,853)	-1,01 (28,849)	
LS MW (SE)	-0,35 (2,072)	-7,07 (2,132)	
95 %-KI	[-4,440; 3,738]	[-11,273; -2,861]	
Veränderung zu Woche 20/21			
n/N (%)	37/101 (37)	30/96 (31)	LS MD 8,70 [2,661; 14,744]
MW (SD)	0,00 (29,397)	1,11 (24,343)	
LS MW (SE)	-0,86 (2,113)	-9,57 (2,218)	
95 %-KI	[-5,032; 3,304]	[-13,938; -5,195]	
Veränderung zu Woche 24			
n/N (%)	25/99 (25)	19/91 (21)	LS MD 10,09 [3,832; 16,354]
MW (SD)	2,00 (25,604)	-7,89 (22,477)	
LS MW (SE)	-1,22 (2,171)	-11,32 (2,318)	
95 %-KI	[-5,503; 3,057]	[-15,881; -6,751]	
Veränderung zu Woche 36			
n/N (%)	41/86 (48)	28/79 (35)	LS MD 14,86 [7,362; 22,360]
MW (SD)	0,81 (18,985)	-15,48 (32,371)	
LS MW (SE)	-2,45 (2,526)	-17,31 (2,852)	
95 %-KI	[-7,421; 2,513]	[-22,919; -11,710]	
Veränderung zu Woche 48			
n/N (%)	4/73 (5)	3/64 (5)	LS MD 19,63 [10,389; 28,869]
MW (SD)	8,33 (31,914)	16,67 (44,096)	
LS MW (SE)	-3,68 (3,049)	-23,31 (3,574)	
95 %-KI	[-9,672; 2,303]	[-30,329; -16,299]	
<b>Alter: ≥ 65 Jahre</b>			
Baseline			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	81/103 (79)	67/88 (76)	-
MW (SD)	72,63 (28,051)	75,87 (26,950)	
Absolute Werte zum Studienende			
n/N (%)	6/67 (9)	2/46 (4)	-
MW (SD)	91,67 (13,944)	100,00 (0,000)	
Effekt über Studiendauer			
n	81	67	LS MD 7,14 [1,413; 12,873] 0,0149  Hedges' g 0,41 [0,078; 0,732]
LS MW (SE)	0,33 (1,931)	-6,81 (2,162)	
95 %-KI	[-3,486; 4,150]	[-11,083; -2,538]	
Veränderung zu Woche 3/4			
n/N (%)	60/100 (60)	49/85 (58)	LS MD 9,31 [3,275; 15,338]
MW (SD)	1,94 (23,388)	-3,74 (22,117)	
LS MW (SE)	3,47 (2,038)	-5,83 (2,277)	
95 %-KI	[-0,550; 7,497]	[-10,326; -1,341]	
Veränderung zu Woche 8/9			
n/N (%)	69/98 (70)	55/80 (69)	LS MD 8,34 [2,553; 14,119]
MW (SD)	4,59 (24,899)	-6,97 (21,201)	
LS MW (SE)	2,06 (1,958)	-6,27 (2,174)	
95 %-KI	[-1,805; 5,934]	[-10,566; -1,977]	
Veränderung zu Woche 12			
n/N (%)	50/95 (53)	31/78 (40)	LS MD 7,66 [1,939; 13,374]
MW (SD)	4,33 (22,540)	-11,29 (23,722)	
LS MW (SE)	1,08 (1,933)	-6,58 (2,151)	
95 %-KI	[-2,743; 4,899]	[-10,830; -2,327]	
Veränderung zu Woche 15/16			
n/N (%)	41/92 (45)	22/76 (29)	
MW (SD)	4,07 (21,660)	-10,61 (24,422)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	0,09 (1,934)	-6,89 (2,171)	LS MD 6,98 [1,232; 12,723]
95 %-KI	[-3,731; 3,916]	[-11,175; -2,596]	
Veränderung zu Woche 20/21			
n/N (%)	30/89 (34)	21/69 (30)	LS MD 6,01 [0,064; 11,949]
MW (SD)	5,00 (20,599)	1,59 (16,587)	
LS MW (SE)	-1,32 (1,982)	-7,32 (2,271)	
95 %-KI	[-5,232; 2,598]	[-11,804; -2,843]	
Veränderung zu Woche 24			
n/N (%)	28/85 (33)	19/64 (30)	LS MD 5,33 [-0,856; 11,511]
MW (SD)	6,55 (22,834)	-3,51 (16,272)	
LS MW (SE)	-2,30 (2,045)	-7,63 (2,385)	
95 %-KI	[-6,340; 1,735]	[-12,332; -2,929]	
Veränderung zu Woche 36			
n/N (%)	39/74 (53)	20/55 (36)	LS MD 3,00 [-4,516; 10,512]
MW (SD)	-5,13 (22,991)	-8,33 (32,218)	
LS MW (SE)	-5,68 (2,419)	-8,68 (2,985)	
95 %-KI	[-10,444; -0,924]	[-14,549; -2,815]	
Veränderung zu Woche 48			
n/N (%)	3/67 (4)	2/46 (4)	LS MD 0,67 [-8,686; 10,023]
MW (SD)	-5,56 (9,623)	8,33 (11,785)	
LS MW (SE)	-9,07 (2,956)	-9,73 (3,781)	
95 %-KI	[-14,872; -3,258]	[-17,156; -2,311]	
<b>Region: USA</b>			
Baseline			
n/N (%)	49/65 (75)	34/51 (67)	-
MW (SD)	68,37 (29,314)	77,45 (24,578)	
Absolute Werte zum Studienende			
n/N (%)	2/39 (5)	3/27 (11)	-
MW (SD)	91,67 (11,785)	88,89 (19,245)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Effekt über Studiendauer			
n	49	34	LS MD 6,84 [-0,376; 14,058] 0,0629  Hedges' g 0,42 [-0,022; 0,862]
LS MW (SE)	2,80 (2,302)	-4,04 (2,772)	
95 %-KI	[-1,787; 7,382]	[-9,560; 1,473]	
Veränderung zu Woche 3/4			
n/N (%)	33/64 (52)	21/49 (43)	LS MD 7,69 [0,004; 15,375]
MW (SD)	0,51 (19,758)	-2,38 (13,214)	
LS MW (SE)	2,99 (2,448)	-4,70 (2,973)	
95 %-KI	[-1,871; 7,844]	[-10,597; 1,193]	
Veränderung zu Woche 8/9			
n/N (%)	42/62 (68)	30/46 (65)	LS MD 7,31 [-0,022; 14,636]
MW (SD)	7,14 (26,581)	-7,78 (22,203)	
LS MW (SE)	2,90 (2,340)	-4,41 (2,819)	
95 %-KI	[-1,753; 7,556]	[-10,009; 1,199]	
Veränderung zu Woche 12			
n/N (%)	26/59 (44)	16/45 (36)	LS MD 7,04 [-0,181; 14,259]
MW (SD)	7,69 (25,919)	-14,58 (29,107)	
LS MW (SE)	2,84 (2,305)	-4,20 (2,772)	
95 %-KI	[-1,748; 7,431]	[-9,714; 1,319]	
Veränderung zu Woche 15/16			
n/N (%)	21/56 (38)	11/44 (25)	LS MD 6,77 [-0,460; 14,003]
MW (SD)	7,14 (23,316)	-1,52 (24,100)	
LS MW (SE)	2,78 (2,306)	-3,99 (2,779)	
95 %-KI	[-1,810; 7,373]	[-9,519; 1,540]	
Veränderung zu Woche 20/21			
n/N (%)	13/54 (24)	9/40 (22)	
MW (SD)	14,10 (16,452)	1,85 (15,466)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	2,70 (2,368)	-3,69 (2,880)	LS MD 6,39 [-1,067; 13,844]
95 %-KI	[-2,012; 7,405]	[-9,413; 2,028]	
Veränderung zu Woche 24			
n/N (%)	9/53 (17)	6/38 (16)	LS MD 6,12 [-1,629; 13,870]
MW (SD)	11,11 (20,412)	-5,56 (8,607)	
LS MW (SE)	2,64 (2,452)	-3,48 (3,010)	
95 %-KI	[-2,230; 7,503]	[-9,451; 2,483]	
Veränderung zu Woche 36			
n/N (%)	22/43 (51)	10/33 (30)	LS MD 5,20 [-4,235; 14,641]
MW (SD)	2,27 (24,286)	-6,67 (16,102)	
LS MW (SE)	2,43 (2,941)	-2,77 (3,735)	
95 %-KI	[-3,372; 8,234]	[-10,133; 4,591]	
Veränderung zu Woche 48			
n/N (%)	2/39 (5)	3/27 (11)	LS MD 4,28 [-7,530; 16,099]
MW (SD)	16,67 (23,570)	-0,00 (16,667)	
LS MW (SE)	2,23 (3,637)	-2,06 (4,727)	
95 %-KI	[-4,929; 9,381]	[-11,355; 7,238]	
<b>Region: Rest der Welt</b>			
Baseline			
n/N (%)	126/153 (82)	125/156 (80)	-
MW (SD)	73,02 (25,979)	71,87 (28,822)	
Absolute Werte zum Studienende			
n/N (%)	8/101 (8)	3/83 (4)	-
MW (SD)	85,42 (16,517)	83,33 (16,667)	
Effekt über Studiendauer			
n	126	125	LS MD 6,74 [1,743; 11,733] 0,0084  Hedges' g
LS MW (SE)	-0,92 (1,769)	-7,66 (1,819)	
95 %-KI	[-4,403; 2,565]	[-11,240; -4,074]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
			0,33 [0,085; 0,583]
Veränderung zu Woche 3/4			
n/N (%)	87/149 (58)	89/151 (59)	LS MD 4,68 [-0,548; 9,909]
MW (SD)	2,87 (20,681)	-1,31 (26,617)	
LS MW (SE)	1,83 (1,860)	-2,85 (1,899)	
95 %-KI	[-1,833; 5,488]	[-6,590; 0,883]	
Veränderung zu Woche 8/9			
n/N (%)	102/148 (69)	97/142 (68)	LS MD 5,59 [0,556; 10,625]
MW (SD)	1,63 (27,502)	-7,22 (26,122)	
LS MW (SE)	0,61 (1,794)	-4,98 (1,823)	
95 %-KI	[-2,920; 4,146]	[-8,567; -1,387]	
Veränderung zu Woche 12			
n/N (%)	72/146 (49)	55/138 (40)	LS MD 6,23 [1,243; 11,211]
MW (SD)	0,23 (29,002)	-6,06 (19,074)	
LS MW (SE)	-0,24 (1,771)	-6,46 (1,808)	
95 %-KI	[-3,726; 3,253]	[-10,025; -2,903]	
Veränderung zu Woche 15/16			
n/N (%)	75/143 (52)	44/134 (33)	LS MD 6,86 [1,858; 11,869]
MW (SD)	-2,00 (25,106)	-5,68 (28,290)	
LS MW (SE)	-1,09 (1,770)	-7,95 (1,825)	
95 %-KI	[-4,573; 2,400]	[-11,545; -4,356]	
Veränderung zu Woche 20/21			
n/N (%)	54/136 (40)	42/125 (34)	LS MD 7,77 [2,613; 12,933]
MW (SD)	-0,62 (26,886)	1,19 (22,510)	
LS MW (SE)	-2,30 (1,804)	-10,07 (1,904)	
95 %-KI	[-5,853; 1,251]	[-13,821; -6,328]	
Veränderung zu Woche 24			
n/N (%)	44/131 (34)	32/117 (27)	
MW (SD)	3,03 (24,714)	-5,73 (21,001)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-3,15 (1,851)	-11,56 (1,993)	LS MD 8,41 [3,060; 13,759]
95 %-KI	[-6,795; 0,493]	[-15,480; -7,642]	
Veränderung zu Woche 36			
n/N (%)	58/117 (50)	38/101 (38)	LS MD 10,59 [4,189; 16,995]
MW (SD)	-3,74 (19,756)	-14,04 (35,201)	
LS MW (SE)	-6,07 (2,142)	-16,66 (2,460)	
95 %-KI	[-10,274; -1,857]	[-21,488; -11,828]	
Veränderung zu Woche 48			
n/N (%)	5/101 (5)	2/83 (2)	LS MD 12,78 [4,898; 20,652]
MW (SD)	-3,33 (24,721)	33,33 (47,140)	
LS MW (SE)	-8,98 (2,572)	-21,75 (3,084)	
95 %-KI	[-14,029; -3,931]	[-27,805; -15,705]	
<b>Stadium bei der Diagnose: I-III</b>			
Baseline			
n/N (%)	111/141 (79)	112/144 (78)	-
MW (SD)	74,77 (25,112)	72,62 (27,750)	
Absolute Werte zum Studienende			
n/N (%)	6/91 (7)	4/76 (5)	-
MW (SD)	91,67 (13,944)	91,67 (16,667)	
Effekt über Studiendauer			
n	111	112	LS MD 7,09 [1,886; 12,296] 0,0078
LS MW (SE)	-1,27 (1,850)	-8,37 (1,886)	
95 %-KI	[-4,921; 2,372]	[-12,081; -4,650]	Hedges' g 0,36 [0,094; 0,623]
Veränderung zu Woche 3/4			
n/N (%)	76/137 (55)	79/138 (57)	LS MD 4,46 [-1,001; 9,925]
MW (SD)	1,75 (21,183)	-2,11 (22,228)	
LS MW (SE)	1,08 (1,949)	-3,38 (1,976)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-2,755; 4,918]	[-7,271; 0,509]	
Veränderung zu Woche 8/9			
n/N (%)	93/136 (68)	89/129 (69)	LS MD 5,62 [0,361; 10,879]
MW (SD)	-0,36 (26,004)	-7,49 (23,437)	
LS MW (SE)	0,04 (1,877)	-5,58 (1,897)	
95 %-KI	[-3,656; 3,743]	[-9,315; -1,839]	
Veränderung zu Woche 12			
n/N (%)	63/133 (47)	48/128 (38)	LS MD 6,43 [1,231; 11,631]
MW (SD)	0,79 (31,740)	-9,38 (23,039)	
LS MW (SE)	-0,68 (1,853)	-7,11 (1,878)	
95 %-KI	[-4,336; 2,970]	[-10,815; -3,413]	
Veränderung zu Woche 15/16			
n/N (%)	64/130 (49)	35/125 (28)	LS MD 7,24 [2,028; 12,455]
MW (SD)	-3,13 (24,284)	-3,33 (22,434)	
LS MW (SE)	-1,41 (1,851)	-8,65 (1,890)	
95 %-KI	[-5,059; 2,240]	[-12,375; -4,927]	
Veränderung zu Woche 20/21			
n/N (%)	46/123 (37)	34/116 (29)	LS MD 8,40 [3,044; 13,755]
MW (SD)	0,72 (26,517)	0,98 (21,688)	
LS MW (SE)	-2,45 (1,887)	-10,85 (1,959)	
95 %-KI	[-6,166; 1,271]	[-14,705; -6,989]	
Veränderung zu Woche 24			
n/N (%)	34/121 (28)	27/109 (25)	LS MD 9,21 [3,673; 14,746]
MW (SD)	1,96 (22,758)	-5,56 (20,149)	
LS MW (SE)	-3,17 (1,938)	-12,38 (2,041)	
95 %-KI	[-6,990; 0,642]	[-16,401; -8,367]	
Veränderung zu Woche 36			
n/N (%)	52/105 (50)	36/92 (39)	
MW (SD)	-3,85 (23,248)	-18,52 (29,755)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-5,67 (2,247)	-17,65 (2,486)	LS MD 11,99 [5,418; 18,559]
95 %-KI	[-10,082; -1,248]	[-22,537; -12,771]	
Veränderung zu Woche 48			
n/N (%)	4/91 (4)	4/76 (5)	LS MD 14,77 [6,726; 22,809]
MW (SD)	-12,50 (15,957)	-0,00 (13,608)	
LS MW (SE)	-8,16 (2,706)	-22,92 (3,093)	
95 %-KI	[-13,468; -2,845]	[-28,993; -16,854]	
<b>Stadium bei der Diagnose: IV</b>			
Baseline			
n/N (%)	59/72 (82)	45/60 (75)	-
MW (SD)	66,95 (29,765)	72,96 (28,931)	
Absolute Werte zum Studienende			
n/N (%)	4/46 (9)	2/33 (6)	-
MW (SD)	79,17 (15,957)	75,00 (11,785)	
Effekt über Studiendauer			
n	59	45	LS MD 3,46 [-3,392; 10,312] 0,3189  Hedges' g 0,20 [-0,191; 0,586]
LS MW (SE)	1,96 (2,259)	-1,50 (2,603)	
95 %-KI	[-2,521; 6,447]	[-6,660; 3,666]	
Veränderung zu Woche 3/4			
n/N (%)	39/71 (55)	29/59 (49)	LS MD 5,79 [-1,420; 12,993]
MW (SD)	2,14 (18,409)	3,45 (24,551)	
LS MW (SE)	3,04 (2,387)	-2,75 (2,745)	
95 %-KI	[-1,686; 7,766]	[-8,177; 2,683]	
Veränderung zu Woche 8/9			
n/N (%)	46/69 (67)	36/56 (64)	LS MD 4,74 [-2,153; 11,639]
MW (SD)	9,06 (28,264)	-6,94 (29,914)	
LS MW (SE)	2,56 (2,293)	-2,19 (2,607)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-1,989; 7,104]	[-7,355; 2,983]	
Veränderung zu Woche 12			
n/N (%)	30/67 (45)	22/52 (42)	LS MD 4,01 [-2,811; 10,837]
MW (SD)	3,89 (18,919)	-4,55 (19,370)	
LS MW (SE)	2,22 (2,262)	-1,79 (2,582)	
95 %-KI	[-2,270; 6,708]	[-6,916; 3,328]	
Veränderung zu Woche 15/16			
n/N (%)	29/64 (45)	18/50 (36)	LS MD 3,28 [-3,594; 10,158]
MW (SD)	3,45 (23,308)	-2,78 (31,441)	
LS MW (SE)	1,88 (2,262)	-1,40 (2,617)	
95 %-KI	[-2,609; 6,370]	[-6,591; 3,788]	
Veränderung zu Woche 20/21			
n/N (%)	18/62 (29)	16/46 (35)	LS MD 2,24 [-4,921; 9,398]
MW (SD)	3,70 (23,952)	2,08 (21,837)	
LS MW (SE)	1,40 (2,315)	-0,84 (2,768)	
95 %-KI	[-3,193; 5,988]	[-6,318; 4,636]	
Veränderung zu Woche 24			
n/N (%)	17/59 (29)	10/44 (23)	LS MD 1,51 [-5,985; 9,000]
MW (SD)	5,88 (25,645)	-3,33 (17,213)	
LS MW (SE)	1,06 (2,387)	-0,45 (2,935)	
95 %-KI	[-3,669; 5,787]	[-6,246; 5,349]	
Veränderung zu Woche 36			
n/N (%)	27/52 (52)	11/41 (27)	LS MD -1,00 [-10,276; 8,282]
MW (SD)	1,23 (16,619)	12,12 (25,918)	
LS MW (SE)	-0,10 (2,816)	0,90 (3,778)	
95 %-KI	[-5,652; 5,451]	[-6,535; 8,328]	
Veränderung zu Woche 48			
n/N (%)	3/46 (7)	1/33 (3)	
MW (SD)	22,22 (19,245)	66,67 (NA)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-1,26 (3,436)	2,24 (4,863)	LS MD -3,50 [-15,195; 8,191]
95 %-KI	[-8,016; 5,497]	[-7,310; 11,794]	
<b>BRCA Status: Positiv</b>			
Baseline			
n/N (%)	23/27 (85)	23/35 (66)	-
MW (SD)	75,36 (29,245)	69,57 (31,644)	
Absolute Werte zum Studienende			
n/N (%)	1/19 (5)	0/15 (0)	-
MW (SD)	66,67 (NA)	NA (NA)	
Effekt über Studiendauer			
n	23	23	LS MD 16,34 [7,373; 25,298] 0,0007  Hedges' g 1,07 [0,445; 1,688]
LS MW (SE)	2,74 (3,076)	-13,59 (3,200)	
95 %-KI	[-3,474; 8,955]	[-20,039; -7,150]	
Veränderung zu Woche 3/4			
n/N (%)	15/27 (56)	18/35 (51)	LS MD 8,91 [-0,616; 18,438]
MW (SD)	6,67 (25,040)	-2,78 (18,302)	
LS MW (SE)	3,75 (3,327)	-5,16 (3,392)	
95 %-KI	[-2,915; 10,417]	[-11,949; 1,629]	
Veränderung zu Woche 8/9			
n/N (%)	19/26 (73)	20/30 (67)	LS MD 12,61 [3,620; 21,593]
MW (SD)	1,75 (19,950)	-10,00 (22,556)	
LS MW (SE)	3,25 (3,140)	-9,36 (3,159)	
95 %-KI	[-3,079; 9,575]	[-15,723; -2,994]	
Veränderung zu Woche 12			
n/N (%)	14/26 (54)	10/30 (33)	LS MD 15,19 [6,280; 24,106]
MW (SD)	2,38 (17,118)	-5,00 (15,811)	
LS MW (SE)	2,90 (3,082)	-12,30 (3,157)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,328; 9,120]	[-18,662; -5,932]	
Veränderung zu Woche 15/16			
n/N (%)	11/26 (42)	8/29 (28)	LS MD 17,78 [8,683; 26,877]
MW (SD)	-4,55 (21,201)	-10,42 (17,678)	
LS MW (SE)	2,54 (3,087)	-15,24 (3,291)	
95 %-KI	[-3,691; 8,779]	[-21,848; -8,624]	
Veränderung zu Woche 20/21			
n/N (%)	9/25 (36)	4/25 (16)	LS MD 21,48 [11,696; 31,256]
MW (SD)	-5,56 (14,434)	-4,17 (20,972)	
LS MW (SE)	2,04 (3,203)	-19,43 (3,686)	
95 %-KI	[-4,406; 8,489]	[-26,783; -12,086]	
Veränderung zu Woche 24			
n/N (%)	7/25 (28)	4/24 (17)	LS MD 24,06 [13,549; 34,577]
MW (SD)	2,38 (17,817)	-4,17 (8,333)	
LS MW (SE)	1,69 (3,355)	-22,37 (4,072)	
95 %-KI	[-5,037; 8,415]	[-30,454; -14,293]	
Veränderung zu Woche 36			
n/N (%)	8/21 (38)	5/20 (25)	LS MD 32,93 [18,813; 47,051]
MW (SD)	-4,17 (19,416)	-36,67 (32,059)	
LS MW (SE)	0,48 (4,204)	-32,45 (5,786)	
95 %-KI	[-7,848; 8,813]	[-43,855; -21,045]	
Veränderung zu Woche 48			
n/N (%)	1/19 (5)	0/15 (0)	LS MD 41,80 [23,180; 60,423]
MW (SD)	33,33 (NA)	NA (NA)	
LS MW (SE)	-0,72 (5,362)	-42,53 (7,789)	
95 %-KI	[-11,299; 9,850]	[-57,858; -27,193]	
<b>BRCA Status: Negativ/Unbekannt</b>			
Baseline			
n/N (%)	152/191 (80)	136/172 (79)	-

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	71,16 (26,645)	73,65 (27,409)	
Absolute Werte zum Studienende			
n/N (%)	9/121 (7)	6/95 (6)	-
MW (SD)	88,89 (14,434)	86,11 (16,387)	
Effekt über Studiendauer			
n	152	136	LS MD 5,19 [0,657; 9,717] 0,0250
LS MW (SE)	-0,44 (1,568)	-5,63 (1,684)	
95 %-KI	[-3,529; 2,643]	[-8,944; -2,317]	Hedges' g 0,27 [0,033; 0,498]
Veränderung zu Woche 3/4			
n/N (%)	105/186 (56)	92/165 (56)	LS MD 4,16 [-0,602; 8,921]
MW (SD)	1,59 (19,683)	-1,27 (25,705)	
LS MW (SE)	1,70 (1,651)	-2,46 (1,770)	
95 %-KI	[-1,549; 4,946]	[-5,942; 1,020]	
Veränderung zu Woche 8/9			
n/N (%)	125/184 (68)	107/158 (68)	LS MD 4,61 [0,032; 9,186]
MW (SD)	3,47 (28,263)	-6,85 (25,693)	
LS MW (SE)	0,76 (1,590)	-3,85 (1,696)	
95 %-KI	[-2,368; 3,892]	[-7,184; -0,508]	
Veränderung zu Woche 12			
n/N (%)	84/179 (47)	61/153 (40)	LS MD 4,92 [0,399; 9,447]
MW (SD)	2,18 (29,812)	-8,47 (22,694)	
LS MW (SE)	0,11 (1,570)	-4,82 (1,678)	
95 %-KI	[-2,983; 3,198]	[-8,117; -1,514]	
Veränderung zu Woche 15/16			
n/N (%)	85/173 (49)	47/149 (32)	LS MD 5,24 [0,701; 9,774]
MW (SD)	0,59 (25,387)	-3,90 (28,702)	
LS MW (SE)	-0,55 (1,569)	-5,79 (1,687)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,636; 2,541]	[-9,106; -2,465]	
Veränderung zu Woche 20/21			
n/N (%)	58/165 (35)	47/140 (34)	LS MD 5,69 [1,021; 10,352]
MW (SD)	3,45 (26,993)	1,77 (21,489)	
LS MW (SE)	-1,48 (1,600)	-7,17 (1,749)	
95 %-KI	[-4,632; 1,665]	[-10,610; -3,730]	
Veränderung zu Woche 24			
n/N (%)	46/159 (29)	34/131 (26)	LS MD 6,00 [1,172; 10,830]
MW (SD)	4,71 (25,009)	-5,88 (20,467)	
LS MW (SE)	-2,14 (1,644)	-8,14 (1,823)	
95 %-KI	[-5,372; 1,095]	[-11,723; -4,556]	
Veränderung zu Woche 36			
n/N (%)	72/139 (52)	43/114 (38)	LS MD 7,08 [1,318; 12,841]
MW (SD)	-1,85 (21,405)	-9,69 (31,335)	
LS MW (SE)	-4,38 (1,910)	-11,46 (2,225)	
95 %-KI	[-8,136; -0,633]	[-15,833; -7,096]	
Veränderung zu Woche 48			
n/N (%)	6/121 (5)	5/95 (5)	LS MD 8,16 [1,079; 15,237]
MW (SD)	-2,78 (22,153)	13,33 (32,059)	
LS MW (SE)	-6,63 (2,303)	-14,79 (2,775)	
95 %-KI	[-11,149; -2,112]	[-20,233; -9,343]	
<b>Baseline ECOG PS: 0</b>			
Baseline			
n/N (%)	100/128 (78)	97/113 (86)	-
MW (SD)	75,83 (25,882)	77,84 (24,143)	
Absolute Werte zum Studienende			
n/N (%)	7/87 (8)	3/72 (4)	-
MW (SD)	83,33 (16,667)	83,33 (16,667)	
Effekt über Studiendauer			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n	100	97	LS MD 4,19 [-0,760; 9,150] 0,0966  Hedges' g 0,24 [-0,043; 0,518]
LS MW (SE)	-1,33 (1,746)	-5,52 (1,804)	
95 %-KI	[-4,770; 2,118]	[-9,078; -1,963]	
Veränderung zu Woche 3/4			
n/N (%)	71/127 (56)	64/111 (58)	LS MD 2,60 [-2,674; 7,867]
MW (SD)	3,29 (19,441)	-1,04 (21,797)	
LS MW (SE)	0,45 (1,857)	-2,14 (1,926)	
95 %-KI	[-3,205; 4,111]	[-5,937; 1,649]	
Veränderung zu Woche 8/9			
n/N (%)	84/126 (67)	76/108 (70)	LS MD 3,29 [-1,735; 8,318]
MW (SD)	-0,40 (25,346)	-7,24 (22,167)	
LS MW (SE)	-0,32 (1,778)	-3,61 (1,826)	
95 %-KI	[-3,826; 3,185]	[-7,212; -0,012]	
Veränderung zu Woche 12			
n/N (%)	54/122 (44)	46/108 (43)	LS MD 3,78 [-1,175; 8,730]
MW (SD)	-0,31 (26,598)	-6,52 (20,929)	
LS MW (SE)	-0,86 (1,750)	-4,64 (1,799)	
95 %-KI	[-4,314; 2,591]	[-8,186; -1,093]	
Veränderung zu Woche 15/16			
n/N (%)	56/120 (47)	35/105 (33)	LS MD 4,26 [-0,697; 9,226]
MW (SD)	-3,57 (26,345)	-7,62 (25,030)	
LS MW (SE)	-1,40 (1,747)	-5,67 (1,808)	
95 %-KI	[-4,849; 2,043]	[-9,231; -2,103]	
Veränderung zu Woche 20/21			
n/N (%)	41/117 (35)	32/101 (32)	LS MD 4,96 [-0,159; 10,077]
MW (SD)	0,81 (25,807)	-2,08 (20,631)	
LS MW (SE)	-2,18 (1,784)	-7,13 (1,883)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-5,694; 1,343]	[-10,844; -3,425]	
Veränderung zu Woche 24			
n/N (%)	27/112 (24)	22/96 (23)	LS MD 5,45 [0,125; 10,766]
MW (SD)	2,47 (19,991)	-4,55 (20,690)	
LS MW (SE)	-2,72 (1,839)	-8,16 (1,975)	
95 %-KI	[-6,340; 0,906]	[-12,050; -4,274]	
Veränderung zu Woche 36			
n/N (%)	50/99 (51)	35/87 (40)	LS MD 7,11 [0,636; 13,589]
MW (SD)	-2,67 (22,426)	-8,57 (32,432)	
LS MW (SE)	-4,57 (2,170)	-11,68 (2,476)	
95 %-KI	[-8,838; -0,307]	[-16,548; -6,822]	
Veränderung zu Woche 48			
n/N (%)	4/87 (5)	3/72 (4)	LS MD 8,78 [0,685; 16,875]
MW (SD)	8,33 (31,914)	22,22 (41,944)	
LS MW (SE)	-6,43 (2,654)	-15,21 (3,150)	
95 %-KI	[-11,638; -1,217]	[-21,389; -9,026]	
<b>Baseline ECOG PS: 1</b>			
Baseline			
n/N (%)	75/90 (83)	61/91 (67)	-
MW (SD)	66,22 (27,533)	65,57 (32,184)	
Absolute Werte zum Studienende			
n/N (%)	3/53 (6)	3/37 (8)	-
MW (SD)	94,44 (9,623)	88,89 (19,245)	
Effekt über Studiendauer			
n	75	61	LS MD 10,68 [3,621; 17,744] 0,0033
LS MW (SE)	1,89 (2,365)	-8,80 (2,682)	
95 %-KI	[-2,791; 6,566]	[-14,098; -3,493]	Hedges' g 0,51 [0,170; 0,857]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	49/86 (57)	45/87 (52)	LS MD 8,49 [1,167; 15,817]
MW (SD)	0,68 (21,773)	-1,11 (27,616)	
LS MW (SE)	4,38 (2,475)	-4,12 (2,769)	
95 %-KI	[-0,513; 9,266]	[-9,584; 1,353]	
Veränderung zu Woche 8/9			
n/N (%)	60/84 (71)	50/78 (64)	LS MD 9,50 [2,410; 16,583]
MW (SD)	8,33 (29,192)	-6,67 (28,966)	
LS MW (SE)	3,23 (2,392)	-6,26 (2,675)	
95 %-KI	[-1,495; 7,965]	[-11,552; -0,972]	
Veränderung zu Woche 12			
n/N (%)	44/83 (53)	24/74 (32)	LS MD 10,20 [3,163; 17,237]
MW (SD)	5,30 (30,239)	-9,03 (22,511)	
LS MW (SE)	2,44 (2,366)	-7,76 (2,664)	
95 %-KI	[-2,245; 7,116]	[-13,032; -2,497]	
Veränderung zu Woche 15/16			
n/N (%)	40/79 (51)	20/72 (28)	LS MD 10,90 [3,815; 17,991]
MW (SD)	5,00 (22,072)	0,00 (31,063)	
LS MW (SE)	1,64 (2,368)	-9,27 (2,697)	
95 %-KI	[-3,049; 6,322]	[-14,599; -3,935]	
Veränderung zu Woche 20/21			
n/N (%)	26/73 (36)	18/63 (29)	LS MD 11,91 [4,579; 19,237]
MW (SD)	4,49 (26,059)	7,41 (22,304)	
LS MW (SE)	0,49 (2,421)	-11,41 (2,820)	
95 %-KI	[-4,291; 5,281]	[-16,981; -5,845]	
Veränderung zu Woche 24			
n/N (%)	26/72 (36)	15/58 (26)	LS MD 12,61 [5,003; 20,219]
MW (SD)	6,41 (27,919)	-5,56 (17,442)	
LS MW (SE)	-0,30 (2,490)	-12,92 (2,953)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-5,223; 4,614]	[-18,740; -7,091]	
Veränderung zu Woche 36			
n/N (%)	30/61 (49)	13/46 (28)	LS MD 15,02 [5,909; 24,136]
MW (SD)	-1,11 (19,045)	-23,08 (30,076)	
LS MW (SE)	-3,04 (2,895)	-18,07 (3,633)	
95 %-KI	[-8,745; 2,656]	[-25,210; -10,924]	
Veränderung zu Woche 48			
n/N (%)	3/53 (6)	2/37 (5)	LS MD 17,43 [6,244; 28,624]
MW (SD)	-5,56 (9,623)	0,00 (0,000)	
LS MW (SE)	-5,78 (3,485)	-23,22 (4,531)	
95 %-KI	[-12,634; 1,065]	[-32,115; -14,322]	
<b>Anzahl vorheriger Therapielinien: 1</b>			
Baseline			
n/N (%)	24/31 (77)	23/29 (79)	-
MW (SD)	69,44 (32,477)	76,81 (22,326)	
Absolute Werte zum Studienende			
n/N (%)	1/22 (5)	0/14 (0)	-
MW (SD)	100,00 (NA)	NA (NA)	
Effekt über Studiendauer			
n	24	23	LS MD 8,01 [-4,825; 20,839] 0,2152  Hedges' g 0,36 [-0,215; 0,939]
LS MW (SE)	2,21 (4,429)	-5,79 (4,550)	
95 %-KI	[-6,719; 11,149]	[-14,957; 3,372]	
Veränderung zu Woche 3/4			
n/N (%)	16/31 (52)	15/29 (52)	LS MD 3,29 [-10,114; 16,691]
MW (SD)	5,21 (20,833)	5,56 (8,133)	
LS MW (SE)	8,33 (4,643)	5,04 (4,778)	
95 %-KI	[-0,990; 17,651]	[-4,535; 14,619]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	20/31 (65)	18/26 (69)	LS MD 5,27 [-7,703; 18,250]
MW (SD)	7,50 (20,573)	-5,56 (33,333)	
LS MW (SE)	5,76 (4,504)	0,48 (4,587)	
95 %-KI	[-3,311; 14,826]	[-8,746; 9,713]	
Veränderung zu Woche 12			
n/N (%)	14/31 (45)	12/24 (50)	LS MD 6,66 [-6,175; 19,501]
MW (SD)	16,67 (25,318)	-1,39 (27,941)	
LS MW (SE)	3,96 (4,448)	-2,71 (4,535)	
95 %-KI	[-5,013; 12,926]	[-11,842; 6,428]	
Veränderung zu Woche 15/16			
n/N (%)	15/31 (48)	11/22 (50)	LS MD 8,05 [-4,781; 20,888]
MW (SD)	-6,67 (25,820)	-9,09 (26,208)	
LS MW (SE)	2,16 (4,429)	-5,90 (4,552)	
95 %-KI	[-6,779; 11,089]	[-15,065; 3,270]	
Veränderung zu Woche 20/21			
n/N (%)	11/30 (37)	9/22 (41)	LS MD 10,04 [-3,025; 23,101]
MW (SD)	3,03 (22,134)	-1,85 (19,444)	
LS MW (SE)	-0,42 (4,464)	-10,46 (4,695)	
95 %-KI	[-9,415; 8,579]	[-19,886; -1,027]	
Veränderung zu Woche 24			
n/N (%)	9/30 (30)	11/20 (55)	LS MD 11,43 [-1,954; 24,810]
MW (SD)	9,26 (20,601)	1,52 (26,304)	
LS MW (SE)	-2,22 (4,532)	-13,65 (4,873)	
95 %-KI	[-11,339; 6,900]	[-23,404; -3,891]	
Veränderung zu Woche 36			
n/N (%)	15/26 (58)	6/18 (33)	LS MD 16,19 [0,843; 31,542]
MW (SD)	-12,22 (25,562)	-5,56 (32,773)	
LS MW (SE)	-8,39 (5,009)	-24,59 (5,866)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-18,390; 1,600]	[-36,215; -12,959]	
Veränderung zu Woche 48			
n/N (%)	0/22 (0)	0/14 (0)	LS MD 20,96 [2,623; 39,291]
MW (SD)	NA (NA)	NA (NA)	
LS MW (SE)	-14,57 (5,784)	-35,53 (7,249)	
95 %-KI	[-26,029; -3,112]	[-49,826; -21,229]	
<b>Anzahl vorheriger Therapielinien: 2</b>			
Baseline			
n/N (%)	74/89 (83)	65/83 (78)	-
MW (SD)	68,92 (28,042)	73,08 (30,998)	
Absolute Werte zum Studienende			
n/N (%)	4/59 (7)	2/50 (4)	-
MW (SD)	79,17 (15,957)	83,33 (23,570)	
Effekt über Studiendauer			
n	74	65	LS MD 6,55 [0,455; 12,648] 0,0354  Hedges' g 0,36 [0,025; 0,697]
LS MW (SE)	0,37 (2,069)	-6,18 (2,277)	
95 %-KI	[-3,726; 4,462]	[-10,685; -1,683]	
Veränderung zu Woche 3/4			
n/N (%)	52/86 (60)	46/80 (57)	LS MD 2,39 [-4,072; 8,846]
MW (SD)	1,28 (23,535)	0,36 (27,997)	
LS MW (SE)	1,45 (2,208)	-0,94 (2,412)	
95 %-KI	[-2,910; 5,808]	[-5,697; 3,820]	
Veränderung zu Woche 8/9			
n/N (%)	62/85 (73)	53/77 (69)	LS MD 4,28 [-1,858; 10,425]
MW (SD)	5,38 (28,112)	-6,29 (22,699)	
LS MW (SE)	0,96 (2,106)	-3,33 (2,280)	
95 %-KI	[-3,207; 5,120]	[-7,833; 1,179]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	39/83 (47)	31/75 (41)	LS MD 5,61 [-0,458; 11,681]
MW (SD)	0,00 (28,613)	-10,75 (19,976)	
LS MW (SE)	0,61 (2,072)	-5,00 (2,257)	
95 %-KI	[-3,489; 4,712]	[-9,462; -0,537]	
Veränderung zu Woche 15/16			
n/N (%)	41/80 (51)	20/74 (27)	LS MD 6,94 [0,813; 13,065]
MW (SD)	0,41 (27,510)	-2,50 (30,720)	
LS MW (SE)	0,27 (2,072)	-6,67 (2,294)	
95 %-KI	[-3,834; 4,368]	[-11,205; -2,139]	
Veränderung zu Woche 20/21			
n/N (%)	31/78 (40)	21/68 (31)	LS MD 8,84 [2,413; 15,258]
MW (SD)	0,00 (23,960)	-2,38 (24,881)	
LS MW (SE)	-0,23 (2,130)	-9,06 (2,443)	
95 %-KI	[-4,436; 3,985]	[-13,881; -4,240]	
Veränderung zu Woche 24			
n/N (%)	25/74 (34)	13/65 (20)	LS MD 10,16 [3,397; 16,929]
MW (SD)	6,00 (27,165)	-12,82 (13,868)	
LS MW (SE)	-0,57 (2,208)	-10,73 (2,606)	
95 %-KI	[-4,930; 3,790]	[-15,869; -5,598]	
Veränderung zu Woche 36			
n/N (%)	32/65 (49)	19/58 (33)	LS MD 14,71 [6,143; 23,287]
MW (SD)	0,52 (22,194)	-21,93 (28,896)	
LS MW (SE)	-1,75 (2,663)	-16,47 (3,416)	
95 %-KI	[-6,992; 3,489]	[-23,178; -9,755]	
Veränderung zu Woche 48			
n/N (%)	3/59 (5)	1/50 (2)	LS MD 19,27 [8,308; 30,226]
MW (SD)	-5,56 (34,694)	0,00 (NA)	
LS MW (SE)	-2,93 (3,309)	-22,20 (4,441)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-9,433; 3,566]	[-30,918; -13,482]	
<b>Anzahl vorheriger Therapielinien: 3</b>			
Baseline			
n/N (%)	77/98 (79)	71/95 (75)	-
MW (SD)	75,11 (23,821)	71,83 (26,961)	
Absolute Werte zum Studienende			
n/N (%)	5/59 (8)	4/46 (9)	-
MW (SD)	90,00 (14,907)	87,50 (15,957)	
Effekt über Studiendauer			
n	77	71	LS MD 6,89 [0,552; 13,231] 0,0333  Hedges' g 0,35 [0,026; 0,676]
LS MW (SE)	-0,89 (2,205)	-7,78 (2,337)	
95 %-KI	[-5,245; 3,474]	[-12,396; -3,158]	
Veränderung zu Woche 3/4			
n/N (%)	52/96 (54)	49/91 (54)	LS MD 7,45 [0,855; 14,051]
MW (SD)	2,24 (16,839)	-5,44 (24,149)	
LS MW (SE)	0,54 (2,300)	-6,92 (2,434)	
95 %-KI	[-4,005; 5,077]	[-11,721; -2,113]	
Veränderung zu Woche 8/9			
n/N (%)	62/94 (66)	56/85 (66)	LS MD 7,20 [0,816; 13,594]
MW (SD)	-0,27 (28,228)	-8,93 (24,815)	
LS MW (SE)	-0,09 (2,228)	-7,30 (2,352)	
95 %-KI	[-4,495; 4,309]	[-11,945; -2,650]	
Veränderung zu Woche 12			
n/N (%)	45/91 (49)	28/84 (33)	LS MD 7,03 [0,700; 13,362]
MW (SD)	-0,37 (28,089)	-7,74 (21,024)	
LS MW (SE)	-0,53 (2,205)	-7,56 (2,331)	
95 %-KI	[-4,892; 3,827]	[-12,172; -2,956]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	40/88 (45)	24/82 (29)	LS MD 6,86 [0,507; 13,206]
MW (SD)	2,08 (21,743)	-4,86 (25,763)	
LS MW (SE)	-0,97 (2,208)	-7,83 (2,342)	
95 %-KI	[-5,337; 3,391]	[-12,458; -3,202]	
Veränderung zu Woche 20/21			
n/N (%)	25/82 (30)	21/75 (28)	LS MD 6,61 [0,103; 13,113]
MW (SD)	4,67 (29,861)	6,35 (17,854)	
LS MW (SE)	-1,60 (2,253)	-8,21 (2,410)	
95 %-KI	[-6,053; 2,849]	[-12,969; -3,452]	
Veränderung zu Woche 24			
n/N (%)	19/80 (24)	14/70 (20)	LS MD 6,43 [-0,265; 13,134]
MW (SD)	-0,00 (21,517)	-4,76 (16,575)	
LS MW (SE)	-2,04 (2,313)	-8,48 (2,492)	
95 %-KI	[-6,608; 2,523]	[-13,393; -3,560]	
Veränderung zu Woche 36			
n/N (%)	33/69 (48)	23/58 (40)	LS MD 5,84 [-1,979; 13,654]
MW (SD)	-0,00 (16,667)	-6,52 (33,986)	
LS MW (SE)	-3,55 (2,666)	-9,39 (2,949)	
95 %-KI	[-8,800; 1,697]	[-15,191; -3,588]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	4/46 (9)	LS MD 5,24 [-4,185; 14,667]
MW (SD)	8,33 (16,667)	16,67 (36,004)	
LS MW (SE)	-5,06 (3,185)	-10,30 (3,591)	
95 %-KI	[-11,319; 1,197]	[-17,357; -3,248]	
<b>Vorherige Verabreichung von Bevacizumab: Ja</b>			
Baseline			
n/N (%)	105/134 (78)	100/132 (76)	-
MW (SD)	73,02 (24,610)	72,17 (28,531)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	3/79 (4)	3/62 (5)	-
MW (SD)	83,33 (16,667)	77,78 (19,245)	
Effekt über Studiendauer			
n	105	100	LS MD 6,94 [1,605; 12,267] 0,0110  Hedges' g 0,36 [0,081; 0,633]
LS MW (SE)	-1,37 (1,866)	-8,31 (1,961)	
95 %-KI	[-5,052; 2,309]	[-12,174; -4,442]	
Veränderung zu Woche 3/4			
n/N (%)	68/130 (52)	69/127 (54)	LS MD 4,01 [-1,599; 9,619]
MW (SD)	1,23 (18,732)	-2,66 (25,505)	
LS MW (SE)	0,00 (1,975)	-4,01 (2,058)	
95 %-KI	[-3,890; 3,890]	[-8,062; 0,042]	
Veränderung zu Woche 8/9			
n/N (%)	86/130 (66)	77/119 (65)	LS MD 5,38 [0,012; 10,742]
MW (SD)	1,16 (25,920)	-7,14 (26,687)	
LS MW (SE)	-0,64 (1,894)	-6,02 (1,959)	
95 %-KI	[-4,375; 3,094]	[-9,878; -2,157]	
Veränderung zu Woche 12			
n/N (%)	55/126 (44)	38/114 (33)	LS MD 6,33 [1,021; 11,646]
MW (SD)	-1,52 (29,445)	-8,33 (23,490)	
LS MW (SE)	-1,09 (1,869)	-7,42 (1,945)	
95 %-KI	[-4,774; 2,597]	[-11,257; -3,587]	
Veränderung zu Woche 15/16			
n/N (%)	58/122 (48)	32/112 (29)	LS MD 7,29 [1,929; 12,650]
MW (SD)	-2,30 (26,204)	-5,21 (28,536)	
LS MW (SE)	-1,54 (1,869)	-8,83 (1,979)	
95 %-KI	[-5,224; 2,150]	[-12,728; -4,926]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	39/114 (34)	28/103 (27)	LS MD 8,66 [3,058; 14,255]
MW (SD)	1,71 (28,561)	4,76 (22,156)	
LS MW (SE)	-2,18 (1,916)	-10,83 (2,105)	
95 %-KI	[-5,954; 1,599]	[-14,978; -6,690]	
Veränderung zu Woche 24			
n/N (%)	29/109 (27)	17/95 (18)	LS MD 9,61 [3,740; 15,485]
MW (SD)	0,00 (20,412)	-10,78 (19,491)	
LS MW (SE)	-2,63 (1,979)	-12,24 (2,239)	
95 %-KI	[-6,524; 1,272]	[-16,644; -7,834]	
Veränderung zu Woche 36			
n/N (%)	45/93 (48)	22/79 (28)	LS MD 12,89 [5,575; 20,210]
MW (SD)	-1,85 (17,488)	-16,67 (35,635)	
LS MW (SE)	-4,16 (2,347)	-17,06 (2,904)	
95 %-KI	[-8,776; 0,449]	[-22,756; -11,355]	
Veränderung zu Woche 48			
n/N (%)	3/79 (4)	2/62 (3)	LS MD 16,17 [6,927; 25,416]
MW (SD)	-16,67 (16,667)	-8,33 (11,785)	
LS MW (SE)	-5,70 (2,876)	-21,87 (3,746)	
95 %-KI	[-11,346; -0,055]	[-29,222; -14,522]	
<b>Vorherige Verabreichung von Bevacizumab: Nein</b>			
Baseline			
n/N (%)	70/84 (83)	59/75 (79)	-
MW (SD)	69,76 (30,202)	74,58 (27,221)	
Absolute Werte zum Studienende			
n/N (%)	7/61 (11)	3/48 (6)	-
MW (SD)	88,10 (15,853)	94,44 (9,623)	
Effekt über Studiendauer			
n	70	59	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	2,04 (2,219)	-4,54 (2,443)	LS MD 6,57 [0,032; 13,116] 0,0489  Hedges' g 0,35 [0,001; 0,699]
95 %-KI	[-2,355; 6,430]	[-9,371; 0,298]	
Veränderung zu Woche 3/4			
n/N (%)	52/83 (63)	41/73 (56)	LS MD 6,43 [-0,442; 13,312]
MW (SD)	3,53 (22,467)	0,41 (23,120)	
LS MW (SE)	4,87 (2,334)	-1,57 (2,577)	
95 %-KI	[0,253; 9,478]	[-6,658; 3,520]	
Veränderung zu Woche 8/9			
n/N (%)	58/80 (72)	50/69 (72)	LS MD 6,49 [-0,137; 13,122]
MW (SD)	6,32 (29,091)	-7,67 (22,889)	
LS MW (SE)	3,69 (2,252)	-2,81 (2,477)	
95 %-KI	[-0,768; 8,141]	[-7,705; 2,092]	
Veränderung zu Woche 12			
n/N (%)	43/79 (54)	33/69 (48)	LS MD 6,53 [-0,014; 13,080]
MW (SD)	6,98 (26,285)	-7,58 (20,022)	
LS MW (SE)	2,86 (2,223)	-3,67 (2,444)	
95 %-KI	[-1,539; 7,261]	[-8,508; 1,163]	
Veränderung zu Woche 15/16			
n/N (%)	38/77 (49)	23/66 (35)	LS MD 6,57 [0,032; 13,116]
MW (SD)	3,51 (22,647)	-4,35 (26,217)	
LS MW (SE)	2,04 (2,219)	-4,54 (2,443)	
95 %-KI	[-2,357; 6,428]	[-9,373; 0,296]	
Veränderung zu Woche 20/21			
n/N (%)	28/76 (37)	23/62 (37)	LS MD 6,63 [-0,038; 13,302]
MW (SD)	2,98 (21,780)	-2,90 (19,881)	
LS MW (SE)	0,86 (2,257)	-5,78 (2,498)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,610; 5,322]	[-10,715; -0,837]	
Veränderung zu Woche 24			
n/N (%)	24/75 (32)	21/60 (35)	LS MD 6,67 [-0,177; 13,522]
MW (SD)	9,72 (27,327)	-1,59 (18,933)	
LS MW (SE)	0,03 (2,313)	-6,64 (2,573)	
95 %-KI	[-4,542; 4,603]	[-11,725; -1,559]	
Veränderung zu Woche 36			
n/N (%)	35/67 (52)	26/55 (47)	LS MD 6,81 [-1,135; 14,758]
MW (SD)	-2,38 (25,290)	-8,97 (29,147)	
LS MW (SE)	-2,80 (2,661)	-9,61 (3,021)	
95 %-KI	[-8,041; 2,443]	[-15,559; -3,663]	
Veränderung zu Woche 48			
n/N (%)	4/61 (7)	3/48 (6)	LS MD 6,95 [-2,626; 16,527]
MW (SD)	16,67 (19,245)	27,78 (34,694)	
LS MW (SE)	-5,63 (3,183)	-12,58 (3,673)	
95 %-KI	[-11,885; 0,626]	[-19,797; -5,363]	
<b>Letztes Platin-freies Intervall: ≤ 3 Monate</b>			
Baseline			
n/N (%)	68/83 (82)	62/91 (68)	-
MW (SD)	74,02 (24,329)	71,77 (27,426)	
Absolute Werte zum Studienende			
n/N (%)	3/55 (5)	5/39 (13)	-
MW (SD)	77,78 (19,245)	83,33 (16,667)	
Effekt über Studiendauer			
n	68	62	LS MD 6,75 [-0,205; 13,700] 0,0570
LS MW (SE)	-3,70 (2,405)	-10,45 (2,560)	
95 %-KI	[-8,462; 1,060]	[-15,512; -5,384]	Hedges' g 0,34 [-0,011; 0,682]



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	48/82 (59)	46/86 (53)	LS MD 4,98 [-2,257; 12,221]
MW (SD)	-2,43 (22,803)	-6,52 (26,869)	
LS MW (SE)	-4,04 (2,523)	-9,02 (2,655)	
95 %-KI	[-9,023; 0,948]	[-14,264; -3,774]	
Veränderung zu Woche 8/9			
n/N (%)	52/81 (64)	46/80 (57)	LS MD 5,79 [-1,202; 12,773]
MW (SD)	-2,56 (28,080)	-9,42 (25,007)	
LS MW (SE)	-3,88 (2,430)	-9,67 (2,562)	
95 %-KI	[-8,693; 0,925]	[-14,737; -4,603]	
Veränderung zu Woche 12			
n/N (%)	33/78 (42)	24/78 (31)	LS MD 6,35 [-0,583; 13,279]
MW (SD)	-6,57 (29,445)	-13,19 (23,560)	
LS MW (SE)	-3,78 (2,404)	-10,13 (2,546)	
95 %-KI	[-8,535; 0,982]	[-15,162; -5,088]	
Veränderung zu Woche 15/16			
n/N (%)	35/76 (46)	14/75 (19)	LS MD 6,91 [-0,064; 13,887]
MW (SD)	-0,48 (24,080)	-9,52 (24,209)	
LS MW (SE)	-3,67 (2,410)	-10,58 (2,572)	
95 %-KI	[-8,440; 1,101]	[-15,667; -5,494]	
Veränderung zu Woche 20/21			
n/N (%)	22/72 (31)	14/67 (21)	LS MD 7,72 [0,505; 14,926]
MW (SD)	0,76 (27,925)	2,38 (18,324)	
LS MW (SE)	-3,52 (2,476)	-11,23 (2,678)	
95 %-KI	[-8,413; 1,380]	[-16,523; -5,940]	
Veränderung zu Woche 24			
n/N (%)	16/72 (22)	12/62 (19)	LS MD 8,28 [0,791; 15,765]
MW (SD)	2,08 (21,837)	-6,94 (16,603)	
LS MW (SE)	-3,41 (2,559)	-11,69 (2,797)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-8,464; 1,646]	[-17,207; -6,167]	
Veränderung zu Woche 36			
n/N (%)	28/63 (44)	18/50 (36)	LS MD 10,21 [1,216; 19,199]
MW (SD)	-0,00 (16,355)	-8,33 (37,158)	
LS MW (SE)	-3,04 (3,031)	-13,25 (3,418)	
95 %-KI	[-9,008; 2,926]	[-19,972; -6,525]	
Veränderung zu Woche 48			
n/N (%)	2/55 (4)	4/39 (10)	LS MD 12,14 [1,065; 23,210]
MW (SD)	-16,67 (23,570)	16,67 (36,004)	
LS MW (SE)	-2,67 (3,701)	-14,81 (4,249)	
95 %-KI	[-9,946; 4,600]	[-23,157; -6,464]	
<b>Letztes Platin-freies Intervall: &gt; 3 Monate</b>			
Baseline			
n/N (%)	107/135 (79)	97/116 (84)	-
MW (SD)	70,25 (28,505)	73,88 (28,454)	
Absolute Werte zum Studienende			
n/N (%)	7/85 (8)	1/71 (1)	-
MW (SD)	90,48 (13,113)	100,00 (NA)	
Effekt über Studiendauer			
n	107	97	LS MD 6,65 [1,677; 11,618] 0,0090  Hedges' g 0,37 [0,092; 0,646]
LS MW (SE)	2,37 (1,721)	-4,28 (1,840)	
95 %-KI	[-1,025; 5,762]	[-7,907; -0,650]	
Veränderung zu Woche 3/4			
n/N (%)	72/131 (55)	64/114 (56)	LS MD 4,62 [-0,666; 9,897]
MW (SD)	5,32 (18,091)	2,08 (22,321)	
LS MW (SE)	5,72 (1,827)	1,10 (1,962)	
95 %-KI	[2,117; 9,314]	[-2,763; 4,962]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	92/129 (71)	81/108 (75)	LS MD 5,51 [0,466; 10,546]
MW (SD)	6,52 (26,376)	-6,17 (25,337)	
LS MW (SE)	4,25 (1,753)	-1,26 (1,860)	
95 %-KI	[0,794; 7,704]	[-4,923; 2,408]	
Veränderung zu Woche 12			
n/N (%)	65/127 (51)	47/105 (45)	LS MD 6,13 [1,162; 11,097]
MW (SD)	6,67 (26,810)	-5,32 (20,591)	
LS MW (SE)	3,22 (1,726)	-2,91 (1,833)	
95 %-KI	[-0,182; 6,626]	[-6,522; 0,707]	
Veränderung zu Woche 15/16			
n/N (%)	61/123 (50)	41/103 (40)	LS MD 6,75 [1,775; 11,731]
MW (SD)	0,27 (25,548)	-3,25 (28,436)	
LS MW (SE)	2,20 (1,721)	-4,56 (1,845)	
95 %-KI	[-1,200; 5,590]	[-8,195; -0,920]	
Veränderung zu Woche 20/21			
n/N (%)	45/118 (38)	37/98 (38)	LS MD 7,64 [2,506; 12,781]
MW (SD)	2,96 (24,947)	0,90 (22,548)	
LS MW (SE)	0,73 (1,753)	-6,91 (1,928)	
95 %-KI	[-2,728; 4,186]	[-10,712; -3,118]	
Veränderung zu Woche 24			
n/N (%)	37/112 (33)	26/93 (28)	LS MD 8,27 [2,925; 13,609]
MW (SD)	5,41 (25,170)	-5,13 (20,960)	
LS MW (SE)	-0,30 (1,802)	-8,56 (2,027)	
95 %-KI	[-3,848; 3,252]	[-12,554; -4,576]	
Veränderung zu Woche 36			
n/N (%)	52/97 (54)	30/84 (36)	LS MD 10,40 [3,900; 16,909]
MW (SD)	-3,21 (23,347)	-15,00 (29,148)	
LS MW (SE)	-3,82 (2,102)	-14,22 (2,556)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-7,952; 0,315]	[-19,243; -9,202]	
Veränderung zu Woche 48			
n/N (%)	5/85 (6)	1/71 (1)	LS MD 12,54 [4,414; 20,669]
MW (SD)	10,00 (22,361)	0,00 (NA)	
LS MW (SE)	-7,34 (2,550)	-19,88 (3,262)	
95 %-KI	[-12,344; -2,333]	[-26,281; -13,478]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Pegyliertes liposomales Doxorubicin</b>			
Baseline			
n/N (%)	62/80 (78)	57/76 (75)	-
MW (SD)	68,55 (28,327)	77,19 (25,710)	
Absolute Werte zum Studienende			
n/N (%)	3/51 (6)	3/41 (7)	-
MW (SD)	88,89 (19,245)	88,89 (19,245)	
Effekt über Studiendauer			
n	62	57	LS MD 5,65 [-1,627; 12,919] 0,1269  Hedges' g 0,28 [-0,079; 0,644]
LS MW (SE)	-0,65 (2,506)	-6,30 (2,655)	
95 %-KI	[-5,619; 4,311]	[-11,557; -1,043]	
Veränderung zu Woche 3/4			
n/N (%)	42/76 (55)	43/74 (58)	LS MD 3,70 [-3,916; 11,311]
MW (SD)	7,94 (18,855)	0,00 (20,574)	
LS MW (SE)	3,12 (2,641)	-0,58 (2,769)	
95 %-KI	[-2,108; 8,338]	[-6,055; 4,891]	
Veränderung zu Woche 8/9			
n/N (%)	52/76 (68)	44/66 (67)	LS MD 4,56 [-2,783; 11,899]
MW (SD)	2,24 (26,203)	-10,23 (27,189)	
LS MW (SE)	1,45 (2,548)	-3,11 (2,662)	
95 %-KI	[-3,594; 6,495]	[-8,377; 2,163]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	34/75 (45)	23/64 (36)	LS MD 5,16 [-2,104; 12,425]
MW (SD)	6,37 (29,017)	-4,35 (23,147)	
LS MW (SE)	0,29 (2,513)	-4,87 (2,640)	
95 %-KI	[-4,694; 5,265]	[-10,103; 0,354]	
Veränderung zu Woche 15/16			
n/N (%)	35/74 (47)	19/62 (31)	LS MD 5,76 [-1,522; 13,047]
MW (SD)	-4,29 (25,675)	-9,65 (26,826)	
LS MW (SE)	-0,88 (2,506)	-6,64 (2,663)	
95 %-KI	[-5,846; 4,087]	[-11,914; -1,370]	
Veränderung zu Woche 20/21			
n/N (%)	27/72 (38)	18/59 (31)	LS MD 6,62 [-0,858; 14,103]
MW (SD)	1,23 (20,634)	-0,93 (20,983)	
LS MW (SE)	-2,54 (2,543)	-9,17 (2,770)	
95 %-KI	[-7,581; 2,493]	[-14,644; -3,689]	
Veränderung zu Woche 24			
n/N (%)	21/69 (30)	16/54 (30)	LS MD 7,23 [-0,502; 14,952]
MW (SD)	7,94 (19,450)	-2,08 (22,669)	
LS MW (SE)	-3,71 (2,601)	-10,93 (2,893)	
95 %-KI	[-8,856; 1,437]	[-16,648; -5,221]	
Veränderung zu Woche 36			
n/N (%)	30/60 (50)	16/48 (33)	LS MD 9,29 [0,149; 18,431]
MW (SD)	-6,67 (24,604)	-15,63 (30,104)	
LS MW (SE)	-7,70 (2,971)	-16,99 (3,543)	
95 %-KI	[-13,560; -1,848]	[-23,966; -10,023]	
Veränderung zu Woche 48			
n/N (%)	1/51 (2)	2/41 (5)	LS MD 11,36 [0,197; 22,514]
MW (SD)	33,33 (NA)	8,33 (11,785)	
LS MW (SE)	-11,70 (3,535)	-23,05 (4,418)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-18,650; -4,748]	[-31,733; -14,374]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Paclitaxel</b>			
Baseline			
n/N (%)	74/88 (84)	70/82 (85)	-
MW (SD)	69,37 (26,750)	69,05 (30,334)	
Absolute Werte zum Studienende			
n/N (%)	1/56 (2)	1/49 (2)	-
MW (SD)	66,67 (NA)	83,33 (NA)	
Effekt über Studiendauer			
n	74	70	LS MD 7,65 [1,412; 13,886] 0,0166  Hedges' g 0,40 [0,072; 0,732]
LS MW (SE)	2,60 (2,179)	-5,05 (2,283)	
95 %-KI	[-1,709; 6,910]	[-9,562; -0,535]	
Veränderung zu Woche 3/4			
n/N (%)	54/87 (62)	49/81 (60)	LS MD 6,82 [0,219; 13,429]
MW (SD)	3,40 (18,705)	-0,68 (28,658)	
LS MW (SE)	4,53 (2,311)	-2,29 (2,425)	
95 %-KI	[-0,027; 9,095]	[-7,073; 2,493]	
Veränderung zu Woche 8/9			
n/N (%)	62/86 (72)	56/79 (71)	LS MD 7,20 [0,889; 13,507]
MW (SD)	7,53 (30,130)	-5,65 (25,282)	
LS MW (SE)	3,66 (2,212)	-3,54 (2,306)	
95 %-KI	[-0,713; 8,029]	[-8,095; 1,015]	
Veränderung zu Woche 12			
n/N (%)	43/84 (51)	36/77 (47)	LS MD 7,46 [1,231; 13,687]
MW (SD)	3,49 (29,448)	-10,65 (23,622)	
LS MW (SE)	3,04 (2,181)	-4,41 (2,276)	
95 %-KI	[-1,268; 7,357]	[-8,913; 0,084]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	45/81 (56)	28/76 (37)	LS MD 7,72 [1,466; 13,976]
MW (SD)	3,33 (25,771)	-0,60 (30,592)	
LS MW (SE)	2,43 (2,183)	-5,29 (2,293)	
95 %-KI	[-1,886; 6,749]	[-9,821; -0,759]	
Veränderung zu Woche 20/21			
n/N (%)	29/77 (38)	26/73 (36)	LS MD 8,09 [1,615; 14,574]
MW (SD)	-0,57 (31,334)	3,21 (24,046)	
LS MW (SE)	1,56 (2,245)	-6,54 (2,395)	
95 %-KI	[-2,880; 5,991]	[-11,267; -1,812]	
Veränderung zu Woche 24			
n/N (%)	21/74 (28)	19/72 (26)	LS MD 8,36 [1,601; 15,112]
MW (SD)	3,17 (29,636)	-9,65 (17,843)	
LS MW (SE)	0,94 (2,326)	-7,41 (2,515)	
95 %-KI	[-3,649; 5,533]	[-12,374; -2,455]	
Veränderung zu Woche 36			
n/N (%)	35/64 (55)	24/63 (38)	LS MD 9,25 [0,966; 17,541]
MW (SD)	0,48 (18,737)	-11,11 (37,963)	
LS MW (SE)	-1,16 (2,792)	-10,41 (3,158)	
95 %-KI	[-6,653; 4,332]	[-16,622; -4,206]	
Veränderung zu Woche 48			
n/N (%)	1/56 (2)	1/49 (2)	LS MD 10,15 [-0,245; 20,546]
MW (SD)	-33,33 (NA)	66,67 (NA)	
LS MW (SE)	-3,26 (3,451)	-13,41 (4,015)	
95 %-KI	[-10,041; 3,515]	[-21,296; -5,531]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Topotecan</b>			
Baseline			
n/N (%)	39/50 (78)	32/49 (65)	-
MW (SD)	81,20 (23,314)	74,48 (26,091)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	6/33 (18)	2/20 (10)	-
MW (SD)	88,89 (13,608)	83,33 (23,570)	
Effekt über Studiendauer			
n	39	32	LS MD 5,32 [-3,182; 13,820] 0,2162  Hedges' g 0,29 [-0,176; 0,765]
LS MW (SE)	-4,27 (2,798)	-9,59 (3,240)	
95 %-KI	[-9,855; 1,320]	[-16,047; -3,126]	
Veränderung zu Woche 3/4			
n/N (%)	24/50 (48)	18/45 (40)	LS MD 2,28 [-6,574; 11,136]
MW (SD)	-10,42 (21,876)	-7,41 (21,559)	
LS MW (SE)	-5,35 (2,912)	-7,63 (3,397)	
95 %-KI	[-11,146; 0,451]	[-14,383; -0,875]	
Veränderung zu Woche 8/9			
n/N (%)	30/48 (62)	27/43 (63)	LS MD 3,58 [-4,971; 12,136]
MW (SD)	-3,89 (21,300)	-6,17 (21,754)	
LS MW (SE)	-4,88 (2,824)	-8,47 (3,257)	
95 %-KI	[-10,520; 0,750]	[-14,960; -1,974]	
Veränderung zu Woche 12			
n/N (%)	21/46 (46)	12/42 (29)	LS MD 4,49 [-3,981; 12,968]
MW (SD)	-7,14 (23,316)	-6,94 (11,143)	
LS MW (SE)	-4,56 (2,797)	-9,05 (3,224)	
95 %-KI	[-10,146; 1,024]	[-15,484; -2,625]	
Veränderung zu Woche 15/16			
n/N (%)	16/44 (36)	8/40 (20)	LS MD 5,40 [-3,105; 13,913]
MW (SD)	0,00 (20,184)	-8,33 (12,599)	
LS MW (SE)	-4,24 (2,799)	-9,64 (3,244)	
95 %-KI	[-9,827; 1,353]	[-16,109; -3,173]	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	11/41 (27)	7/33 (21)	LS MD 6,71 [-2,045; 15,456]
MW (SD)	12,12 (19,848)	-0,00 (9,623)	
LS MW (SE)	-3,77 (2,854)	-10,48 (3,366)	
95 %-KI	[-9,467; 1,918]	[-17,176; -3,783]	
Veränderung zu Woche 24			
n/N (%)	11/41 (27)	3/29 (10)	LS MD 7,62 [-1,430; 16,663]
MW (SD)	0,00 (21,082)	0,00 (0,000)	
LS MW (SE)	-3,45 (2,927)	-11,07 (3,510)	
95 %-KI	[-9,278; 2,378]	[-18,036; -4,097]	
Veränderung zu Woche 36			
n/N (%)	15/36 (42)	8/23 (35)	LS MD 10,74 [0,020; 21,459]
MW (SD)	1,11 (18,330)	-10,42 (15,269)	
LS MW (SE)	-2,34 (3,356)	-13,08 (4,290)	
95 %-KI	[-8,982; 4,302]	[-21,545; -4,613]	
Veränderung zu Woche 48			
n/N (%)	5/33 (15)	2/20 (10)	LS MD 13,86 [0,765; 26,960]
MW (SD)	3,33 (18,257)	-8,33 (11,785)	
LS MW (SE)	-1,23 (3,989)	-15,09 (5,351)	
95 %-KI	[-9,093; 6,635]	[-25,624; -4,559]	
<p><i>Analysepopulation: ITT</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023</i></p> <p><i>Modell: Veränderung zu Baseline ~ Behandlung + Baseline-Wert * Zeit in Wochen + Behandlung * Zeit in Wochen + zufällige Effekte durch die Patientin</i></p> <p><i>Die Berechnung des LS-MWs erfolgt durch ein MMRM mit dem oben angegebenen Modell. Basierend hierauf werden KI und p-Wert ermittelt. Hedges' g basiert ebenfalls auf den LS-MW und ist somit auf das Modell angepasst.</i></p> <p><i>Es werden ausschließlich gemeinsame Analysezeitpunkte dargestellt.</i></p> <p><i>Ein LS MD und Hedges' g größer als Null bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

### 3. EORTC QLQ-OV28

#### 3.1 EORTC QLQ-OV28 abdominale / gastrointestinale Symptome

##### EORTC QLQ-OV28 abdominale / gastrointestinale Symptome: Subgruppenanalyse

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
<b>EORTC QLQ-OV28 abdominale / gastrointestinale Symptome</b>			
<b>Alter: &lt; 65 Jahre</b>			
Baseline			
n/N (%)	91/115 (79)	92/119 (77)	-
MW (SD)	25,58 (24,229)	30,37 (23,934)	
Absolute Werte zum Studienende			
n/N (%)	4/73 (5)	4/64 (6)	-
MW (SD)	33,33 (16,355)	12,50 (14,611)	
Effekt über Studiendauer			
n	91	92	LS MD -7,08 [-11,954; -2,213] 0,0046  Hedges' g -0,42 [-0,716; -0,130]
LS MW (SE)	-4,60 (1,712)	2,48 (1,775)	
95 %-KI	[-7,978; -1,220]	[-1,016; 5,986]	
Veränderung zu Woche 3/4			
n/N (%)	58/113 (51)	61/115 (53)	LS MD -5,80 [-11,131; -0,464]
MW (SD)	-3,14 (21,606)	-1,28 (19,256)	
LS MW (SE)	-5,34 (1,887)	0,46 (1,938)	
95 %-KI	[-9,056; -1,621]	[-3,357; 4,275]	
Veränderung zu Woche 8/9			
n/N (%)	74/112 (66)	72/108 (67)	LS MD -6,36 [-11,339; -1,386]
MW (SD)	-5,63 (23,829)	-0,15 (19,932)	
LS MW (SE)	-5,01 (1,765)	1,35 (1,800)	
95 %-KI	[-8,495; -1,533]	[-2,200; 4,897]	
Veränderung zu Woche 12			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	46/110 (42)	40/105 (38)	LS MD -6,76 [-11,625; -1,891]
MW (SD)	-9,66 (27,453)	-1,94 (16,764)	
LS MW (SE)	-4,79 (1,720)	1,97 (1,764)	
95 %-KI	[-8,182; -1,391]	[-1,509; 5,451]	
Veränderung zu Woche 15/16			
n/N (%)	53/107 (50)	33/102 (32)	LS MD -7,15 [-12,035; -2,271]
MW (SD)	-5,87 (26,113)	-3,37 (17,891)	
LS MW (SE)	-4,56 (1,713)	2,59 (1,782)	
95 %-KI	[-7,941; -1,177]	[-0,921; 6,108]	
Veränderung zu Woche 20/21			
n/N (%)	36/101 (36)	29/96 (30)	LS MD -7,72 [-12,833; -2,602]
MW (SD)	-3,55 (30,549)	-5,17 (18,059)	
LS MW (SE)	-4,23 (1,768)	3,48 (1,896)	
95 %-KI	[-7,722; -0,747]	[-0,254; 7,220]	
Veränderung zu Woche 24			
n/N (%)	25/99 (25)	19/91 (21)	LS MD -8,11 [-13,525; -2,701]
MW (SD)	-4,89 (24,497)	-0,58 (17,849)	
LS MW (SE)	-4,01 (1,848)	4,11 (2,031)	
95 %-KI	[-7,650; -0,365]	[0,107; 8,104]	
Veränderung zu Woche 36			
n/N (%)	41/86 (48)	28/79 (35)	LS MD -9,47 [-16,500; -2,436]
MW (SD)	-5,96 (24,795)	0,79 (21,896)	
LS MW (SE)	-3,23 (2,324)	6,24 (2,719)	
95 %-KI	[-7,796; 1,341]	[0,898; 11,583]	
Veränderung zu Woche 48			
n/N (%)	4/73 (5)	3/64 (5)	LS MD -10,82 [-20,003; -1,643]
MW (SD)	1,39 (15,957)	3,70 (28,509)	
LS MW (SE)	-2,45 (2,986)	8,38 (3,594)	
95 %-KI	[-8,314; 3,417]	[1,317; 15,433]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
<b>Alter: ≥ 65 Jahre</b>			
Baseline			
n/N (%)	79/103 (77)	65/88 (74)	-
MW (SD)	22,77 (19,130)	24,96 (23,593)	
Absolute Werte zum Studienende			
n/N (%)	6/67 (9)	2/46 (4)	-
MW (SD)	13,89 (19,484)	16,67 (7,857)	
Effekt über Studiendauer			
n	79	65	LS MD -3,33 [-7,657; 0,992] 0,1299  Hedges' g -0,25 [-0,584; 0,075]
LS MW (SE)	-1,20 (1,430)	2,14 (1,661)	
95 %-KI	[-4,025; 1,632]	[-1,146; 5,418]	
Veränderung zu Woche 3/4			
n/N (%)	57/100 (57)	44/85 (52)	LS MD -2,48 [-7,287; 2,328]
MW (SD)	3,22 (17,785)	1,14 (18,312)	
LS MW (SE)	-0,87 (1,602)	1,61 (1,845)	
95 %-KI	[-4,032; 2,286]	[-2,029; 5,242]	
Veränderung zu Woche 8/9			
n/N (%)	67/98 (68)	52/80 (65)	LS MD -2,85 [-7,284; 1,580]
MW (SD)	-4,78 (15,662)	0,32 (18,125)	
LS MW (SE)	-1,01 (1,481)	1,84 (1,689)	
95 %-KI	[-3,941; 1,912]	[-1,497; 5,173]	
Veränderung zu Woche 12			
n/N (%)	48/95 (51)	32/78 (41)	LS MD -3,11 [-7,430; 1,204]
MW (SD)	-1,97 (16,508)	-1,04 (15,029)	
LS MW (SE)	-1,11 (1,437)	2,00 (1,648)	
95 %-KI	[-3,956; 1,730]	[-1,257; 5,256]	
Veränderung zu Woche 15/16			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	40/92 (43)	21/76 (28)	LS MD -3,37 [-7,710; 0,963]
MW (SD)	-2,75 (15,486)	-0,53 (19,157)	
LS MW (SE)	-1,21 (1,431)	2,16 (1,668)	
95 %-KI	[-4,043; 1,620]	[-1,134; 5,458]	
Veränderung zu Woche 20/21			
n/N (%)	29/89 (33)	21/69 (30)	LS MD -3,75 [-8,336; 0,844]
MW (SD)	-3,07 (18,520)	-4,50 (13,102)	
LS MW (SE)	-1,35 (1,487)	2,39 (1,798)	
95 %-KI	[-4,293; 1,587]	[-1,154; 5,940]	
Veränderung zu Woche 24			
n/N (%)	29/85 (34)	18/64 (28)	LS MD -4,01 [-8,915; 0,901]
MW (SD)	-6,67 (18,127)	6,17 (20,951)	
LS MW (SE)	-1,45 (1,568)	2,55 (1,949)	
95 %-KI	[-4,548; 1,644]	[-1,284; 6,394]	
Veränderung zu Woche 36			
n/N (%)	41/74 (55)	19/55 (35)	LS MD -4,90 [-11,494; 1,693]
MW (SD)	0,81 (16,197)	2,34 (17,304)	
LS MW (SE)	-1,79 (2,035)	3,11 (2,699)	
95 %-KI	[-5,794; 2,213]	[-2,194; 8,414]	
Veränderung zu Woche 48			
n/N (%)	4/67 (6)	2/46 (4)	LS MD -5,79 [-14,564; 2,975]
MW (SD)	-8,33 (14,699)	-0,00 (15,713)	
LS MW (SE)	-2,13 (2,667)	3,67 (3,629)	
95 %-KI	[-7,370; 3,111]	[-3,465; 10,796]	
<b>Region: USA</b>			
Baseline			
n/N (%)	47/65 (72)	34/51 (67)	-
MW (SD)	18,20 (19,477)	26,47 (23,293)	
Absolute Werte zum Studienende			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	2/39 (5)	3/27 (11)	-
MW (SD)	36,11 (19,642)	22,22 (11,111)	
Effekt über Studiendauer			
n	47	34	LS MD -0,42 [-6,361; 5,522] 0,8886  Hedges' g -0,03 [-0,473; 0,410]
LS MW (SE)	0,16 (1,879)	0,57 (2,287)	
95 %-KI	[-3,589; 3,900]	[-3,979; 5,128]	
Veränderung zu Woche 3/4			
n/N (%)	32/64 (50)	20/49 (41)	LS MD 3,68 [-2,968; 10,325]
MW (SD)	6,25 (16,320)	-2,22 (20,974)	
LS MW (SE)	2,26 (2,100)	-1,42 (2,588)	
95 %-KI	[-1,902; 6,420]	[-6,545; 3,706]	
Veränderung zu Woche 8/9			
n/N (%)	41/62 (66)	30/46 (65)	LS MD 1,83 [-4,301; 7,961]
MW (SD)	-1,73 (15,372)	-2,96 (19,008)	
LS MW (SE)	1,31 (1,938)	-0,52 (2,369)	
95 %-KI	[-2,544; 5,164]	[-5,227; 4,187]	
Veränderung zu Woche 12			
n/N (%)	25/59 (42)	16/45 (36)	LS MD 0,54 [-5,423; 6,496]
MW (SD)	0,44 (15,625)	-5,21 (18,310)	
LS MW (SE)	0,65 (1,884)	0,11 (2,295)	
95 %-KI	[-3,108; 4,400]	[-4,458; 4,677]	
Veränderung zu Woche 15/16			
n/N (%)	20/56 (36)	11/44 (25)	LS MD -0,76 [-6,714; 5,201]
MW (SD)	-0,56 (14,853)	0,51 (19,947)	
LS MW (SE)	-0,02 (1,884)	0,74 (2,294)	
95 %-KI	[-3,773; 3,737]	[-3,828; 5,305]	
Veränderung zu Woche 20/21			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	12/54 (22)	9/40 (22)	LS MD -2,60 [-8,852; 3,643]
MW (SD)	-0,00 (12,535)	-4,94 (18,097)	
LS MW (SE)	-0,97 (1,978)	1,64 (2,418)	
95 %-KI	[-4,898; 2,964]	[-3,165; 6,441]	
Veränderung zu Woche 24			
n/N (%)	9/53 (17)	6/38 (16)	LS MD -3,90 [-10,534; 2,737]
MW (SD)	-3,70 (10,393)	0,93 (14,236)	
LS MW (SE)	-1,63 (2,101)	2,27 (2,583)	
95 %-KI	[-5,797; 2,535]	[-2,851; 7,386]	
Veränderung zu Woche 36			
n/N (%)	21/43 (49)	10/33 (30)	LS MD -8,33 [-17,126; 0,460]
MW (SD)	-3,17 (20,977)	-3,33 (16,605)	
LS MW (SE)	-3,91 (2,777)	4,43 (3,478)	
95 %-KI	[-9,383; 1,567]	[-2,432; 11,282]	
Veränderung zu Woche 48			
n/N (%)	2/39 (5)	3/27 (11)	LS MD -12,77 [-24,421; -1,115]
MW (SD)	-5,56 (23,570)	9,26 (19,510)	
LS MW (SE)	-6,18 (3,666)	6,58 (4,641)	
95 %-KI	[-13,404; 1,035]	[-2,557; 15,723]	
<b>Region: Rest der Welt</b>			
Baseline			
n/N (%)	123/153 (80)	123/156 (79)	-
MW (SD)	26,59 (22,519)	28,59 (24,098)	
Absolute Werte zum Studienende			
n/N (%)	8/101 (8)	3/83 (4)	-
MW (SD)	18,06 (19,642)	5,56 (5,556)	
Effekt über Studiendauer			
n	123	123	LS MD -6,95 [-10,944; -2,959]
LS MW (SE)	-3,98 (1,399)	2,97 (1,470)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,737; -1,223]	[0,076; 5,868]	0,0007 Hedges' g -0,44 [-0,688; -0,183]
Veränderung zu Woche 3/4			
n/N (%)	83/149 (56)	85/151 (56)	LS MD -6,58 [-10,929; -2,223]
MW (SD)	-2,40 (20,807)	0,20 (18,375)	
LS MW (SE)	-5,12 (1,541)	1,45 (1,594)	
95 %-KI	[-8,155; -2,090]	[-1,680; 4,587]	
Veränderung zu Woche 8/9			
n/N (%)	100/148 (68)	94/142 (66)	LS MD -6,74 [-10,805; -2,673]
MW (SD)	-6,66 (21,907)	1,00 (19,158)	
LS MW (SE)	-4,63 (1,444)	2,11 (1,481)	
95 %-KI	[-7,469; -1,784]	[-0,802; 5,028]	
Veränderung zu Woche 12			
n/N (%)	69/146 (47)	56/138 (41)	LS MD -6,85 [-10,835; -2,871]
MW (SD)	-7,97 (24,542)	-0,50 (15,179)	
LS MW (SE)	-4,28 (1,407)	2,57 (1,455)	
95 %-KI	[-7,052; -1,506]	[-0,291; 5,440]	
Veränderung zu Woche 15/16			
n/N (%)	73/143 (51)	43/134 (32)	LS MD -6,97 [-10,969; -2,966]
MW (SD)	-5,62 (23,699)	-2,97 (17,996)	
LS MW (SE)	-3,93 (1,400)	3,04 (1,476)	
95 %-KI	[-6,690; -1,173]	[0,129; 5,943]	
Veränderung zu Woche 20/21			
n/N (%)	53/136 (39)	41/125 (33)	LS MD -7,13 [-11,335; -2,927]
MW (SD)	-4,09 (27,866)	-4,88 (15,772)	
LS MW (SE)	-3,44 (1,440)	3,70 (1,583)	
95 %-KI	[-6,271; -0,600]	[0,581; 6,809]	
Veränderung zu Woche 24			



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	45/131 (34)	31/117 (26)	LS MD -7,24 [-11,701; -2,789]
MW (SD)	-6,27 (22,729)	3,05 (20,480)	
LS MW (SE)	-3,09 (1,501)	4,16 (1,703)	
95 %-KI	[-6,042; -0,134]	[0,808; 7,505]	
Veränderung zu Woche 36			
n/N (%)	61/117 (52)	37/101 (37)	LS MD -7,64 [-13,442; -1,830]
MW (SD)	-2,37 (21,298)	2,70 (20,813)	
LS MW (SE)	-1,90 (1,870)	5,74 (2,302)	
95 %-KI	[-5,571; 1,776]	[1,220; 10,258]	
Veränderung zu Woche 48			
n/N (%)	6/101 (6)	2/83 (2)	LS MD -8,03 [-15,609; -0,447]
MW (SD)	-2,78 (14,380)	-8,33 (27,499)	
LS MW (SE)	-0,71 (2,391)	7,32 (3,052)	
95 %-KI	[-5,400; 3,986]	[1,332; 13,311]	
<b>Stadium bei der Diagnose: I-III</b>			
Baseline			
n/N (%)	110/141 (78)	112/144 (78)	-
MW (SD)	22,92 (21,351)	27,28 (23,928)	
Absolute Werte zum Studienende			
n/N (%)	6/91 (7)	4/76 (5)	-
MW (SD)	11,11 (13,608)	19,44 (10,638)	
Effekt über Studiendauer			
n	110	112	LS MD -6,60 [-10,499; -2,702] 0,0010  Hedges' g -0,45 [-0,713; -0,180]
LS MW (SE)	-2,93 (1,369)	3,67 (1,428)	
95 %-KI	[-5,633; -0,234]	[0,854; 6,480]	
Veränderung zu Woche 3/4			
n/N (%)	73/137 (53)	76/138 (55)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	-0,37 (19,949)	1,17 (19,058)	LS MD -5,57 [-9,850; -1,286]
LS MW (SE)	-3,75 (1,516)	1,82 (1,561)	
95 %-KI	[-6,736; -0,767]	[-1,254; 4,887]	
Veränderung zu Woche 8/9			
n/N (%)	93/136 (68)	88/129 (68)	LS MD -6,02 [-10,008; -2,025]
MW (SD)	-4,81 (19,498)	0,19 (17,976)	
LS MW (SE)	-3,40 (1,415)	2,62 (1,450)	
95 %-KI	[-6,185; -0,607]	[-0,235; 5,476]	
Veränderung zu Woche 12			
n/N (%)	62/133 (47)	49/128 (38)	LS MD -6,33 [-10,230; -2,432]
MW (SD)	-6,99 (23,004)	-1,47 (16,346)	
LS MW (SE)	-3,15 (1,378)	3,18 (1,420)	
95 %-KI	[-5,863; -0,431]	[0,386; 5,981]	
Veränderung zu Woche 15/16			
n/N (%)	64/130 (49)	35/125 (28)	LS MD -6,65 [-10,550; -2,740]
MW (SD)	-3,28 (22,986)	1,11 (17,402)	
LS MW (SE)	-2,90 (1,370)	3,75 (1,432)	
95 %-KI	[-5,599; -0,197]	[0,925; 6,568]	
Veränderung zu Woche 20/21			
n/N (%)	46/123 (37)	33/116 (28)	LS MD -7,09 [-11,178; -3,010]
MW (SD)	-3,14 (27,954)	-3,03 (16,439)	
LS MW (SE)	-2,54 (1,411)	4,55 (1,521)	
95 %-KI	[-5,324; 0,238]	[1,558; 7,544]	
Veränderung zu Woche 24			
n/N (%)	35/121 (29)	26/109 (24)	LS MD -7,41 [-11,724; -3,092]
MW (SD)	-3,78 (20,405)	1,71 (18,511)	
LS MW (SE)	-2,29 (1,474)	5,11 (1,626)	
95 %-KI	[-5,197; 0,609]	[1,916; 8,312]	
Veränderung zu Woche 36			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	54/105 (51)	35/92 (38)	LS MD -8,49 [-14,080; -2,890]
MW (SD)	-1,34 (21,513)	2,22 (20,130)	
LS MW (SE)	-1,44 (1,853)	7,04 (2,168)	
95 %-KI	[-5,081; 2,200]	[2,786; 11,302]	
Veränderung zu Woche 48			
n/N (%)	5/91 (5)	4/76 (5)	LS MD -9,56 [-16,863; -2,262]
MW (SD)	-5,56 (14,164)	9,72 (15,957)	
LS MW (SE)	-0,59 (2,383)	8,97 (2,862)	
95 %-KI	[-5,266; 4,091]	[3,356; 14,593]	
<b>Stadium bei der Diagnose: IV</b>			
Baseline			
n/N (%)	56/72 (78)	43/60 (72)	-
MW (SD)	27,08 (23,404)	31,01 (24,071)	
Absolute Werte zum Studienende			
n/N (%)	4/46 (9)	2/33 (6)	-
MW (SD)	37,50 (18,356)	2,78 (3,928)	
Effekt über Studiendauer			
n	56	43	LS MD -2,65 [-9,165; 3,870] 0,4221  Hedges' g -0,16 [-0,561; 0,235]
LS MW (SE)	-4,26 (2,118)	-1,61 (2,503)	
95 %-KI	[-8,464; -0,051]	[-6,577; 3,357]	
Veränderung zu Woche 3/4			
n/N (%)	38/71 (54)	27/59 (46)	LS MD -2,63 [-9,719; 4,459]
MW (SD)	0,00 (20,341)	-6,17 (15,123)	
LS MW (SE)	-3,53 (2,313)	-0,90 (2,733)	
95 %-KI	[-8,102; 1,048]	[-6,299; 4,505]	
Veränderung zu Woche 8/9			
n/N (%)	44/69 (64)	34/56 (61)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	-7,20 (22,466)	-1,14 (22,297)	LS MD -2,64 [-9,254; 3,979]
LS MW (SE)	-3,85 (2,172)	-1,21 (2,527)	
95 %-KI	[-8,158; 0,458]	[-6,221; 3,797]	
Veränderung zu Woche 12			
n/N (%)	28/67 (42)	22/52 (42)	LS MD -2,64 [-9,133; 3,847]
MW (SD)	-6,94 (20,321)	-1,52 (15,637)	
LS MW (SE)	-4,08 (2,124)	-1,43 (2,479)	
95 %-KI	[-8,293; 0,142]	[-6,353; 3,488]	
Veränderung zu Woche 15/16			
n/N (%)	27/64 (42)	17/50 (34)	LS MD -2,65 [-9,191; 3,893]
MW (SD)	-8,02 (20,749)	-11,76 (14,284)	
LS MW (SE)	-4,30 (2,121)	-1,65 (2,518)	
95 %-KI	[-8,514; -0,089]	[-6,647; 3,341]	
Veränderung zu Woche 20/21			
n/N (%)	17/62 (27)	16/46 (35)	LS MD -2,66 [-9,573; 4,261]
MW (SD)	-3,92 (20,485)	-8,33 (15,449)	
LS MW (SE)	-4,62 (2,194)	-1,97 (2,713)	
95 %-KI	[-8,977; -0,272]	[-7,336; 3,400]	
Veränderung zu Woche 24			
n/N (%)	18/59 (31)	10/44 (23)	LS MD -2,66 [-10,028; 4,704]
MW (SD)	-8,64 (22,645)	-1,11 (9,370)	
LS MW (SE)	-4,85 (2,296)	-2,19 (2,932)	
95 %-KI	[-9,397; -0,304]	[-7,978; 3,601]	
Veränderung zu Woche 36			
n/N (%)	27/52 (52)	11/41 (27)	LS MD -2,68 [-12,406; 7,046]
MW (SD)	-5,35 (20,700)	-5,05 (15,001)	
LS MW (SE)	-5,62 (2,882)	-2,94 (4,012)	
95 %-KI	[-11,305; 0,055]	[-10,840; 4,951]	
Veränderung zu Woche 48			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	3/46 (7)	1/33 (3)	LS MD -2,70 [-15,484; 10,087]
MW (SD)	0,00 (19,245)	-27,78 (NA)	
LS MW (SE)	-6,40 (3,690)	-3,70 (5,352)	
95 %-KI	[-13,661; 0,861]	[-14,229; 6,828]	
<b>BRCA Status: Positiv</b>			
Baseline			
n/N (%)	24/27 (89)	23/35 (66)	-
MW (SD)	26,39 (20,412)	34,30 (24,938)	
Absolute Werte zum Studienende			
n/N (%)	1/19 (5)	0/15 (0)	-
MW (SD)	38,89 (NA)	NA (NA)	
Effekt über Studiendauer			
n	24	23	LS MD 1,85 [-8,033; 11,724] 0,7084  Hedges' g 0,11 [-0,463; 0,681]
LS MW (SE)	-0,52 (3,299)	-2,37 (3,580)	
95 %-KI	[-7,183; 6,140]	[-9,565; 4,830]	
Veränderung zu Woche 3/4			
n/N (%)	16/27 (59)	17/35 (49)	LS MD 3,61 [-6,898; 14,110]
MW (SD)	-1,39 (11,915)	-11,11 (22,309)	
LS MW (SE)	0,05 (3,575)	-3,55 (3,779)	
95 %-KI	[-7,106; 7,213]	[-11,109; 4,004]	
Veränderung zu Woche 8/9			
n/N (%)	21/26 (81)	20/30 (67)	LS MD 2,75 [-7,156; 12,665]
MW (SD)	-0,00 (21,373)	-3,61 (19,768)	
LS MW (SE)	-0,22 (3,376)	-2,98 (3,527)	
95 %-KI	[-7,022; 6,572]	[-10,076; 4,116]	
Veränderung zu Woche 12			
n/N (%)	14/26 (54)	11/30 (37)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	0,00 (26,420)	-4,55 (18,562)	LS MD 2,16 [-7,659; 11,977]
LS MW (SE)	-0,42 (3,309)	-2,58 (3,523)	
95 %-KI	[-7,098; 6,259]	[-9,671; 4,514]	
Veränderung zu Woche 15/16			
n/N (%)	12/26 (46)	7/29 (24)	LS MD 1,56 [-8,435; 11,561]
MW (SD)	-9,26 (18,093)	-10,32 (22,550)	
LS MW (SE)	-0,61 (3,305)	-2,18 (3,665)	
95 %-KI	[-7,288; 6,060]	[-9,531; 5,176]	
Veränderung zu Woche 20/21			
n/N (%)	10/25 (40)	4/25 (16)	LS MD 0,71 [-9,992; 11,416]
MW (SD)	-8,89 (15,090)	-16,67 (27,592)	
LS MW (SE)	-0,89 (3,411)	-1,60 (4,085)	
95 %-KI	[-7,759; 5,975]	[-9,745; 6,536]	
Veränderung zu Woche 24			
n/N (%)	8/25 (32)	4/24 (17)	LS MD 0,12 [-11,360; 11,592]
MW (SD)	-10,42 (14,977)	-12,50 (18,908)	
LS MW (SE)	-1,09 (3,557)	-1,20 (4,497)	
95 %-KI	[-8,222; 6,049]	[-10,132; 7,726]	
Veränderung zu Woche 36			
n/N (%)	10/21 (48)	5/20 (25)	LS MD -1,93 [-17,250; 13,398]
MW (SD)	-1,11 (19,209)	-11,11 (11,111)	
LS MW (SE)	-1,75 (4,403)	0,17 (6,346)	
95 %-KI	[-10,491; 6,983]	[-12,366; 12,711]	
Veränderung zu Woche 48			
n/N (%)	1/19 (5)	0/15 (0)	LS MD -3,97 [-24,145; 16,207]
MW (SD)	11,11 (NA)	NA (NA)	
LS MW (SE)	-2,42 (5,580)	1,55 (8,517)	
95 %-KI	[-13,453; 8,610]	[-15,279; 18,375]	
<b>BRCA Status: Negativ/Unbekannt</b>			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Baseline			
n/N (%)	146/191 (76)	134/172 (78)	-
MW (SD)	23,93 (22,284)	27,07 (23,614)	
Absolute Werte zum Studienende			
n/N (%)	9/121 (7)	6/95 (6)	-
MW (SD)	19,75 (20,244)	13,89 (12,044)	
Effekt über Studiendauer			
n	146	134	LS MD -6,45 [-9,963; -2,933] 0,0004  Hedges' g -0,43 [-0,669; -0,194]
LS MW (SE)	-3,29 (1,208)	3,16 (1,317)	
95 %-KI	[-5,671; -0,914]	[0,564; 5,747]	
Veränderung zu Woche 3/4			
n/N (%)	99/186 (53)	88/165 (53)	LS MD -5,52 [-9,410; -1,626]
MW (SD)	0,24 (21,024)	1,83 (17,441)	
LS MW (SE)	-3,72 (1,343)	1,80 (1,456)	
95 %-KI	[-6,357; -1,077]	[-1,062; 4,663]	
Veränderung zu Woche 8/9			
n/N (%)	120/184 (65)	104/158 (66)	LS MD -5,92 [-9,527; -2,311]
MW (SD)	-6,14 (20,054)	0,75 (19,011)	
LS MW (SE)	-3,53 (1,249)	2,39 (1,344)	
95 %-KI	[-5,992; -1,076]	[-0,259; 5,029]	
Veränderung zu Woche 12			
n/N (%)	80/179 (45)	61/153 (40)	LS MD -6,20 [-9,716; -2,684]
MW (SD)	-6,74 (22,076)	-1,00 (15,500)	
LS MW (SE)	-3,41 (1,214)	2,79 (1,311)	
95 %-KI	[-5,797; -1,015]	[0,214; 5,375]	
Veränderung zu Woche 15/16			
n/N (%)	81/173 (47)	47/149 (32)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	-3,83 (22,673)	-1,06 (17,516)	LS MD -6,48 [-10,002; -2,960]
LS MW (SE)	-3,28 (1,208)	3,20 (1,320)	
95 %-KI	[-5,658; -0,898]	[0,606; 5,801]	
Veränderung zu Woche 20/21			
n/N (%)	55/165 (33)	46/140 (33)	LS MD -6,88 [-10,576; -3,189]
MW (SD)	-2,32 (27,168)	-3,86 (14,669)	
LS MW (SE)	-3,09 (1,250)	3,79 (1,402)	
95 %-KI	[-5,555; -0,634]	[1,030; 6,546]	
Veränderung zu Woche 24			
n/N (%)	46/159 (29)	33/131 (25)	LS MD -7,16 [-11,082; -3,245]
MW (SD)	-5,05 (22,050)	4,55 (18,965)	
LS MW (SE)	-2,97 (1,311)	4,20 (1,502)	
95 %-KI	[-5,546; -0,387]	[1,244; 7,150]	
Veränderung zu Woche 36			
n/N (%)	72/139 (52)	42/114 (37)	LS MD -8,13 [-13,274; -2,980]
MW (SD)	-2,78 (21,455)	2,91 (20,357)	
LS MW (SE)	-2,53 (1,671)	5,60 (2,023)	
95 %-KI	[-5,809; 0,754]	[1,630; 9,570]	
Veränderung zu Woche 48			
n/N (%)	7/121 (6)	5/95 (5)	LS MD -9,09 [-15,860; -2,321]
MW (SD)	-5,56 (15,045)	2,22 (21,731)	
LS MW (SE)	-2,09 (2,167)	7,00 (2,687)	
95 %-KI	[-6,341; 2,165]	[1,729; 12,275]	
<b>Baseline ECOG PS: 0</b>			
Baseline			
n/N (%)	99/128 (77)	95/113 (84)	-
MW (SD)	18,74 (19,930)	24,44 (21,370)	
Absolute Werte zum Studienende			
n/N (%)	7/87 (8)	3/72 (4)	-



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	28,57 (20,141)	18,52 (16,973)	
Effekt über Studiendauer			
n	99	95	LS MD -4,33 [-8,278; -0,381] 0,0318  Hedges' g -0,31 [-0,594; -0,027]
LS MW (SE)	-0,99 (1,366)	3,34 (1,456)	
95 %-KI	[-3,681; 1,710]	[0,472; 6,216]	
Veränderung zu Woche 3/4			
n/N (%)	69/127 (54)	62/111 (56)	LS MD -2,75 [-7,134; 1,636]
MW (SD)	0,48 (17,716)	-1,43 (16,589)	
LS MW (SE)	-1,01 (1,516)	1,74 (1,624)	
95 %-KI	[-3,997; 1,972]	[-1,460; 4,933]	
Veränderung zu Woche 8/9			
n/N (%)	83/126 (66)	74/108 (69)	LS MD -3,43 [-7,493; 0,639]
MW (SD)	-2,68 (18,392)	0,45 (18,247)	
LS MW (SE)	-1,00 (1,413)	2,43 (1,495)	
95 %-KI	[-3,787; 1,785]	[-0,520; 5,373]	
Veränderung zu Woche 12			
n/N (%)	52/122 (43)	46/108 (43)	LS MD -3,90 [-7,859; 0,056]
MW (SD)	-1,39 (21,527)	1,57 (15,301)	
LS MW (SE)	-0,99 (1,375)	2,91 (1,454)	
95 %-KI	[-3,705; 1,719]	[0,041; 5,777]	
Veränderung zu Woche 15/16			
n/N (%)	55/120 (46)	34/105 (32)	LS MD -4,38 [-8,329; -0,423]
MW (SD)	-1,21 (19,531)	1,80 (17,975)	
LS MW (SE)	-0,98 (1,367)	3,39 (1,459)	
95 %-KI	[-3,681; 1,712]	[0,515; 6,269]	
Veränderung zu Woche 20/21			
n/N (%)	39/117 (33)	31/101 (31)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	1,57 (22,402)	-0,54 (15,137)	LS MD -5,05 [-9,179; -0,929]
LS MW (SE)	-0,97 (1,409)	4,08 (1,542)	
95 %-KI	[-3,751; 1,806]	[1,043; 7,119]	
Veränderung zu Woche 24			
n/N (%)	28/112 (25)	21/96 (22)	LS MD -5,53 [-9,888; -1,170]
MW (SD)	-2,58 (16,938)	2,91 (18,140)	
LS MW (SE)	-0,96 (1,473)	4,56 (1,647)	
95 %-KI	[-3,868; 1,938]	[1,322; 7,807]	
Veränderung zu Woche 36			
n/N (%)	51/99 (52)	35/87 (40)	LS MD -7,16 [-12,831; -1,481]
MW (SD)	-0,65 (22,073)	2,38 (19,770)	
LS MW (SE)	-0,94 (1,860)	6,22 (2,208)	
95 %-KI	[-4,591; 2,718]	[1,882; 10,557]	
Veränderung zu Woche 48			
n/N (%)	5/87 (6)	3/72 (4)	LS MD -8,78 [-16,224; -1,343]
MW (SD)	-0,00 (14,164)	-3,70 (28,509)	
LS MW (SE)	-0,91 (2,398)	7,87 (2,933)	
95 %-KI	[-5,618; 3,800]	[2,116; 13,634]	
<b>Baseline ECOG PS: 1</b>			
Baseline			
n/N (%)	71/90 (79)	61/91 (67)	-
MW (SD)	31,99 (22,530)	33,79 (26,669)	
Absolute Werte zum Studienende			
n/N (%)	3/53 (6)	3/37 (8)	-
MW (SD)	5,56 (5,556)	9,26 (3,208)	
Effekt über Studiendauer			
n	71	61	LS MD -7,03 [-13,012; -1,054] 0,0215 Hedges' g
LS MW (SE)	-5,93 (1,995)	1,10 (2,273)	
95 %-KI	[-9,882; -1,980]	[-3,393; 5,597]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
			-0,41 [-0,751; -0,059]
Veränderung zu Woche 3/4			
n/N (%)	46/86 (53)	42/87 (48)	LS MD -6,25 [-12,715; 0,207]
MW (SD)	-0,70 (23,143)	1,19 (21,934)	
LS MW (SE)	-6,56 (2,198)	-0,30 (2,433)	
95 %-KI	[-10,896; -2,221]	[-5,104; 4,496]	
Veränderung zu Woche 8/9			
n/N (%)	58/84 (69)	49/78 (63)	LS MD -6,61 [-12,649; -0,563]
MW (SD)	-8,87 (22,407)	-0,79 (20,663)	
LS MW (SE)	-6,27 (2,053)	0,33 (2,269)	
95 %-KI	[-10,335; -2,215]	[-4,153; 4,816]	
Veränderung zu Woche 12			
n/N (%)	42/83 (51)	25/74 (34)	LS MD -6,85 [-12,796; -0,908]
MW (SD)	-11,11 (23,313)	-7,33 (16,015)	
LS MW (SE)	-6,08 (2,003)	0,78 (2,243)	
95 %-KI	[-10,042; -2,111]	[-3,660; 5,212]	
Veränderung zu Woche 15/16			
n/N (%)	38/79 (48)	20/72 (28)	LS MD -7,10 [-13,113; -1,084]
MW (SD)	-9,33 (24,908)	-9,17 (17,031)	
LS MW (SE)	-5,88 (1,999)	1,22 (2,295)	
95 %-KI	[-9,836; -1,920]	[-3,315; 5,756]	
Veränderung zu Woche 20/21			
n/N (%)	26/73 (36)	18/63 (29)	LS MD -7,45 [-13,845; -1,055]
MW (SD)	-10,68 (28,886)	-11,42 (15,419)	
LS MW (SE)	-5,59 (2,074)	1,86 (2,491)	
95 %-KI	[-9,696; -1,493]	[-3,060; 6,771]	
Veränderung zu Woche 24			
n/N (%)	26/72 (36)	15/58 (26)	
MW (SD)	-9,36 (24,722)	1,11 (21,741)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-5,40 (2,177)	2,30 (2,700)	LS MD -7,70 [-14,530; -0,864]
95 %-KI	[-9,696; -1,096]	[-3,020; 7,621]	
Veränderung zu Woche 36			
n/N (%)	31/61 (51)	12/46 (26)	LS MD -8,54 [-17,613; 0,531]
MW (SD)	-5,73 (19,294)	-1,39 (21,205)	
LS MW (SE)	-4,72 (2,770)	3,83 (3,697)	
95 %-KI	[-10,166; 0,735]	[-3,443; 11,093]	
Veränderung zu Woche 48			
n/N (%)	3/53 (6)	2/37 (5)	LS MD -9,39 [-21,317; 2,547]
MW (SD)	-9,26 (17,859)	11,11 (0,000)	
LS MW (SE)	-4,04 (3,579)	5,35 (4,915)	
95 %-KI	[-11,071; 3,000]	[-4,310; 15,009]	
<b>Anzahl vorheriger Therapielinien: 1</b>			
Baseline			
n/N (%)	24/31 (77)	21/29 (72)	-
MW (SD)	30,09 (23,337)	21,16 (19,612)	
Absolute Werte zum Studienende			
n/N (%)	1/22 (5)	0/14 (0)	-
MW (SD)	0,00 (NA)	NA (NA)	
Effekt über Studiendauer			
n	24	21	LS MD -9,22 [-17,448; -0,985] 0,0291  Hedges' g -0,67 [-1,272; -0,066]
LS MW (SE)	-4,10 (2,733)	5,12 (2,992)	
95 %-KI	[-9,634; 1,435]	[-0,919; 11,153]	
Veränderung zu Woche 3/4			
n/N (%)	16/31 (52)	13/29 (45)	LS MD -5,17 [-14,639; 4,307]
MW (SD)	0,35 (15,378)	-2,14 (14,080)	
LS MW (SE)	-5,28 (3,178)	-0,12 (3,515)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-11,628; 1,064]	[-7,115; 6,883]	
Veränderung zu Woche 8/9			
n/N (%)	20/31 (65)	16/26 (62)	LS MD -6,85 [-15,448; 1,752]
MW (SD)	-6,39 (14,563)	4,86 (27,806)	
LS MW (SE)	-4,79 (2,898)	2,06 (3,123)	
95 %-KI	[-10,621; 1,039]	[-4,210; 8,324]	
Veränderung zu Woche 12			
n/N (%)	14/31 (45)	12/24 (50)	LS MD -8,03 [-16,307; 0,257]
MW (SD)	-13,89 (23,138)	-1,39 (12,338)	
LS MW (SE)	-4,45 (2,779)	3,58 (2,990)	
95 %-KI	[-10,063; 1,169]	[-2,449; 9,604]	
Veränderung zu Woche 15/16			
n/N (%)	15/31 (48)	11/22 (50)	LS MD -9,20 [-17,433; -0,972]
MW (SD)	-9,26 (16,489)	5,05 (22,561)	
LS MW (SE)	-4,10 (2,733)	5,10 (2,991)	
95 %-KI	[-9,638; 1,431]	[-0,935; 11,133]	
Veränderung zu Woche 20/21			
n/N (%)	11/30 (37)	9/22 (41)	LS MD -10,88 [-19,501; -2,268]
MW (SD)	-4,04 (14,506)	6,17 (12,560)	
LS MW (SE)	-3,61 (2,799)	7,27 (3,224)	
95 %-KI	[-9,266; 2,041]	[0,804; 13,739]	
Veränderung zu Woche 24			
n/N (%)	9/30 (30)	10/20 (50)	LS MD -12,06 [-21,246; -2,877]
MW (SD)	-11,11 (25,000)	7,78 (13,659)	
LS MW (SE)	-3,27 (2,934)	8,79 (3,522)	
95 %-KI	[-9,165; 2,627]	[1,763; 15,823]	
Veränderung zu Woche 36			
n/N (%)	15/26 (58)	6/18 (33)	
MW (SD)	2,22 (24,738)	12,04 (9,569)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-2,09 (3,802)	14,01 (5,057)	LS MD -16,10 [-28,562; -3,635]
95 %-KI	[-9,626; 5,445]	[4,006; 24,009]	
Veränderung zu Woche 48			
n/N (%)	0/22 (0)	0/14 (0)	LS MD -20,14 [-36,965; -3,305]
MW (SD)	NA (NA)	NA (NA)	
LS MW (SE)	-0,91 (5,026)	19,22 (6,960)	
95 %-KI	[-10,839; 9,013]	[5,480; 32,965]	
<b>Anzahl vorheriger Therapielinien: 2</b>			
Baseline			
n/N (%)	73/89 (82)	65/83 (78)	-
MW (SD)	23,81 (20,836)	30,09 (25,056)	
Absolute Werte zum Studienende			
n/N (%)	4/59 (7)	2/50 (4)	-
MW (SD)	20,83 (17,786)	8,33 (3,928)	
Effekt über Studiendauer			
n	73	65	LS MD -3,54 [-8,874; 1,802] 0,1924  Hedges' g -0,22 [-0,559; 0,112]
LS MW (SE)	-3,93 (1,786)	-0,40 (2,014)	
95 %-KI	[-7,469; -0,398]	[-4,379; 3,585]	
Veränderung zu Woche 3/4			
n/N (%)	50/86 (58)	44/80 (55)	LS MD -3,00 [-8,813; 2,813]
MW (SD)	-1,11 (20,757)	-0,63 (20,656)	
LS MW (SE)	-4,94 (1,966)	-1,94 (2,185)	
95 %-KI	[-8,821; -1,063]	[-6,250; 2,366]	
Veränderung zu Woche 8/9			
n/N (%)	61/85 (72)	52/77 (68)	LS MD -3,24 [-8,660; 2,181]
MW (SD)	-7,54 (19,318)	-4,06 (16,136)	
LS MW (SE)	-4,49 (1,839)	-1,25 (2,024)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-8,128; -0,855]	[-5,250; 2,746]	
Veränderung zu Woche 12			
n/N (%)	38/83 (46)	31/75 (41)	LS MD -3,41 [-8,723; 1,909]
MW (SD)	-5,85 (19,372)	-3,05 (17,144)	
LS MW (SE)	-4,18 (1,794)	-0,77 (1,991)	
95 %-KI	[-7,727; -0,625]	[-4,706; 3,168]	
Veränderung zu Woche 15/16			
n/N (%)	39/80 (49)	19/74 (26)	LS MD -3,57 [-8,937; 1,787]
MW (SD)	-6,52 (23,623)	-7,60 (16,060)	
LS MW (SE)	-3,86 (1,788)	-0,29 (2,029)	
95 %-KI	[-7,400; -0,321]	[-4,296; 3,725]	
Veränderung zu Woche 20/21			
n/N (%)	31/78 (40)	20/68 (29)	LS MD -3,81 [-9,494; 1,865]
MW (SD)	-2,87 (21,124)	-9,44 (16,031)	
LS MW (SE)	-3,41 (1,848)	0,40 (2,197)	
95 %-KI	[-7,063; 0,243]	[-3,930; 4,739]	
Veränderung zu Woche 24			
n/N (%)	26/74 (35)	13/65 (20)	LS MD -3,98 [-10,039; 2,075]
MW (SD)	-5,51 (21,351)	3,42 (25,714)	
LS MW (SE)	-3,09 (1,933)	0,89 (2,381)	
95 %-KI	[-6,912; 0,723]	[-3,803; 5,579]	
Veränderung zu Woche 36			
n/N (%)	34/65 (52)	18/58 (31)	LS MD -4,56 [-12,581; 3,467]
MW (SD)	-0,78 (19,534)	2,16 (24,855)	
LS MW (SE)	-2,01 (2,435)	2,54 (3,272)	
95 %-KI	[-6,804; 2,778]	[-3,887; 8,975]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	1/50 (2)	
MW (SD)	-1,39 (12,319)	11,11 (NA)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-0,93 (3,129)	4,20 (4,367)	LS MD -5,13 [-15,692; 5,427]
95 %-KI	[-7,082; 5,218]	[-4,380; 12,781]	
<b>Anzahl vorheriger Therapielinien: 3</b>			
Baseline			
n/N (%)	73/98 (74)	71/95 (75)	-
MW (SD)	22,83 (22,653)	28,40 (23,822)	
Absolute Werte zum Studienende			
n/N (%)	5/59 (8)	4/46 (9)	-
MW (SD)	26,67 (22,703)	16,67 (14,344)	
Effekt über Studiendauer			
n	73	71	LS MD -5,31 [-10,359; -0,258] 0,0395  Hedges' g -0,35 [-0,674; -0,016]
LS MW (SE)	-1,51 (1,757)	3,80 (1,850)	
95 %-KI	[-4,982; 1,967]	[0,145; 7,457]	
Veränderung zu Woche 3/4			
n/N (%)	49/96 (51)	48/91 (53)	LS MD -4,44 [-9,931; 1,060]
MW (SD)	1,04 (20,770)	0,58 (18,452)	
LS MW (SE)	-0,79 (1,924)	3,65 (2,011)	
95 %-KI	[-4,580; 3,009]	[-0,315; 7,615]	
Veränderung zu Woche 8/9			
n/N (%)	60/94 (64)	56/85 (66)	LS MD -4,82 [-9,971; 0,335]
MW (SD)	-2,48 (22,714)	2,48 (18,347)	
LS MW (SE)	-1,10 (1,803)	3,72 (1,879)	
95 %-KI	[-4,665; 2,461]	[0,004; 7,428]	
Veränderung zu Woche 12			
n/N (%)	42/91 (46)	29/84 (35)	LS MD -5,09 [-10,134; -0,038]
MW (SD)	-2,91 (25,183)	-0,00 (16,197)	
LS MW (SE)	-1,32 (1,762)	3,76 (1,843)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-4,808; 2,160]	[0,120; 7,405]	
Veränderung zu Woche 15/16			
n/N (%)	39/88 (44)	24/82 (29)	LS MD -5,35 [-10,415; -0,292]
MW (SD)	-0,71 (22,338)	-1,39 (17,202)	
LS MW (SE)	-1,55 (1,759)	3,81 (1,855)	
95 %-KI	[-5,024; 1,934]	[0,142; 7,476]	
Veränderung zu Woche 20/21			
n/N (%)	23/82 (28)	21/75 (28)	LS MD -5,74 [-11,021; -0,452]
MW (SD)	-3,62 (34,880)	-5,29 (15,662)	
LS MW (SE)	-1,86 (1,822)	3,88 (1,956)	
95 %-KI	[-5,461; 1,738]	[0,015; 7,735]	
Veränderung zu Woche 24			
n/N (%)	19/80 (24)	14/70 (20)	LS MD -6,00 [-11,574; -0,434]
MW (SD)	-3,80 (19,603)	-1,59 (16,369)	
LS MW (SE)	-2,08 (1,909)	3,92 (2,077)	
95 %-KI	[-5,850; 1,684]	[-0,174; 8,016]	
Veränderung zu Woche 36			
n/N (%)	33/69 (48)	23/58 (40)	LS MD -6,92 [-14,067; 0,221]
MW (SD)	-6,60 (20,826)	-1,93 (17,132)	
LS MW (SE)	-2,84 (2,409)	4,08 (2,716)	
95 %-KI	[-7,581; 1,896]	[-1,260; 9,421]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	4/46 (9)	LS MD -7,84 [-17,097; 1,415]
MW (SD)	-5,56 (19,245)	-0,00 (24,428)	
LS MW (SE)	-3,60 (3,095)	4,24 (3,548)	
95 %-KI	[-9,684; 2,480]	[-2,732; 11,210]	
<b>Vorherige Verabreichung von Bevacizumab: Ja</b>			
Baseline			
n/N (%)	99/134 (74)	98/132 (74)	-

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	21,27 (19,842)	28,29 (25,998)	
Absolute Werte zum Studienende			
n/N (%)	3/79 (4)	3/62 (5)	-
MW (SD)	20,37 (13,981)	16,67 (14,699)	
Effekt über Studiendauer			
n	99	98	LS MD -6,56 [-10,977; -2,134] 0,0039
LS MW (SE)	-0,65 (1,527)	5,91 (1,633)	
95 %-KI	[-3,661; 2,365]	[2,687; 9,127]	Hedges' g -0,42 [-0,699; -0,134]
Veränderung zu Woche 3/4			
n/N (%)	63/130 (48)	66/127 (52)	LS MD -5,01 [-9,844; -0,166]
MW (SD)	4,07 (17,076)	2,36 (18,747)	
LS MW (SE)	-0,84 (1,687)	4,17 (1,776)	
95 %-KI	[-4,159; 2,483]	[0,672; 7,662]	
Veränderung zu Woche 8/9			
n/N (%)	82/130 (63)	74/119 (62)	LS MD -5,72 [-10,214; -1,226]
MW (SD)	-3,17 (18,718)	2,85 (19,118)	
LS MW (SE)	-0,75 (1,573)	4,97 (1,639)	
95 %-KI	[-3,852; 2,350]	[1,740; 8,199]	
Veränderung zu Woche 12			
n/N (%)	51/126 (40)	38/114 (33)	LS MD -6,22 [-10,626; -1,815]
MW (SD)	-1,96 (24,566)	0,44 (14,578)	
LS MW (SE)	-0,69 (1,533)	5,53 (1,614)	
95 %-KI	[-3,714; 2,336]	[2,348; 8,715]	
Veränderung zu Woche 15/16			
n/N (%)	55/122 (45)	31/112 (28)	LS MD -6,72 [-11,173; -2,269]
MW (SD)	-3,84 (21,407)	0,72 (17,844)	
LS MW (SE)	-0,63 (1,530)	6,09 (1,653)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,647; 2,391]	[2,835; 9,351]	
Veränderung zu Woche 20/21			
n/N (%)	37/114 (32)	28/103 (27)	LS MD -7,44 [-12,180; -2,692]
MW (SD)	-1,80 (26,838)	-3,77 (16,077)	
LS MW (SE)	-0,54 (1,588)	6,90 (1,808)	
95 %-KI	[-3,671; 2,590]	[3,337; 10,455]	
Veränderung zu Woche 24			
n/N (%)	29/109 (27)	17/95 (18)	LS MD -7,94 [-13,022; -2,852]
MW (SD)	0,96 (15,788)	8,82 (19,251)	
LS MW (SE)	-0,48 (1,669)	7,46 (1,973)	
95 %-KI	[-3,766; 2,808]	[3,577; 11,338]	
Veränderung zu Woche 36			
n/N (%)	45/93 (48)	21/79 (27)	LS MD -9,65 [-16,482; -2,824]
MW (SD)	-1,01 (16,703)	6,61 (14,446)	
LS MW (SE)	-0,27 (2,132)	9,38 (2,755)	
95 %-KI	[-4,458; 3,920]	[3,973; 14,795]	
Veränderung zu Woche 48			
n/N (%)	3/79 (4)	2/62 (3)	LS MD -11,37 [-20,414; -2,325]
MW (SD)	-0,00 (14,699)	19,44 (11,785)	
LS MW (SE)	-0,06 (2,762)	11,31 (3,702)	
95 %-KI	[-5,483; 5,366]	[4,042; 18,579]	
<b>Vorherige Verabreichung von Bevacizumab: Nein</b>			
Baseline			
n/N (%)	71/84 (85)	59/75 (79)	-
MW (SD)	28,47 (24,197)	27,87 (20,044)	
Absolute Werte zum Studienende			
n/N (%)	7/61 (11)	3/48 (6)	-
MW (SD)	22,22 (23,130)	11,11 (11,111)	
Effekt über Studiendauer			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n	71	59	LS MD -3,09 [-8,032; 1,848] 0,2177  Hedges' g -0,22 [-0,564; 0,129]
LS MW (SE)	-5,98 (1,661)	-2,88 (1,867)	
95 %-KI	[-9,264; -2,688]	[-6,579; 0,811]	
Veränderung zu Woche 3/4			
n/N (%)	52/83 (63)	39/73 (53)	LS MD -2,07 [-7,588; 3,444]
MW (SD)	-4,91 (22,186)	-4,70 (18,317)	
LS MW (SE)	-6,28 (1,859)	-4,20 (2,094)	
95 %-KI	[-9,943; -2,608]	[-8,333; -0,075]	
Veränderung zu Woche 8/9			
n/N (%)	59/80 (74)	50/69 (72)	LS MD -2,49 [-7,604; 2,620]
MW (SD)	-8,08 (22,151)	-4,11 (18,539)	
LS MW (SE)	-6,15 (1,725)	-3,66 (1,931)	
95 %-KI	[-9,563; -2,741]	[-7,477; 0,156]	
Veränderung zu Woche 12			
n/N (%)	43/79 (54)	34/69 (49)	LS MD -2,79 [-7,750; 2,178]
MW (SD)	-10,21 (19,733)	-3,76 (17,231)	
LS MW (SE)	-6,07 (1,674)	-3,28 (1,873)	
95 %-KI	[-9,379; -2,753]	[-6,986; 0,426]	
Veränderung zu Woche 15/16			
n/N (%)	38/77 (49)	23/66 (35)	LS MD -3,08 [-8,019; 1,859]
MW (SD)	-5,53 (23,379)	-6,28 (18,449)	
LS MW (SE)	-5,98 (1,660)	-2,90 (1,867)	
95 %-KI	[-9,267; -2,692]	[-6,593; 0,793]	
Veränderung zu Woche 20/21			
n/N (%)	28/76 (37)	22/62 (35)	LS MD -3,50 [-8,615; 1,615]
MW (SD)	-5,36 (24,450)	-6,31 (16,201)	
LS MW (SE)	-5,86 (1,709)	-2,36 (1,946)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-9,238; -2,476]	[-6,202; 1,488]	
Veränderung zu Woche 24			
n/N (%)	25/75 (33)	20/60 (33)	LS MD -3,79 [-9,172; 1,583]
MW (SD)	-13,73 (23,951)	-2,50 (18,511)	
LS MW (SE)	-5,77 (1,788)	-1,98 (2,057)	
95 %-KI	[-9,302; -2,239]	[-6,037; 2,084]	
Veränderung zu Woche 36			
n/N (%)	37/67 (55)	26/55 (47)	LS MD -4,80 [-11,723; 2,118]
MW (SD)	-4,47 (25,554)	-2,78 (22,947)	
LS MW (SE)	-5,48 (2,266)	-0,67 (2,692)	
95 %-KI	[-9,934; -1,017]	[-5,967; 4,622]	
Veränderung zu Woche 48			
n/N (%)	5/61 (8)	3/48 (6)	LS MD -5,81 [-14,853; 3,231]
MW (SD)	-5,56 (16,667)	-9,26 (19,510)	
LS MW (SE)	-5,18 (2,935)	0,63 (3,543)	
95 %-KI	[-10,948; 0,588]	[-6,330; 7,592]	
<b>Letztes Platin-freies Intervall: ≤ 3 Monate</b>			
Baseline			
n/N (%)	63/83 (76)	62/91 (68)	-
MW (SD)	20,02 (19,643)	33,69 (23,930)	
Absolute Werte zum Studienende			
n/N (%)	3/55 (5)	5/39 (13)	-
MW (SD)	31,48 (19,510)	14,44 (13,380)	
Effekt über Studiendauer			
n	63	62	LS MD -6,13 [-11,544; -0,720] 0,0267
LS MW (SE)	-3,56 (1,823)	2,57 (1,979)	
95 %-KI	[-7,170; 0,054]	[-1,343; 6,492]	Hedges' g -0,41 [-0,760; -0,051]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	46/82 (56)	44/86 (51)	LS MD -6,07 [-11,968; -0,163]
MW (SD)	-0,34 (21,981)	-3,41 (19,475)	
LS MW (SE)	-3,43 (2,003)	2,63 (2,144)	
95 %-KI	[-7,388; 0,522]	[-1,599; 6,864]	
Veränderung zu Woche 8/9			
n/N (%)	50/81 (62)	46/80 (57)	LS MD -6,10 [-11,617; -0,574]
MW (SD)	-3,42 (17,875)	-1,33 (19,358)	
LS MW (SE)	-3,49 (1,867)	2,61 (2,003)	
95 %-KI	[-7,184; 0,206]	[-1,356; 6,568]	
Veränderung zu Woche 12			
n/N (%)	31/78 (40)	25/78 (32)	LS MD -6,12 [-11,525; -0,709]
MW (SD)	-3,94 (19,094)	0,89 (17,836)	
LS MW (SE)	-3,53 (1,824)	2,59 (1,969)	
95 %-KI	[-7,143; 0,086]	[-1,308; 6,485]	
Veränderung zu Woche 15/16			
n/N (%)	34/76 (45)	13/75 (17)	LS MD -6,14 [-11,569; -0,707]
MW (SD)	-3,76 (26,756)	-7,26 (18,756)	
LS MW (SE)	-3,57 (1,828)	2,57 (1,990)	
95 %-KI	[-7,190; 0,055]	[-1,368; 6,508]	
Veränderung zu Woche 20/21			
n/N (%)	21/72 (29)	14/67 (21)	LS MD -6,17 [-11,861; -0,475]
MW (SD)	-4,50 (24,946)	-11,51 (16,662)	
LS MW (SE)	-3,62 (1,914)	2,54 (2,114)	
95 %-KI	[-7,410; 0,162]	[-1,633; 6,721]	
Veränderung zu Woche 24			
n/N (%)	16/72 (22)	12/62 (19)	LS MD -6,19 [-12,212; -0,166]
MW (SD)	-5,90 (20,028)	-4,63 (20,355)	
LS MW (SE)	-3,66 (2,024)	2,53 (2,257)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-7,661; 0,334]	[-1,928; 6,979]	
Veränderung zu Woche 36			
n/N (%)	28/63 (44)	18/50 (36)	LS MD -6,26 [-14,072; 1,549]
MW (SD)	-4,80 (21,015)	-4,01 (18,357)	
LS MW (SE)	-3,80 (2,625)	2,46 (2,989)	
95 %-KI	[-8,964; 1,367]	[-3,416; 8,343]	
Veränderung zu Woche 48			
n/N (%)	2/55 (4)	4/39 (10)	LS MD -6,33 [-16,515; 3,847]
MW (SD)	8,33 (3,928)	-0,00 (24,428)	
LS MW (SE)	-3,93 (3,422)	2,40 (3,923)	
95 %-KI	[-10,662; 2,796]	[-5,312; 10,113]	
<b>Letztes Platin-freies Intervall: &gt; 3 Monate</b>			
Baseline			
n/N (%)	107/135 (79)	95/116 (82)	-
MW (SD)	26,78 (22,980)	24,50 (23,240)	
Absolute Werte zum Studienende			
n/N (%)	7/85 (8)	1/71 (1)	-
MW (SD)	17,46 (20,141)	11,11 (NA)	
Effekt über Studiendauer			
n	107	95	LS MD -4,66 [-8,955; -0,363] 0,0337  Hedges' g -0,30 [-0,579; -0,023]
LS MW (SE)	-2,60 (1,470)	2,06 (1,609)	
95 %-KI	[-5,497; 0,302]	[-1,111; 5,234]	
Veränderung zu Woche 3/4			
n/N (%)	69/131 (53)	61/114 (54)	LS MD -2,35 [-7,120; 2,412]
MW (SD)	0,24 (18,681)	2,00 (18,145)	
LS MW (SE)	-2,93 (1,632)	-0,57 (1,791)	
95 %-KI	[-6,138; 0,286]	[-4,096; 2,951]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	91/129 (71)	78/108 (72)	LS MD -3,35 [-7,762; 1,064]
MW (SD)	-6,21 (21,540)	0,85 (19,058)	
LS MW (SE)	-2,78 (1,523)	0,56 (1,643)	
95 %-KI	[-5,786; 0,217]	[-2,673; 3,802]	
Veränderung zu Woche 12			
n/N (%)	63/127 (50)	47/105 (45)	LS MD -4,05 [-8,344; 0,253]
MW (SD)	-6,61 (24,438)	-2,84 (14,829)	
LS MW (SE)	-2,68 (1,481)	1,36 (1,601)	
95 %-KI	[-5,606; 0,236]	[-1,796; 4,516]	
Veränderung zu Woche 15/16			
n/N (%)	59/123 (48)	41/103 (40)	LS MD -4,74 [-9,045; -0,439]
MW (SD)	-4,97 (19,198)	-0,68 (18,053)	
LS MW (SE)	-2,59 (1,470)	2,16 (1,614)	
95 %-KI	[-5,486; 0,315]	[-1,025; 5,337]	
Veränderung zu Woche 20/21			
n/N (%)	44/118 (37)	36/98 (37)	LS MD -5,74 [-10,250; -1,223]
MW (SD)	-2,78 (26,318)	-2,31 (15,222)	
LS MW (SE)	-2,44 (1,510)	3,29 (1,724)	
95 %-KI	[-5,421; 0,533]	[-0,103; 6,688]	
Veränderung zu Woche 24			
n/N (%)	38/112 (34)	25/93 (27)	LS MD -6,43 [-11,223; -1,643]
MW (SD)	-5,82 (21,827)	6,22 (18,378)	
LS MW (SE)	-2,34 (1,574)	4,09 (1,857)	
95 %-KI	[-5,445; 0,756]	[0,435; 7,741]	
Veränderung zu Woche 36			
n/N (%)	54/97 (56)	29/84 (35)	LS MD -8,82 [-15,125; -2,516]
MW (SD)	-1,42 (21,232)	4,79 (20,505)	
LS MW (SE)	-2,00 (1,967)	6,82 (2,536)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-5,869; 1,860]	[1,835; 11,797]	
Veränderung zu Woche 48			
n/N (%)	6/85 (7)	1/71 (1)	LS MD -11,21 [-19,513; -2,904]
MW (SD)	-7,41 (15,582)	11,11 (NA)	
LS MW (SE)	-1,66 (2,523)	9,54 (3,394)	
95 %-KI	[-6,618; 3,290]	[2,882; 16,207]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Pegyliertes liposomales Doxorubicin</b>			
Baseline			
n/N (%)	60/80 (75)	55/76 (72)	-
MW (SD)	25,56 (20,205)	26,57 (24,327)	
Absolute Werte zum Studienende			
n/N (%)	3/51 (6)	3/41 (7)	-
MW (SD)	14,81 (21,033)	12,96 (8,486)	
Effekt über Studiendauer			
n	60	55	LS MD -9,28 [-14,826; -3,740] 0,0012  Hedges' g -0,62 [-0,991; -0,242]
LS MW (SE)	-3,93 (1,891)	5,35 (2,063)	
95 %-KI	[-7,681; -0,181]	[1,267; 9,437]	
Veränderung zu Woche 3/4			
n/N (%)	39/76 (51)	39/74 (53)	LS MD -9,18 [-15,251; -3,112]
MW (SD)	-6,70 (19,998)	2,85 (16,806)	
LS MW (SE)	-5,80 (2,106)	3,38 (2,240)	
95 %-KI	[-9,961; -1,640]	[-1,041; 7,803]	
Veränderung zu Woche 8/9			
n/N (%)	50/76 (66)	42/66 (64)	LS MD -9,22 [-14,889; -3,560]
MW (SD)	-4,67 (20,554)	3,31 (20,201)	
LS MW (SE)	-5,00 (1,965)	4,22 (2,082)	
95 %-KI	[-8,891; -1,111]	[0,104; 8,344]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	33/75 (44)	23/64 (36)	LS MD -9,26 [-14,793; -3,717]
MW (SD)	-7,74 (22,176)	-0,72 (13,115)	
LS MW (SE)	-4,44 (1,909)	4,81 (2,043)	
95 %-KI	[-8,224; -0,658]	[0,767; 8,861]	
Veränderung zu Woche 15/16			
n/N (%)	33/74 (45)	19/62 (31)	LS MD -9,29 [-14,835; -3,736]
MW (SD)	-4,55 (25,552)	3,51 (19,353)	
LS MW (SE)	-3,88 (1,891)	5,40 (2,067)	
95 %-KI	[-7,631; -0,131]	[1,310; 9,498]	
Veränderung zu Woche 20/21			
n/N (%)	26/72 (36)	18/59 (31)	LS MD -9,33 [-15,132; -3,525]
MW (SD)	-2,56 (26,351)	0,93 (13,508)	
LS MW (SE)	-3,08 (1,935)	6,25 (2,206)	
95 %-KI	[-6,915; 0,751]	[1,886; 10,608]	
Veränderung zu Woche 24			
n/N (%)	22/69 (32)	15/54 (28)	LS MD -9,36 [-15,491; -3,227]
MW (SD)	-10,61 (22,932)	1,85 (14,649)	
LS MW (SE)	-2,52 (2,011)	6,84 (2,366)	
95 %-KI	[-6,500; 1,456]	[2,168; 11,507]	
Veränderung zu Woche 36			
n/N (%)	31/60 (52)	16/48 (33)	LS MD -9,46 [-17,407; -1,520]
MW (SD)	-0,93 (28,134)	4,17 (16,912)	
LS MW (SE)	-0,60 (2,494)	8,86 (3,175)	
95 %-KI	[-5,516; 4,310]	[2,615; 15,106]	
Veränderung zu Woche 48			
n/N (%)	2/51 (4)	2/41 (5)	LS MD -9,57 [-19,931; 0,796]
MW (SD)	2,78 (11,785)	-0,00 (15,713)	
LS MW (SE)	1,32 (3,191)	10,88 (4,198)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-4,958; 7,590]	[2,631; 19,136]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Paclitaxel</b>			
Baseline			
n/N (%)	73/88 (83)	70/82 (85)	-
MW (SD)	26,16 (24,575)	31,67 (24,562)	
Absolute Werte zum Studienende			
n/N (%)	1/56 (2)	1/49 (2)	-
MW (SD)	33,33 (NA)	0,00 (NA)	
Effekt über Studiendauer			
n	73	70	LS MD -2,52 [-7,713; 2,667] 0,3381  Hedges' g -0,16 [-0,489; 0,168]
LS MW (SE)	-2,47 (1,796)	0,06 (1,913)	
95 %-KI	[-6,017; 1,087]	[-3,723; 3,839]	
Veränderung zu Woche 3/4			
n/N (%)	54/87 (62)	49/81 (60)	LS MD -2,09 [-7,787; 3,609]
MW (SD)	2,59 (20,659)	-2,61 (22,825)	
LS MW (SE)	-3,34 (1,973)	-1,25 (2,104)	
95 %-KI	[-7,235; 0,549]	[-5,402; 2,894]	
Veränderung zu Woche 8/9			
n/N (%)	62/86 (72)	55/79 (70)	LS MD -2,29 [-7,588; 3,016]
MW (SD)	-5,54 (21,449)	-4,55 (19,688)	
LS MW (SE)	-2,94 (1,842)	-0,66 (1,947)	
95 %-KI	[-6,585; 0,696]	[-4,504; 3,187]	
Veränderung zu Woche 12			
n/N (%)	41/84 (49)	37/77 (48)	LS MD -2,42 [-7,610; 2,762]
MW (SD)	-4,47 (24,945)	-2,40 (17,885)	
LS MW (SE)	-2,67 (1,799)	-0,24 (1,905)	
95 %-KI	[-6,224; 0,893]	[-4,008; 3,524]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	44/81 (54)	27/76 (36)	LS MD -2,56 [-7,774; 2,650]
MW (SD)	-6,41 (18,585)	-7,00 (19,096)	
LS MW (SE)	-2,39 (1,800)	0,18 (1,924)	
95 %-KI	[-5,948; 1,175]	[-3,628; 3,978]	
Veränderung zu Woche 20/21			
n/N (%)	28/77 (36)	25/73 (34)	LS MD -2,76 [-8,250; 2,732]
MW (SD)	-0,60 (28,139)	-10,89 (15,671)	
LS MW (SE)	-1,99 (1,877)	0,77 (2,052)	
95 %-KI	[-5,697; 1,721]	[-3,279; 4,821]	
Veränderung zu Woche 24			
n/N (%)	21/74 (28)	19/72 (26)	LS MD -2,90 [-8,734; 2,940]
MW (SD)	1,64 (21,264)	3,80 (24,220)	
LS MW (SE)	-1,71 (1,979)	1,19 (2,203)	
95 %-KI	[-5,615; 2,196]	[-3,154; 5,529]	
Veränderung zu Woche 36			
n/N (%)	36/64 (56)	23/63 (37)	LS MD -3,37 [-11,057; 4,317]
MW (SD)	-0,74 (14,426)	-0,48 (23,684)	
LS MW (SE)	-0,75 (2,545)	2,62 (2,971)	
95 %-KI	[-5,758; 4,252]	[-3,223; 8,457]	
Veränderung zu Woche 48			
n/N (%)	1/56 (2)	1/49 (2)	LS MD -3,84 [-13,948; 6,263]
MW (SD)	5,56 (NA)	-27,78 (NA)	
LS MW (SE)	0,20 (3,305)	4,05 (3,944)	
95 %-KI	[-6,289; 6,696]	[-3,702; 11,795]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Topotecan</b>			
Baseline			
n/N (%)	37/50 (74)	32/49 (65)	-
MW (SD)	18,47 (18,659)	23,09 (20,840)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	6/33 (18)	2/20 (10)	-
MW (SD)	23,15 (22,060)	22,22 (15,713)	
Effekt über Studiendauer			
n	37	32	LS MD -4,21 [-11,006; 2,588] 0,2207  Hedges' g -0,30 [-0,772; 0,179]
LS MW (SE)	-2,07 (2,239)	2,14 (2,565)	
95 %-KI	[-6,551; 2,410]	[-2,978; 7,254]	
Veränderung zu Woche 3/4			
n/N (%)	22/50 (44)	17/45 (38)	LS MD -2,49 [-9,948; 4,976]
MW (SD)	5,56 (15,239)	-0,65 (5,153)	
LS MW (SE)	0,26 (2,470)	2,74 (2,833)	
95 %-KI	[-4,651; 5,166]	[-2,880; 8,368]	
Veränderung zu Woche 8/9			
n/N (%)	29/48 (60)	27/43 (63)	LS MD -3,21 [-10,122; 3,699]
MW (SD)	-5,52 (17,806)	4,32 (14,150)	
LS MW (SE)	-0,72 (2,303)	2,49 (2,603)	
95 %-KI	[-5,319; 3,872]	[-2,698; 7,675]	
Veränderung zu Woche 12			
n/N (%)	20/46 (43)	12/42 (29)	LS MD -3,72 [-10,475; 3,035]
MW (SD)	-5,00 (19,571)	-0,46 (15,436)	
LS MW (SE)	-1,41 (2,245)	2,31 (2,541)	
95 %-KI	[-5,899; 3,079]	[-2,760; 7,380]	
Veränderung zu Woche 15/16			
n/N (%)	16/44 (36)	8/40 (20)	LS MD -4,23 [-11,031; 2,575]
MW (SD)	0,69 (24,078)	-0,00 (5,143)	
LS MW (SE)	-2,10 (2,240)	2,13 (2,567)	
95 %-KI	[-6,578; 2,386]	[-2,989; 7,252]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	11/41 (27)	7/33 (21)	LS MD -4,95 [-12,168; 2,260]
MW (SD)	-12,12 (15,678)	1,59 (17,188)	
LS MW (SE)	-3,08 (2,325)	1,88 (2,752)	
95 %-KI	[-7,720; 1,565]	[-3,596; 7,350]	
Veränderung zu Woche 24			
n/N (%)	11/41 (27)	3/29 (10)	LS MD -5,46 [-13,176; 2,252]
MW (SD)	-10,61 (12,779)	0,00 (0,000)	
LS MW (SE)	-3,76 (2,444)	1,70 (2,970)	
95 %-KI	[-8,630; 1,103]	[-4,192; 7,588]	
Veränderung zu Woche 36			
n/N (%)	15/36 (42)	8/23 (35)	LS MD -7,20 [-17,551; 3,143]
MW (SD)	-10,37 (16,649)	1,39 (14,773)	
LS MW (SE)	-6,12 (3,123)	1,09 (4,068)	
95 %-KI	[-12,291; 0,055]	[-6,943; 9,115]	
Veränderung zu Woche 48			
n/N (%)	5/33 (15)	2/20 (10)	LS MD -8,95 [-22,686; 4,794]
MW (SD)	-7,78 (17,392)	19,44 (11,785)	
LS MW (SE)	-8,47 (4,048)	0,47 (5,445)	
95 %-KI	[-16,454; -0,490]	[-10,261; 11,209]	
<p><i>Analysepopulation: ITT</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023</i></p> <p><i>Modell: Veränderung zu Baseline ~ Behandlung + Baseline-Wert * Zeit in Wochen + Behandlung * Zeit in Wochen + zufällige Effekte durch die Patientin</i></p> <p><i>Die Berechnung des LS-MW's erfolgt durch ein MMRM mit dem oben angegebenen Modell. Basierend hierauf werden KI und p-Wert ermittelt. Hedges' g basiert ebenfalls auf den LS-MW und ist somit auf das Modell angepasst.</i></p> <p><i>Es werden ausschließlich gemeinsame Analysezeitpunkte dargestellt.</i></p> <p><i>Ein LS MD und Hedges' g kleiner als Null bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

### 3.2 EORTC QLQ-OV28 Einstellung bez. Krankheit / Behandlung

#### EORTC QLQ-OV28 Einstellung bez. Krankheit / Behandlung: Subgruppenanalyse

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
<b>EORTC QLQ-OV28 Einstellung bez. Krankheit / Behandlung</b>			
<b>Alter: &lt; 65 Jahre</b>			
Baseline			
n/N (%)	90/115 (78)	92/119 (77)	-
MW (SD)	45,25 (27,313)	45,89 (26,927)	
Absolute Werte zum Studienende			
n/N (%)	4/73 (5)	4/64 (6)	-
MW (SD)	63,89 (39,933)	52,78 (27,778)	
Effekt über Studiendauer			
n	90	92	LS MD 7,00 [1,632; 12,359] 0,0109  Hedges' g 0,38 [0,087; 0,674]
LS MW (SE)	7,14 (1,887)	0,14 (1,950)	
95 %-KI	[3,410; 10,863]	[-3,706; 3,987]	
Veränderung zu Woche 3/4			
n/N (%)	57/113 (50)	58/115 (50)	LS MD 5,33 [-0,616; 11,274]
MW (SD)	11,70 (21,839)	2,30 (19,608)	
LS MW (SE)	8,74 (2,110)	3,41 (2,153)	
95 %-KI	[4,587; 12,896]	[-0,825; 7,650]	
Veränderung zu Woche 8/9			
n/N (%)	72/112 (64)	72/108 (67)	LS MD 6,06 [0,573; 11,541]
MW (SD)	9,26 (27,217)	0,77 (23,905)	
LS MW (SE)	8,04 (1,954)	1,98 (1,979)	
95 %-KI	[4,186; 11,893]	[-1,919; 5,884]	
Veränderung zu Woche 12			
n/N (%)	45/110 (41)	39/105 (37)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	12,96 (22,660)	-0,57 (17,090)	LS MD 6,57 [1,219; 11,915]
LS MW (SE)	7,55 (1,897)	0,98 (1,934)	
95 %-KI	[3,803; 11,294]	[-2,834; 4,797]	
Veränderung zu Woche 15/16			
n/N (%)	52/107 (49)	32/102 (31)	LS MD 7,08 [1,697; 12,457]
MW (SD)	9,08 (28,329)	1,04 (17,929)	
LS MW (SE)	7,06 (1,889)	-0,02 (1,958)	
95 %-KI	[3,328; 10,788]	[-3,882; 3,844]	
Veränderung zu Woche 20/21			
n/N (%)	35/101 (35)	29/96 (30)	LS MD 7,81 [2,097; 13,514]
MW (SD)	8,10 (19,119)	-3,45 (19,943)	
LS MW (SE)	6,36 (1,962)	-1,45 (2,107)	
95 %-KI	[2,486; 10,227]	[-5,600; 2,702]	
Veränderung zu Woche 24			
n/N (%)	25/99 (25)	19/91 (21)	LS MD 8,32 [2,204; 14,427]
MW (SD)	10,22 (23,986)	-2,34 (18,362)	
LS MW (SE)	5,87 (2,067)	-2,45 (2,278)	
95 %-KI	[1,793; 9,938]	[-6,933; 2,034]	
Veränderung zu Woche 36			
n/N (%)	40/86 (47)	28/79 (35)	LS MD 10,06 [1,836; 18,291]
MW (SD)	7,92 (25,095)	-4,37 (24,257)	
LS MW (SE)	4,18 (2,671)	-5,88 (3,133)	
95 %-KI	[-1,067; 9,431]	[-12,035; 0,272]	
Veränderung zu Woche 48			
n/N (%)	4/73 (5)	3/64 (5)	LS MD 11,81 [0,868; 22,756]
MW (SD)	22,22 (35,136)	-18,52 (16,973)	
LS MW (SE)	2,50 (3,491)	-9,31 (4,196)	
95 %-KI	[-4,357; 9,355]	[-17,554; -1,072]	
<b>Alter: ≥ 65 Jahre</b>			



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Baseline			
n/N (%)	79/103 (77)	64/88 (73)	-
MW (SD)	49,09 (24,820)	52,26 (28,598)	
Absolute Werte zum Studienende			
n/N (%)	6/67 (9)	2/46 (4)	-
MW (SD)	79,63 (14,768)	83,33 (23,570)	
Effekt über Studiendauer			
n	79	64	LS MD 11,79 [5,503; 18,078] 0,0003  Hedges' g 0,62 [0,286; 0,961]
LS MW (SE)	4,45 (2,069)	-7,34 (2,414)	
95 %-KI	[0,357; 8,544]	[-12,111; -2,570]	
Veränderung zu Woche 3/4			
n/N (%)	56/100 (56)	44/85 (52)	LS MD 10,22 [3,310; 17,124]
MW (SD)	4,56 (21,584)	-3,54 (20,721)	
LS MW (SE)	4,70 (2,297)	-5,52 (2,647)	
95 %-KI	[0,166; 9,227]	[-10,738; -0,303]	
Veränderung zu Woche 8/9			
n/N (%)	67/98 (68)	50/80 (62)	LS MD 10,90 [4,491; 17,311]
MW (SD)	5,14 (23,715)	-6,89 (24,373)	
LS MW (SE)	4,59 (2,138)	-6,31 (2,439)	
95 %-KI	[0,364; 8,815]	[-11,129; -1,494]	
Veränderung zu Woche 12			
n/N (%)	47/95 (49)	31/78 (40)	LS MD 11,38 [5,113; 17,646]
MW (SD)	8,27 (25,639)	-6,45 (18,981)	
LS MW (SE)	4,51 (2,080)	-6,87 (2,389)	
95 %-KI	[0,400; 8,629]	[-11,587; -2,143]	
Veränderung zu Woche 15/16			
n/N (%)	39/92 (42)	21/76 (28)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	7,41 (18,085)	-7,41 (18,370)	LS MD 11,86 [5,555; 18,162]
LS MW (SE)	4,44 (2,071)	-7,42 (2,424)	
95 %-KI	[0,343; 8,536]	[-12,208; -2,629]	
Veränderung zu Woche 20/21			
n/N (%)	29/89 (33)	21/69 (30)	LS MD 12,54 [5,879; 19,205]
MW (SD)	6,13 (24,049)	-8,99 (23,470)	
LS MW (SE)	4,33 (2,141)	-8,21 (2,613)	
95 %-KI	[0,100; 8,565]	[-13,363; -3,056]	
Veränderung zu Woche 24			
n/N (%)	29/85 (34)	18/64 (28)	LS MD 13,02 [5,917; 20,125]
MW (SD)	7,66 (26,578)	-11,11 (21,559)	
LS MW (SE)	4,26 (2,245)	-8,76 (2,826)	
95 %-KI	[-0,175; 8,691]	[-14,331; -3,195]	
Veränderung zu Woche 36			
n/N (%)	41/74 (55)	19/55 (35)	LS MD 14,66 [5,227; 24,098]
MW (SD)	5,69 (24,984)	-16,96 (31,289)	
LS MW (SE)	4,00 (2,857)	-10,66 (3,884)	
95 %-KI	[-1,619; 9,621]	[-18,295; -3,028]	
Veränderung zu Woche 48			
n/N (%)	4/67 (6)	2/46 (4)	LS MD 16,30 [3,846; 28,762]
MW (SD)	13,89 (33,179)	16,67 (23,570)	
LS MW (SE)	3,74 (3,700)	-12,56 (5,196)	
95 %-KI	[-3,526; 11,015]	[-22,767; -2,352]	
<b>Region: USA</b>			
Baseline			
n/N (%)	47/65 (72)	34/51 (67)	-
MW (SD)	47,75 (26,305)	42,48 (23,286)	
Absolute Werte zum Studienende			
n/N (%)	2/39 (5)	3/27 (11)	-

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	77,78 (15,713)	59,26 (44,905)	
Effekt über Studiendauer			
n	47	34	LS MD 10,00 [1,815; 18,183] 0,0173  Hedges' g 0,55 [0,096; 0,995]
LS MW (SE)	10,01 (2,625)	0,01 (3,153)	
95 %-KI	[4,780; 15,242]	[-6,265; 6,289]	
Veränderung zu Woche 3/4			
n/N (%)	31/64 (48)	20/49 (41)	LS MD 8,12 [-1,018; 17,253]
MW (SD)	6,63 (22,426)	-0,56 (22,649)	
LS MW (SE)	9,19 (2,928)	1,07 (3,554)	
95 %-KI	[3,383; 14,988]	[-5,971; 8,107]	
Veränderung zu Woche 8/9			
n/N (%)	40/62 (65)	30/46 (65)	LS MD 8,96 [0,526; 17,396]
MW (SD)	11,67 (24,518)	1,85 (25,452)	
LS MW (SE)	9,56 (2,707)	0,59 (3,260)	
95 %-KI	[4,173; 14,938]	[-5,884; 7,073]	
Veränderung zu Woche 12			
n/N (%)	25/59 (42)	16/45 (36)	LS MD 9,55 [1,348; 17,756]
MW (SD)	11,56 (24,318)	-6,25 (22,940)	
LS MW (SE)	9,81 (2,632)	0,26 (3,161)	
95 %-KI	[4,571; 15,059]	[-6,030; 6,556]	
Veränderung zu Woche 15/16			
n/N (%)	20/56 (36)	11/44 (25)	LS MD 10,14 [1,937; 18,349]
MW (SD)	19,44 (24,149)	10,10 (15,279)	
LS MW (SE)	10,07 (2,632)	-0,07 (3,162)	
95 %-KI	[4,830; 15,318]	[-6,364; 6,227]	
Veränderung zu Woche 20/21			
n/N (%)	12/54 (22)	9/40 (22)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	9,26 (12,385)	-0,00 (21,517)	LS MD 10,99 [2,377; 19,596]
LS MW (SE)	10,44 (2,757)	-0,54 (3,333)	
95 %-KI	[4,963; 15,926]	[-7,161; 6,077]	
Veränderung zu Woche 24			
n/N (%)	9/53 (17)	6/38 (16)	LS MD 11,58 [2,432; 20,722]
MW (SD)	13,58 (17,372)	5,56 (16,851)	
LS MW (SE)	10,70 (2,925)	-0,87 (3,557)	
95 %-KI	[4,903; 16,504]	[-7,922; 6,175]	
Veränderung zu Woche 36			
n/N (%)	21/43 (49)	10/33 (30)	LS MD 13,60 [1,489; 25,716]
MW (SD)	16,40 (28,679)	0,00 (17,372)	
LS MW (SE)	11,59 (3,848)	-2,01 (4,774)	
95 %-KI	[4,005; 19,180]	[-11,422; 7,402]	
Veränderung zu Woche 48			
n/N (%)	2/39 (5)	3/27 (11)	LS MD 15,63 [-0,415; 31,670]
MW (SD)	16,67 (70,711)	3,70 (27,962)	
LS MW (SE)	12,48 (5,068)	-3,15 (6,356)	
95 %-KI	[2,500; 22,462]	[-15,664; 9,372]	
<b>Region: Rest der Welt</b>			
Baseline			
n/N (%)	122/153 (80)	122/156 (78)	-
MW (SD)	46,77 (26,222)	50,18 (28,685)	
Absolute Werte zum Studienende			
n/N (%)	8/101 (8)	3/83 (4)	-
MW (SD)	72,22 (29,696)	66,67 (0,000)	
Effekt über Studiendauer			
n	122	122	LS MD 8,55 [3,820; 13,290] 0,0004 Hedges' g
LS MW (SE)	4,48 (1,647)	-4,08 (1,741)	
95 %-KI	[1,230; 7,722]	[-7,508; -0,650]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
			0,46 [0,201; 0,710]
Veränderung zu Woche 3/4			
n/N (%)	82/149 (55)	82/151 (54)	LS MD 6,70 [1,505; 11,896]
MW (SD)	8,74 (21,825)	-0,14 (19,714)	
LS MW (SE)	5,96 (1,832)	-0,74 (1,899)	
95 %-KI	[2,355; 9,563]	[-4,476; 2,994]	
Veränderung zu Woche 8/9			
n/N (%)	99/148 (67)	92/142 (65)	LS MD 7,50 [2,688; 12,316]
MW (SD)	5,50 (25,906)	-3,74 (23,886)	
LS MW (SE)	5,32 (1,705)	-2,18 (1,749)	
95 %-KI	[1,960; 8,676]	[-5,628; 1,260]	
Veränderung zu Woche 12			
n/N (%)	67/146 (46)	54/138 (39)	LS MD 8,06 [3,354; 12,772]
MW (SD)	10,20 (24,343)	-2,26 (16,492)	
LS MW (SE)	4,87 (1,658)	-3,19 (1,717)	
95 %-KI	[1,603; 8,136]	[-6,575; 0,188]	
Veränderung zu Woche 15/16			
n/N (%)	71/143 (50)	42/134 (31)	LS MD 8,62 [3,876; 13,372]
MW (SD)	5,24 (23,661)	-5,56 (17,908)	
LS MW (SE)	4,42 (1,648)	-4,20 (1,749)	
95 %-KI	[1,173; 7,668]	[-7,647; -0,760]	
Veränderung zu Woche 20/21			
n/N (%)	52/136 (38)	41/125 (33)	LS MD 9,43 [4,381; 14,470]
MW (SD)	6,73 (22,981)	-7,05 (21,482)	
LS MW (SE)	3,78 (1,700)	-5,65 (1,898)	
95 %-KI	[0,431; 7,127]	[-9,380; -1,913]	
Veränderung zu Woche 24			
n/N (%)	45/131 (34)	31/117 (26)	
MW (SD)	7,90 (26,551)	-8,96 (20,168)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	3,33 (1,779)	-6,66 (2,062)	LS MD 9,99 [4,588; 15,386]
95 %-KI	[-0,171; 6,832]	[-10,710; -2,602]	
Veränderung zu Woche 36			
n/N (%)	60/117 (51)	37/101 (37)	LS MD 11,91 [4,673; 19,148]
MW (SD)	3,43 (22,759)	-12,01 (29,558)	
LS MW (SE)	1,79 (2,252)	-10,12 (2,860)	
95 %-KI	[-2,632; 6,216]	[-15,732; -4,504]	
Veränderung zu Woche 48			
n/N (%)	6/101 (6)	2/83 (2)	LS MD 13,83 [4,246; 23,423]
MW (SD)	18,52 (20,688)	-16,67 (23,570)	
LS MW (SE)	0,25 (2,911)	-13,58 (3,837)	
95 %-KI	[-5,460; 5,968]	[-21,111; -6,050]	
<b>Stadium bei der Diagnose: I-III</b>			
Baseline			
n/N (%)	109/141 (77)	111/144 (77)	-
MW (SD)	48,62 (26,699)	48,75 (27,795)	
Absolute Werte zum Studienende			
n/N (%)	6/91 (7)	4/76 (5)	-
MW (SD)	70,37 (31,946)	61,11 (36,851)	
Effekt über Studiendauer			
n	109	111	LS MD 7,65 [2,557; 12,744] 0,0034
LS MW (SE)	3,82 (1,787)	-3,83 (1,865)	
95 %-KI	[0,292; 7,341]	[-7,509; -0,160]	Hedges' g 0,40 [0,131; 0,665]
Veränderung zu Woche 3/4			
n/N (%)	71/137 (52)	74/138 (54)	LS MD 5,74 [0,135; 11,337]
MW (SD)	8,45 (22,652)	0,60 (19,969)	
LS MW (SE)	5,97 (1,984)	0,23 (2,040)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[2,063; 9,871]	[-3,781; 4,243]	
Veränderung zu Woche 8/9			
n/N (%)	92/136 (68)	86/129 (67)	LS MD 6,56 [1,354; 11,774]
MW (SD)	4,59 (26,260)	-2,07 (23,892)	
LS MW (SE)	5,04 (1,849)	-1,53 (1,891)	
95 %-KI	[1,393; 8,681]	[-5,252; 2,197]	
Veränderung zu Woche 12			
n/N (%)	60/133 (45)	48/128 (38)	LS MD 7,14 [2,056; 12,232]
MW (SD)	9,44 (24,448)	-4,40 (18,442)	
LS MW (SE)	4,39 (1,799)	-2,76 (1,852)	
95 %-KI	[0,839; 7,932]	[-6,407; 0,890]	
Veränderung zu Woche 15/16			
n/N (%)	62/130 (48)	34/125 (27)	LS MD 7,72 [2,621; 12,826]
MW (SD)	4,48 (24,265)	-1,31 (15,657)	
LS MW (SE)	3,73 (1,788)	-3,99 (1,870)	
95 %-KI	[0,208; 7,261]	[-7,675; -0,304]	
Veränderung zu Woche 20/21			
n/N (%)	45/123 (37)	33/116 (28)	LS MD 8,55 [3,196; 13,907]
MW (SD)	6,67 (22,894)	-9,43 (21,177)	
LS MW (SE)	2,80 (1,842)	-5,75 (1,994)	
95 %-KI	[-0,827; 6,435]	[-9,673; -1,823]	
Veränderung zu Woche 24			
n/N (%)	35/121 (29)	26/109 (24)	LS MD 9,13 [3,453; 14,810]
MW (SD)	5,08 (25,185)	-6,84 (19,136)	
LS MW (SE)	2,15 (1,926)	-6,98 (2,138)	
95 %-KI	[-1,640; 5,946]	[-11,184; -2,773]	
Veränderung zu Woche 36			
n/N (%)	53/105 (50)	35/92 (38)	
MW (SD)	3,35 (24,996)	-11,75 (26,533)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-0,08 (2,428)	-11,20 (2,874)	LS MD 11,12 [3,686; 18,552]
95 %-KI	[-4,849; 4,690]	[-16,843; -5,554]	
Veränderung zu Woche 48			
n/N (%)	5/91 (5)	4/76 (5)	LS MD 13,11 [3,361; 22,852]
MW (SD)	8,89 (30,832)	-5,56 (29,397)	
LS MW (SE)	-2,31 (3,128)	-15,42 (3,808)	
95 %-KI	[-8,454; 3,829]	[-22,894; -7,944]	
<b>Stadium bei der Diagnose: IV</b>			
Baseline			
n/N (%)	56/72 (78)	43/60 (72)	-
MW (SD)	44,94 (25,608)	48,32 (28,160)	
Absolute Werte zum Studienende			
n/N (%)	4/46 (9)	2/33 (6)	-
MW (SD)	77,78 (20,286)	66,67 (0,000)	
Effekt über Studiendauer			
n	56	43	LS MD 9,78 [3,166; 16,398] 0,0042
LS MW (SE)	9,12 (2,147)	-0,66 (2,538)	
95 %-KI	[4,857; 13,389]	[-5,694; 4,377]	Hedges' g 0,59 [0,189; 1,001]
Veränderung zu Woche 3/4			
n/N (%)	38/71 (54)	26/59 (44)	LS MD 10,74 [3,343; 18,133]
MW (SD)	5,85 (19,924)	-2,99 (18,740)	
LS MW (SE)	7,27 (2,421)	-3,46 (2,856)	
95 %-KI	[2,488; 12,058]	[-9,105; 2,175]	
Veränderung zu Woche 8/9			
n/N (%)	43/69 (62)	34/56 (61)	LS MD 10,32 [3,589; 17,046]
MW (SD)	11,89 (23,929)	-3,59 (25,910)	
LS MW (SE)	8,09 (2,226)	-2,23 (2,565)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[3,673; 12,499]	[-7,315; 2,852]	
Veränderung zu Woche 12			
n/N (%)	28/67 (42)	21/52 (40)	LS MD 10,02 [3,466; 16,581]
MW (SD)	10,91 (20,978)	-0,53 (17,735)	
LS MW (SE)	8,66 (2,157)	-1,37 (2,499)	
95 %-KI	[4,371; 12,939]	[-6,328; 3,591]	
Veränderung zu Woche 15/16			
n/N (%)	27/64 (42)	17/50 (34)	LS MD 9,73 [3,078; 16,381]
MW (SD)	16,67 (23,215)	-3,92 (24,197)	
LS MW (SE)	9,22 (2,150)	-0,51 (2,557)	
95 %-KI	[4,951; 13,498]	[-5,578; 4,568]	
Veränderung zu Woche 20/21			
n/N (%)	17/62 (27)	16/46 (35)	LS MD 9,31 [2,089; 16,529]
MW (SD)	6,86 (17,952)	0,69 (21,264)	
LS MW (SE)	10,04 (2,250)	0,73 (2,838)	
95 %-KI	[5,575; 14,500]	[-4,884; 6,341]	
Veränderung zu Woche 24			
n/N (%)	18/59 (31)	10/44 (23)	LS MD 9,02 [1,143; 16,888]
MW (SD)	15,43 (25,031)	-3,33 (22,861)	
LS MW (SE)	10,61 (2,387)	1,59 (3,143)	
95 %-KI	[5,880; 15,333]	[-4,612; 7,795]	
Veränderung zu Woche 36			
n/N (%)	27/52 (52)	11/41 (27)	LS MD 8,01 [-3,094; 19,108]
MW (SD)	12,96 (24,216)	2,02 (27,585)	
LS MW (SE)	12,56 (3,158)	4,55 (4,575)	
95 %-KI	[6,338; 18,778]	[-4,452; 13,555]	
Veränderung zu Woche 48			
n/N (%)	3/46 (7)	1/33 (3)	
MW (SD)	33,33 (33,333)	0,00 (NA)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	14,51 (4,180)	7,51 (6,278)	LS MD 7,00 [-8,072; 22,069]
95 %-KI	[6,286; 22,732]	[-4,838; 19,860]	
<b>BRCA Status: Positiv</b>			
Baseline			
n/N (%)	24/27 (89)	23/35 (66)	-
MW (SD)	43,98 (27,507)	43,96 (29,105)	
Absolute Werte zum Studienende			
n/N (%)	1/19 (5)	0/15 (0)	-
MW (SD)	55,56 (NA)	NA (NA)	
Effekt über Studiendauer			
n	24	23	LS MD 14,55 [5,491; 23,608] 0,0023
LS MW (SE)	8,28 (2,977)	-6,27 (3,361)	
95 %-KI	[2,244; 14,310]	[-13,032; 0,487]	Hedges' g 0,93 [0,327; 1,536]
Veränderung zu Woche 3/4			
n/N (%)	16/27 (59)	17/35 (49)	LS MD 10,90 [0,636; 21,171]
MW (SD)	8,33 (20,082)	0,65 (13,873)	
LS MW (SE)	7,46 (3,530)	-3,44 (3,766)	
95 %-KI	[0,423; 14,499]	[-10,936; 4,051]	
Veränderung zu Woche 8/9			
n/N (%)	21/26 (81)	20/30 (67)	LS MD 12,66 [3,536; 21,793]
MW (SD)	8,99 (27,804)	-6,11 (17,466)	
LS MW (SE)	7,86 (3,149)	-4,81 (3,280)	
95 %-KI	[1,522; 14,189]	[-11,400; 1,780]	
Veränderung zu Woche 12			
n/N (%)	14/26 (54)	9/30 (30)	LS MD 13,90 [4,956; 22,839]
MW (SD)	12,70 (25,730)	-4,94 (12,560)	
LS MW (SE)	8,13 (3,005)	-5,77 (3,259)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[2,051; 14,211]	[-12,331; 0,798]	
Veränderung zu Woche 15/16			
n/N (%)	11/26 (42)	7/29 (24)	LS MD 15,13 [5,846; 24,415]
MW (SD)	1,01 (19,534)	-4,76 (10,843)	
LS MW (SE)	8,41 (2,982)	-6,72 (3,513)	
95 %-KI	[2,363; 14,451]	[-13,769; 0,323]	
Veränderung zu Woche 20/21			
n/N (%)	10/25 (40)	4/25 (16)	LS MD 16,89 [6,301; 27,482]
MW (SD)	13,33 (10,210)	-2,78 (5,556)	
LS MW (SE)	8,80 (3,158)	-8,09 (4,247)	
95 %-KI	[2,433; 15,169]	[-16,536; 0,356]	
Veränderung zu Woche 24			
n/N (%)	8/25 (32)	4/24 (17)	LS MD 18,12 [6,179; 30,069]
MW (SD)	13,89 (23,570)	-2,78 (5,556)	
LS MW (SE)	9,08 (3,411)	-9,05 (4,927)	
95 %-KI	[2,241; 15,913]	[-18,813; 0,719]	
Veränderung zu Woche 36			
n/N (%)	10/21 (48)	5/20 (25)	LS MD 22,35 [4,295; 40,405]
MW (SD)	2,22 (16,397)	-8,89 (19,876)	
LS MW (SE)	10,02 (4,790)	-12,33 (7,734)	
95 %-KI	[0,538; 19,508]	[-27,610; 2,956]	
Veränderung zu Woche 48			
n/N (%)	1/19 (5)	0/15 (0)	LS MD 26,58 [1,464; 51,689]
MW (SD)	33,33 (NA)	NA (NA)	
LS MW (SE)	10,97 (6,555)	-15,61 (10,828)	
95 %-KI	[-1,983; 23,921]	[-37,002; 5,786]	
<b>BRCA Status: Negativ/Unbekannt</b>			
Baseline			
n/N (%)	145/191 (76)	133/172 (77)	-

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	47,55 (26,007)	49,29 (27,502)	
Absolute Werte zum Studienende			
n/N (%)	9/121 (7)	6/95 (6)	-
MW (SD)	75,31 (27,654)	62,96 (28,689)	
Effekt über Studiendauer			
n	145	133	LS MD 7,79 [3,293; 12,295] 0,0008  Hedges' g 0,41 [0,172; 0,647]
LS MW (SE)	5,42 (1,545)	-2,38 (1,682)	
95 %-KI	[2,376; 8,461]	[-5,686; 0,935]	
Veränderung zu Woche 3/4			
n/N (%)	97/186 (52)	85/165 (52)	LS MD 6,30 [1,339; 11,252]
MW (SD)	8,13 (22,295)	-0,39 (21,307)	
LS MW (SE)	6,69 (1,710)	0,40 (1,850)	
95 %-KI	[3,329; 10,052]	[-3,241; 4,032]	
Veränderung zu Woche 8/9			
n/N (%)	118/184 (64)	102/158 (65)	LS MD 6,94 [2,335; 11,542]
MW (SD)	6,97 (25,279)	-1,63 (25,424)	
LS MW (SE)	6,14 (1,595)	-0,79 (1,710)	
95 %-KI	[3,006; 9,283]	[-4,159; 2,572]	
Veränderung zu Woche 12			
n/N (%)	78/179 (44)	61/153 (40)	LS MD 7,39 [2,895; 11,882]
MW (SD)	10,19 (24,082)	-2,91 (18,802)	
LS MW (SE)	5,76 (1,553)	-1,63 (1,672)	
95 %-KI	[2,705; 8,820]	[-4,917; 1,664]	
Veränderung zu Woche 15/16			
n/N (%)	80/173 (46)	46/149 (31)	LS MD 7,84 [3,330; 12,347]
MW (SD)	9,38 (24,886)	-1,93 (19,359)	
LS MW (SE)	5,38 (1,546)	-2,46 (1,686)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[2,336; 8,424]	[-5,776; 0,859]	
Veränderung zu Woche 20/21			
n/N (%)	54/165 (33)	46/140 (33)	LS MD 8,48 [3,742; 13,220]
MW (SD)	6,07 (22,696)	-6,04 (22,309)	
LS MW (SE)	4,83 (1,597)	-3,65 (1,794)	
95 %-KI	[1,691; 7,977]	[-7,176; -0,119]	
Veränderung zu Woche 24			
n/N (%)	46/159 (29)	33/131 (25)	LS MD 8,93 [3,899; 13,964]
MW (SD)	7,97 (25,624)	-7,07 (21,304)	
LS MW (SE)	4,45 (1,672)	-4,48 (1,923)	
95 %-KI	[1,163; 7,740]	[-8,259; -0,700]	
Veränderung zu Woche 36			
n/N (%)	71/139 (51)	42/114 (37)	LS MD 10,47 [3,858; 17,091]
MW (SD)	7,43 (25,904)	-9,52 (28,679)	
LS MW (SE)	3,14 (2,114)	-7,33 (2,588)	
95 %-KI	[-1,011; 7,292]	[-12,413; -2,254]	
Veränderung zu Woche 48			
n/N (%)	7/121 (6)	5/95 (5)	LS MD 12,02 [3,322; 20,712]
MW (SD)	15,87 (33,858)	-4,44 (25,580)	
LS MW (SE)	1,83 (2,727)	-10,19 (3,434)	
95 %-KI	[-3,522; 7,182]	[-16,925; -3,449]	
<b>Baseline ECOG PS: 0</b>			
Baseline			
n/N (%)	98/128 (77)	94/113 (83)	-
MW (SD)	50,00 (24,678)	50,35 (26,309)	
Absolute Werte zum Studienende			
n/N (%)	7/87 (8)	3/72 (4)	-
MW (SD)	63,49 (26,227)	59,26 (44,905)	
Effekt über Studiendauer			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n	98	94	LS MD 6,30 [0,834; 11,768] 0,0241  Hedges' g 0,33 [0,043; 0,613]
LS MW (SE)	4,04 (1,899)	-2,26 (2,011)	
95 %-KI	[0,295; 7,793]	[-6,224; 1,710]	
Veränderung zu Woche 3/4			
n/N (%)	67/127 (53)	59/111 (53)	LS MD 5,50 [-0,518; 11,523]
MW (SD)	6,38 (22,101)	-0,38 (19,679)	
LS MW (SE)	5,41 (2,098)	-0,09 (2,222)	
95 %-KI	[1,283; 9,546]	[-4,463; 4,286]	
Veränderung zu Woche 8/9			
n/N (%)	81/126 (64)	73/108 (68)	LS MD 5,84 [0,248; 11,437]
MW (SD)	6,31 (27,439)	-0,61 (23,780)	
LS MW (SE)	4,83 (1,960)	-1,01 (2,053)	
95 %-KI	[0,965; 8,696]	[-5,058; 3,034]	
Veränderung zu Woche 12			
n/N (%)	50/122 (41)	45/108 (42)	LS MD 6,08 [0,621; 11,541]
MW (SD)	6,44 (22,345)	-1,48 (19,332)	
LS MW (SE)	4,42 (1,910)	-1,66 (2,003)	
95 %-KI	[0,654; 8,190]	[-5,608; 2,291]	
Veränderung zu Woche 15/16			
n/N (%)	53/120 (44)	33/105 (31)	LS MD 6,32 [0,846; 11,792]
MW (SD)	6,29 (26,466)	-2,02 (20,498)	
LS MW (SE)	4,01 (1,900)	-2,31 (2,014)	
95 %-KI	[0,263; 7,764]	[-6,278; 1,667]	
Veränderung zu Woche 20/21			
n/N (%)	38/117 (32)	31/101 (31)	LS MD 6,66 [0,917; 12,400]
MW (SD)	3,22 (20,326)	-7,53 (25,562)	
LS MW (SE)	3,43 (1,959)	-3,23 (2,135)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-0,434; 7,294]	[-7,436; 0,978]	
Veränderung zu Woche 24			
n/N (%)	28/112 (25)	21/96 (22)	LS MD 6,90 [0,810; 12,984]
MW (SD)	4,76 (22,917)	-7,94 (24,125)	
LS MW (SE)	3,02 (2,048)	-3,88 (2,284)	
95 %-KI	[-1,014; 7,056]	[-8,371; 0,619]	
Veränderung zu Woche 36			
n/N (%)	50/99 (51)	35/87 (40)	LS MD 7,71 [-0,259; 15,685]
MW (SD)	4,44 (25,985)	-6,67 (29,422)	
LS MW (SE)	1,62 (2,575)	-6,09 (3,061)	
95 %-KI	[-3,440; 6,680]	[-12,106; -0,080]	
Veränderung zu Woche 48			
n/N (%)	5/87 (6)	3/72 (4)	LS MD 8,53 [-1,932; 18,991]
MW (SD)	15,56 (38,968)	3,70 (27,962)	
LS MW (SE)	0,22 (3,309)	-8,31 (4,058)	
95 %-KI	[-6,280; 6,718]	[-16,279; -0,342]	
<b>Baseline ECOG PS: 1</b>			
Baseline			
n/N (%)	71/90 (79)	61/91 (67)	-
MW (SD)	42,96 (27,761)	45,90 (29,916)	
Absolute Werte zum Studienende			
n/N (%)	3/53 (6)	3/37 (8)	-
MW (SD)	96,30 (6,415)	66,67 (0,000)	
Effekt über Studiendauer			
n	71	61	LS MD 12,97 [6,851; 19,081] 0,0001
LS MW (SE)	8,40 (2,026)	-4,57 (2,335)	
95 %-KI	[4,388; 12,412]	[-9,182; 0,052]	Hedges' g 0,73 [0,378; 1,085]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	46/86 (53)	42/87 (48)	LS MD 8,80 [2,043; 15,549]
MW (SD)	10,75 (21,609)	0,79 (20,735)	
LS MW (SE)	8,75 (2,286)	-0,05 (2,548)	
95 %-KI	[4,239; 13,260]	[-5,070; 4,977]	
Veränderung zu Woche 8/9			
n/N (%)	58/84 (69)	48/78 (62)	LS MD 10,68 [4,469; 16,884]
MW (SD)	8,62 (22,898)	-4,86 (25,307)	
LS MW (SE)	8,59 (2,103)	-2,08 (2,332)	
95 %-KI	[4,434; 12,750]	[-6,692; 2,524]	
Veränderung zu Woche 12			
n/N (%)	42/83 (51)	24/74 (32)	LS MD 11,99 [5,920; 18,066]
MW (SD)	15,48 (25,666)	-6,02 (15,706)	
LS MW (SE)	8,48 (2,037)	-3,51 (2,296)	
95 %-KI	[4,449; 12,515]	[-8,052; 1,030]	
Veränderung zu Woche 15/16			
n/N (%)	38/79 (48)	20/72 (28)	LS MD 13,31 [7,151; 19,468]
MW (SD)	11,26 (21,085)	-2,78 (14,809)	
LS MW (SE)	8,37 (2,029)	-4,94 (2,362)	
95 %-KI	[4,352; 12,391]	[-9,606; -0,269]	
Veränderung zu Woche 20/21			
n/N (%)	26/73 (36)	18/63 (29)	LS MD 15,19 [8,549; 21,830]
MW (SD)	13,03 (21,827)	-4,32 (10,873)	
LS MW (SE)	8,21 (2,120)	-6,98 (2,614)	
95 %-KI	[4,021; 12,407]	[-12,132; -1,820]	
Veränderung zu Woche 24			
n/N (%)	26/72 (36)	15/58 (26)	LS MD 16,51 [9,314; 23,699]
MW (SD)	13,25 (27,220)	-5,19 (14,467)	
LS MW (SE)	8,10 (2,247)	-8,40 (2,878)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[3,667; 12,541]	[-14,072; -2,733]	
Veränderung zu Woche 36			
n/N (%)	31/61 (51)	12/46 (26)	LS MD 21,02 [11,078; 30,960]
MW (SD)	10,57 (22,967)	-17,59 (20,899)	
LS MW (SE)	7,73 (2,964)	-13,29 (4,104)	
95 %-KI	[1,895; 13,555]	[-21,361; -5,227]	
Veränderung zu Woche 48			
n/N (%)	3/53 (6)	2/37 (5)	LS MD 25,53 [12,177; 38,889]
MW (SD)	22,22 (22,222)	-16,67 (23,570)	
LS MW (SE)	7,35 (3,918)	-18,19 (5,563)	
95 %-KI	[-0,354; 15,048]	[-29,118; -7,253]	
<b>Anzahl vorheriger Therapielinien: 1</b>			
Baseline			
n/N (%)	24/31 (77)	21/29 (72)	-
MW (SD)	45,60 (26,617)	59,79 (30,118)	
Absolute Werte zum Studienende			
n/N (%)	1/22 (5)	0/14 (0)	-
MW (SD)	66,67 (NA)	NA (NA)	
Effekt über Studiendauer			
n	24	21	LS MD 6,51 [-7,169; 20,189] 0,3421  Hedges' g 0,29 [-0,303; 0,875]
LS MW (SE)	-0,35 (4,536)	-6,86 (4,923)	
95 %-KI	[-9,523; 8,819]	[-16,792; 3,068]	
Veränderung zu Woche 3/4			
n/N (%)	15/31 (48)	13/29 (45)	LS MD 1,63 [-13,238; 16,502]
MW (SD)	9,26 (19,435)	2,56 (28,384)	
LS MW (SE)	5,09 (4,974)	3,46 (5,410)	
95 %-KI	[-4,867; 15,056]	[-7,352; 14,277]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	20/31 (65)	16/26 (62)	LS MD 3,65 [-10,371; 17,662]
MW (SD)	5,56 (25,105)	-6,25 (39,330)	
LS MW (SE)	2,85 (4,698)	-0,80 (5,025)	
95 %-KI	[-6,614; 12,306]	[-10,908; 9,309]	
Veränderung zu Woche 12			
n/N (%)	14/31 (45)	12/24 (50)	LS MD 5,06 [-8,662; 18,772]
MW (SD)	4,37 (26,346)	-0,93 (26,992)	
LS MW (SE)	1,27 (4,583)	-3,78 (4,906)	
95 %-KI	[-7,981; 10,525]	[-13,677; 6,112]	
Veränderung zu Woche 15/16			
n/N (%)	15/31 (48)	11/22 (50)	LS MD 6,46 [-7,211; 20,141]
MW (SD)	5,56 (21,311)	3,03 (19,303)	
LS MW (SE)	-0,30 (4,536)	-6,77 (4,921)	
95 %-KI	[-9,473; 8,870]	[-16,691; 3,159]	
Veränderung zu Woche 20/21			
n/N (%)	11/30 (37)	9/22 (41)	LS MD 8,48 [-5,587; 22,544]
MW (SD)	-1,52 (21,672)	-12,35 (29,630)	
LS MW (SE)	-2,55 (4,594)	-11,03 (5,170)	
95 %-KI	[-11,825; 6,725]	[-21,413; -0,644]	
Veränderung zu Woche 24			
n/N (%)	9/30 (30)	10/20 (50)	LS MD 9,89 [-4,749; 24,525]
MW (SD)	-1,23 (16,144)	-2,22 (22,098)	
LS MW (SE)	-4,12 (4,719)	-14,01 (5,488)	
95 %-KI	[-13,623; 5,376]	[-24,986; -3,037]	
Veränderung zu Woche 36			
n/N (%)	15/26 (58)	6/18 (33)	LS MD 14,72 [-3,401; 32,842]
MW (SD)	-5,56 (25,459)	-33,33 (41,574)	
LS MW (SE)	-9,52 (5,586)	-24,24 (7,200)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-20,632; 1,592]	[-38,496; -9,985]	
Veränderung zu Woche 48			
n/N (%)	0/22 (0)	0/14 (0)	LS MD 19,55 [-3,561; 42,668]
MW (SD)	NA (NA)	NA (NA)	
LS MW (SE)	-14,92 (6,914)	-34,47 (9,447)	
95 %-KI	[-28,589; -1,243]	[-53,124; -15,815]	
<b>Anzahl vorheriger Therapielinien: 2</b>			
Baseline			
n/N (%)	73/89 (82)	65/83 (78)	-
MW (SD)	43,99 (25,013)	47,01 (28,516)	
Absolute Werte zum Studienende			
n/N (%)	4/59 (7)	2/50 (4)	-
MW (SD)	63,89 (39,933)	66,67 (0,000)	
Effekt über Studiendauer			
n	73	65	LS MD 7,15 [1,257; 13,036] 0,0178  Hedges' g 0,41 [0,073; 0,749]
LS MW (SE)	7,39 (1,955)	0,25 (2,224)	
95 %-KI	[3,523; 11,264]	[-4,149; 4,643]	
Veränderung zu Woche 3/4			
n/N (%)	50/86 (58)	43/80 (54)	LS MD 4,05 [-2,591; 10,687]
MW (SD)	4,89 (23,453)	0,00 (19,092)	
LS MW (SE)	6,42 (2,239)	2,38 (2,501)	
95 %-KI	[2,009; 10,838]	[-2,552; 7,303]	
Veränderung zu Woche 8/9			
n/N (%)	60/85 (71)	52/77 (68)	LS MD 5,43 [-0,565; 11,422]
MW (SD)	7,41 (24,775)	-0,43 (22,109)	
LS MW (SE)	6,86 (2,037)	1,43 (2,241)	
95 %-KI	[2,830; 10,881]	[-2,998; 5,853]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	38/83 (46)	31/75 (41)	LS MD 6,39 [0,562; 12,228]
MW (SD)	12,87 (21,694)	-2,15 (16,081)	
LS MW (SE)	7,16 (1,965)	0,76 (2,187)	
95 %-KI	[3,269; 11,048]	[-3,559; 5,086]	
Veränderung zu Woche 15/16			
n/N (%)	38/80 (48)	18/74 (24)	LS MD 7,36 [1,426; 13,297]
MW (SD)	9,65 (22,986)	-3,70 (20,166)	
LS MW (SE)	7,46 (1,959)	0,10 (2,248)	
95 %-KI	[3,581; 11,340]	[-4,343; 4,541]	
Veränderung zu Woche 20/21			
n/N (%)	31/78 (40)	20/68 (29)	LS MD 8,74 [2,234; 15,250]
MW (SD)	9,68 (18,086)	-3,33 (20,104)	
LS MW (SE)	7,89 (2,065)	-0,85 (2,516)	
95 %-KI	[3,811; 11,974]	[-5,811; 4,112]	
Veränderung zu Woche 24			
n/N (%)	26/74 (35)	13/65 (20)	LS MD 9,71 [2,556; 16,861]
MW (SD)	13,68 (28,512)	-7,69 (17,792)	
LS MW (SE)	8,20 (2,209)	-1,51 (2,802)	
95 %-KI	[3,836; 12,555]	[-7,030; 4,003]	
Veränderung zu Woche 36			
n/N (%)	34/65 (52)	18/58 (31)	LS MD 13,02 [2,754; 23,291]
MW (SD)	8,50 (21,893)	-3,09 (26,896)	
LS MW (SE)	9,23 (2,998)	-3,79 (4,117)	
95 %-KI	[3,336; 15,128]	[-11,882; 4,302]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	1/50 (2)	LS MD 16,34 [2,299; 30,374]
MW (SD)	22,22 (24,003)	0,00 (NA)	
LS MW (SE)	10,27 (4,024)	-6,07 (5,664)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[2,362; 18,177]	[-17,197; 5,064]	
<b>Anzahl vorheriger Therapielinien: 3</b>			
Baseline			
n/N (%)	72/98 (73)	70/95 (74)	-
MW (SD)	50,62 (27,081)	46,51 (25,750)	
Absolute Werte zum Studienende			
n/N (%)	5/59 (8)	4/46 (9)	-
MW (SD)	82,22 (14,907)	61,11 (36,851)	
Effekt über Studiendauer			
n	72	70	LS MD 11,41 [5,248; 17,575] 0,0004
LS MW (SE)	6,42 (2,145)	-4,99 (2,271)	
95 %-KI	[2,174; 10,660]	[-9,484; -0,504]	
Veränderung zu Woche 3/4			
n/N (%)	48/96 (50)	46/91 (51)	LS MD 10,86 [4,196; 17,519]
MW (SD)	11,23 (20,897)	-1,21 (18,918)	
LS MW (SE)	7,37 (2,331)	-3,48 (2,452)	
95 %-KI	[2,773; 11,973]	[-8,321; 1,351]	
Veränderung zu Woche 8/9			
n/N (%)	59/94 (63)	54/85 (64)	LS MD 11,10 [4,825; 17,372]
MW (SD)	7,72 (26,922)	-3,09 (20,750)	
LS MW (SE)	6,96 (2,196)	-4,14 (2,302)	
95 %-KI	[2,617; 11,297]	[-8,691; 0,407]	
Veränderung zu Woche 12			
n/N (%)	40/91 (44)	27/84 (32)	LS MD 11,27 [5,111; 17,424]
MW (SD)	10,56 (25,899)	-5,35 (15,825)	
LS MW (SE)	6,67 (2,150)	-4,60 (2,261)	
95 %-KI	[2,413; 10,917]	[-9,073; -0,131]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	38/88 (43)	24/82 (29)	LS MD 11,44 [5,261; 17,611]
MW (SD)	8,19 (27,178)	-3,70 (16,920)	
LS MW (SE)	6,37 (2,147)	-5,06 (2,277)	
95 %-KI	[2,127; 10,621]	[-9,564; -0,561]	
Veränderung zu Woche 20/21			
n/N (%)	22/82 (27)	21/75 (28)	LS MD 11,68 [5,244; 18,110]
MW (SD)	8,08 (25,006)	-5,29 (19,122)	
LS MW (SE)	5,96 (2,218)	-5,72 (2,394)	
95 %-KI	[1,573; 10,342]	[-10,446; -0,993]	
Veränderung zu Woche 24			
n/N (%)	19/80 (24)	14/70 (20)	LS MD 11,85 [5,084; 18,607]
MW (SD)	7,02 (23,192)	-8,73 (21,868)	
LS MW (SE)	5,67 (2,317)	-6,18 (2,535)	
95 %-KI	[1,092; 10,240]	[-11,178; -1,181]	
Veränderung zu Woche 36			
n/N (%)	32/69 (46)	23/58 (40)	LS MD 12,42 [3,844; 21,004]
MW (SD)	10,76 (26,548)	-8,21 (21,508)	
LS MW (SE)	4,67 (2,887)	-7,76 (3,279)	
95 %-KI	[-1,013; 10,347]	[-14,205; -1,309]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	4/46 (9)	LS MD 13,00 [1,965; 24,039]
MW (SD)	13,89 (41,944)	-5,56 (29,397)	
LS MW (SE)	3,67 (3,677)	-9,33 (4,254)	
95 %-KI	[-3,559; 10,894]	[-17,693; -0,975]	
<b>Vorherige Verabreichung von Bevacizumab: Ja</b>			
Baseline			
n/N (%)	98/134 (73)	97/132 (73)	-
MW (SD)	49,55 (24,467)	48,00 (26,862)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	3/79 (4)	3/62 (5)	-
MW (SD)	59,26 (44,905)	48,15 (32,075)	
Effekt über Studiendauer			
n	98	97	LS MD 8,95 [4,098; 13,803] 0,0004  Hedges' g 0,52 [0,234; 0,805]
LS MW (SE)	5,41 (1,673)	-3,54 (1,801)	
95 %-KI	[2,104; 8,709]	[-7,095; 0,008]	
Veränderung zu Woche 3/4			
n/N (%)	62/130 (48)	64/127 (50)	LS MD 5,36 [-0,081; 10,801]
MW (SD)	8,24 (19,395)	-0,69 (19,283)	
LS MW (SE)	5,93 (1,903)	0,57 (2,005)	
95 %-KI	[2,182; 9,672]	[-3,378; 4,513]	
Veränderung zu Woche 8/9			
n/N (%)	80/130 (62)	72/119 (61)	LS MD 7,01 [2,060; 11,957]
MW (SD)	5,14 (23,583)	-0,46 (23,024)	
LS MW (SE)	5,69 (1,740)	-1,32 (1,810)	
95 %-KI	[2,257; 9,120]	[-4,888; 2,248]	
Veränderung zu Woche 12			
n/N (%)	49/126 (39)	37/114 (32)	LS MD 8,16 [3,339; 12,986]
MW (SD)	13,15 (23,315)	-4,80 (16,675)	
LS MW (SE)	5,52 (1,683)	-2,64 (1,774)	
95 %-KI	[2,201; 8,842]	[-6,140; 0,858]	
Veränderung zu Woche 15/16			
n/N (%)	54/122 (44)	31/112 (28)	LS MD 9,32 [4,419; 14,214]
MW (SD)	5,56 (24,491)	-3,94 (14,782)	
LS MW (SE)	5,35 (1,677)	-3,96 (1,828)	
95 %-KI	[2,044; 8,664]	[-7,565; -0,359]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	36/114 (32)	28/103 (27)	LS MD 10,96 [5,637; 16,292]
MW (SD)	8,02 (18,896)	-6,35 (19,698)	
LS MW (SE)	5,12 (1,759)	-5,85 (2,043)	
95 %-KI	[1,646; 8,584]	[-9,871; -1,827]	
Veränderung zu Woche 24			
n/N (%)	29/109 (27)	17/95 (18)	LS MD 12,12 [6,302; 17,935]
MW (SD)	11,11 (20,358)	-10,46 (15,451)	
LS MW (SE)	4,95 (1,873)	-7,17 (2,270)	
95 %-KI	[1,258; 8,638]	[-11,634; -2,707]	
Veränderung zu Woche 36			
n/N (%)	44/93 (47)	21/79 (27)	LS MD 16,07 [7,861; 24,288]
MW (SD)	6,57 (23,881)	-15,87 (22,925)	
LS MW (SE)	4,37 (2,507)	-11,70 (3,308)	
95 %-KI	[-0,551; 9,300]	[-18,198; -5,203]	
Veränderung zu Woche 48			
n/N (%)	3/79 (4)	2/62 (3)	LS MD 20,03 [8,884; 31,178]
MW (SD)	0,00 (40,062)	-11,11 (15,713)	
LS MW (SE)	3,80 (3,340)	-16,23 (4,531)	
95 %-KI	[-2,759; 10,361]	[-25,128; -7,332]	
<b>Vorherige Verabreichung von Bevacizumab: Nein</b>			
Baseline			
n/N (%)	71/84 (85)	59/75 (79)	-
MW (SD)	43,58 (28,166)	49,34 (29,272)	
Absolute Werte zum Studienende			
n/N (%)	7/61 (11)	3/48 (6)	-
MW (SD)	79,37 (16,265)	77,78 (19,245)	
Effekt über Studiendauer			
n	71	59	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	6,47 (2,417)	-2,64 (2,694)	LS MD 9,10 [1,926; 16,280] 0,0133  Hedges' g 0,44 [0,092; 0,791]
95 %-KI	[1,681; 11,251]	[-7,966; 2,693]	
Veränderung zu Woche 3/4			
n/N (%)	51/83 (61)	38/73 (52)	LS MD 9,24 [1,441; 17,038]
MW (SD)	8,06 (24,828)	0,58 (21,912)	
LS MW (SE)	8,02 (2,633)	-1,22 (2,938)	
95 %-KI	[2,826; 13,222]	[-7,012; 4,581]	
Veränderung zu Woche 8/9			
n/N (%)	59/80 (74)	50/69 (72)	LS MD 9,18 [1,840; 16,527]
MW (SD)	10,17 (28,010)	-5,11 (26,006)	
LS MW (SE)	7,39 (2,486)	-1,80 (2,753)	
95 %-KI	[2,469; 12,302]	[-7,240; 3,644]	
Veränderung zu Woche 12			
n/N (%)	43/79 (54)	33/69 (48)	LS MD 9,14 [1,958; 16,331]
MW (SD)	7,62 (25,140)	-1,35 (19,594)	
LS MW (SE)	6,94 (2,430)	-2,21 (2,692)	
95 %-KI	[2,128; 11,749]	[-7,531; 3,120]	
Veränderung zu Woche 15/16			
n/N (%)	37/77 (48)	22/66 (33)	LS MD 9,11 [1,932; 16,278]
MW (SD)	12,46 (23,910)	0,00 (22,745)	
LS MW (SE)	6,49 (2,416)	-2,61 (2,692)	
95 %-KI	[1,708; 11,276]	[-7,939; 2,713]	
Veränderung zu Woche 20/21			
n/N (%)	28/76 (37)	22/62 (35)	LS MD 9,05 [1,647; 16,451]
MW (SD)	6,15 (24,443)	-5,05 (23,936)	
LS MW (SE)	5,85 (2,470)	-3,20 (2,797)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[0,967; 10,740]	[-8,723; 2,332]	
Veränderung zu Woche 24			
n/N (%)	25/75 (33)	20/60 (33)	LS MD 9,01 [1,286; 16,734]
MW (SD)	6,22 (30,103)	-3,33 (23,390)	
LS MW (SE)	5,41 (2,556)	-3,60 (2,938)	
95 %-KI	[0,354; 10,459]	[-9,401; 2,195]	
Veränderung zu Woche 36			
n/N (%)	37/67 (55)	26/55 (47)	LS MD 8,88 [-0,740; 18,491]
MW (SD)	7,06 (26,406)	-4,27 (30,482)	
LS MW (SE)	3,87 (3,098)	-5,00 (3,731)	
95 %-KI	[-2,224; 9,973]	[-12,339; 2,338]	
Veränderung zu Woche 48			
n/N (%)	5/61 (8)	3/48 (6)	LS MD 8,74 [-3,521; 21,002]
MW (SD)	28,89 (24,343)	0,00 (33,333)	
LS MW (SE)	2,34 (3,884)	-6,40 (4,807)	
95 %-KI	[-5,291; 9,977]	[-15,845; 3,049]	
<b>Letztes Platin-freies Intervall: ≤ 3 Monate</b>			
Baseline			
n/N (%)	63/83 (76)	62/91 (68)	-
MW (SD)	47,97 (25,465)	42,65 (25,385)	
Absolute Werte zum Studienende			
n/N (%)	3/55 (5)	5/39 (13)	-
MW (SD)	59,26 (44,905)	62,22 (32,011)	
Effekt über Studiendauer			
n	63	62	LS MD 13,99 [7,936; 20,050] < 0,0001
LS MW (SE)	7,66 (2,071)	-6,34 (2,240)	
95 %-KI	[3,551; 11,760]	[-10,771; -1,904]	Hedges' g 0,82 [0,451; 1,181]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	46/82 (56)	44/86 (51)	LS MD 12,96 [6,296; 19,626]
MW (SD)	6,76 (23,008)	-1,77 (18,397)	
LS MW (SE)	7,67 (2,323)	-5,29 (2,442)	
95 %-KI	[3,084; 12,256]	[-10,108; -0,473]	
Veränderung zu Woche 8/9			
n/N (%)	49/81 (60)	45/80 (56)	LS MD 13,42 [7,279; 19,568]
MW (SD)	9,52 (25,154)	-7,41 (20,922)	
LS MW (SE)	7,66 (2,135)	-5,76 (2,253)	
95 %-KI	[3,438; 11,889]	[-10,215; -1,306]	
Veränderung zu Woche 12			
n/N (%)	31/78 (40)	23/78 (29)	LS MD 13,75 [7,732; 19,763]
MW (SD)	7,17 (22,689)	-6,28 (16,353)	
LS MW (SE)	7,66 (2,074)	-6,09 (2,214)	
95 %-KI	[3,549; 11,769]	[-10,471; -1,707]	
Veränderung zu Woche 15/16			
n/N (%)	34/76 (45)	13/75 (17)	LS MD 14,07 [7,977; 20,167]
MW (SD)	10,13 (22,451)	-7,69 (18,913)	
LS MW (SE)	7,65 (2,078)	-6,42 (2,259)	
95 %-KI	[3,536; 11,772]	[-10,887; -1,949]	
Veränderung zu Woche 20/21			
n/N (%)	21/72 (29)	14/67 (21)	LS MD 14,54 [7,982; 21,088]
MW (SD)	9,52 (21,165)	-3,97 (20,722)	
LS MW (SE)	7,65 (2,193)	-6,89 (2,455)	
95 %-KI	[3,308; 11,988]	[-11,736; -2,039]	
Veränderung zu Woche 24			
n/N (%)	16/72 (22)	12/62 (19)	LS MD 14,86 [7,781; 21,937]
MW (SD)	9,03 (17,786)	-9,26 (24,995)	
LS MW (SE)	7,64 (2,343)	-7,22 (2,669)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[3,016; 12,270]	[-12,480; -1,952]	
Veränderung zu Woche 36			
n/N (%)	28/63 (44)	18/50 (36)	LS MD 15,97 [6,258; 25,683]
MW (SD)	12,30 (21,242)	-9,88 (22,511)	
LS MW (SE)	7,63 (3,143)	-8,34 (3,701)	
95 %-KI	[1,443; 13,812]	[-15,624; -1,062]	
Veränderung zu Woche 48			
n/N (%)	2/55 (4)	4/39 (10)	LS MD 17,08 [4,076; 30,087]
MW (SD)	-5,56 (7,857)	2,78 (22,906)	
LS MW (SE)	7,61 (4,180)	-9,47 (4,963)	
95 %-KI	[-0,606; 15,829]	[-19,227; 0,287]	
<b>Letztes Platin-freies Intervall: &gt; 3 Monate</b>			
Baseline			
n/N (%)	106/135 (79)	94/116 (81)	-
MW (SD)	46,49 (26,686)	52,36 (28,625)	
Absolute Werte zum Studienende			
n/N (%)	7/85 (8)	1/71 (1)	-
MW (SD)	79,37 (16,265)	66,67 (NA)	
Effekt über Studiendauer			
n	106	94	LS MD 5,63 [0,243; 11,015] 0,0406  Hedges' g 0,29 [0,013; 0,572]
LS MW (SE)	4,72 (1,833)	-0,91 (2,011)	
95 %-KI	[1,106; 8,340]	[-4,870; 3,058]	
Veränderung zu Woche 3/4			
n/N (%)	67/131 (51)	58/114 (51)	LS MD 2,32 [-3,660; 8,299]
MW (SD)	9,12 (21,248)	0,96 (21,558)	
LS MW (SE)	5,91 (2,037)	3,60 (2,241)	
95 %-KI	[1,905; 9,924]	[-0,815; 8,005]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	90/129 (70)	77/108 (71)	LS MD 3,74 [-1,790; 9,271]
MW (SD)	6,05 (25,866)	0,58 (25,738)	
LS MW (SE)	5,40 (1,900)	1,66 (2,053)	
95 %-KI	[1,657; 9,149]	[-2,382; 5,707]	
Veränderung zu Woche 12			
n/N (%)	61/127 (48)	47/105 (45)	LS MD 4,73 [-0,651; 10,120]
MW (SD)	12,30 (24,951)	-1,65 (18,819)	
LS MW (SE)	5,04 (1,848)	0,31 (1,999)	
95 %-KI	[1,400; 8,689]	[-3,630; 4,251]	
Veränderung zu Woche 15/16			
n/N (%)	57/123 (46)	40/103 (39)	LS MD 5,73 [0,335; 11,123]
MW (SD)	7,31 (25,570)	-0,56 (18,136)	
LS MW (SE)	4,69 (1,834)	-1,04 (2,016)	
95 %-KI	[1,069; 8,305]	[-5,016; 2,932]	
Veränderung zu Woche 20/21			
n/N (%)	43/118 (36)	36/98 (37)	LS MD 7,15 [1,482; 12,817]
MW (SD)	6,07 (21,578)	-6,48 (21,963)	
LS MW (SE)	4,18 (1,882)	-2,97 (2,158)	
95 %-KI	[0,464; 7,887]	[-7,225; 1,276]	
Veränderung zu Woche 24			
n/N (%)	38/112 (34)	25/93 (27)	LS MD 8,14 [2,120; 14,168]
MW (SD)	8,77 (27,961)	-5,33 (17,893)	
LS MW (SE)	3,82 (1,961)	-4,33 (2,329)	
95 %-KI	[-0,047; 7,681]	[-8,909; 0,255]	
Veränderung zu Woche 36			
n/N (%)	53/97 (55)	29/84 (35)	LS MD 11,55 [3,590; 19,516]
MW (SD)	3,88 (26,365)	-9,20 (30,871)	
LS MW (SE)	2,59 (2,449)	-8,96 (3,199)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-2,223; 7,402]	[-15,246; -2,683]	
Veränderung zu Woche 48			
n/N (%)	6/85 (7)	1/71 (1)	LS MD 14,96 [4,451; 25,474]
MW (SD)	25,93 (33,457)	-33,33 (NA)	
LS MW (SE)	1,36 (3,141)	-13,60 (4,291)	
95 %-KI	[-4,806; 7,529]	[-22,026; -5,177]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Pegyliertes liposomales Doxorubicin</b>			
Baseline			
n/N (%)	60/80 (75)	54/76 (71)	-
MW (SD)	43,80 (25,223)	54,94 (26,995)	
Absolute Werte zum Studienende			
n/N (%)	3/51 (6)	3/41 (7)	-
MW (SD)	70,37 (16,973)	77,78 (19,245)	
Effekt über Studiendauer			
n	60	54	LS MD 6,08 [-1,567; 13,732] 0,1180  Hedges' g 0,30 [-0,072; 0,668]
LS MW (SE)	2,88 (2,559)	-3,20 (2,821)	
95 %-KI	[-2,194; 7,958]	[-8,788; 2,387]	
Veränderung zu Woche 3/4			
n/N (%)	38/76 (50)	39/74 (53)	LS MD 6,98 [-1,465; 15,430]
MW (SD)	10,38 (21,850)	-1,14 (21,599)	
LS MW (SE)	5,17 (2,878)	-1,81 (3,088)	
95 %-KI	[-0,512; 10,855]	[-7,908; 4,285]	
Veränderung zu Woche 8/9			
n/N (%)	50/76 (66)	40/66 (61)	LS MD 6,60 [-1,234; 14,433]
MW (SD)	6,22 (29,454)	-9,44 (29,724)	
LS MW (SE)	4,20 (2,669)	-2,40 (2,853)	
95 %-KI	[-1,087; 9,482]	[-8,048; 3,244]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	33/75 (44)	23/64 (36)	LS MD 6,33 [-1,308; 13,971]
MW (SD)	5,56 (20,972)	-2,42 (20,910)	
LS MW (SE)	3,52 (2,586)	-2,82 (2,793)	
95 %-KI	[-1,610; 8,641]	[-8,349; 2,717]	
Veränderung zu Woche 15/16			
n/N (%)	32/74 (43)	19/62 (31)	LS MD 6,06 [-1,594; 13,722]
MW (SD)	3,65 (26,535)	1,75 (17,864)	
LS MW (SE)	2,83 (2,559)	-3,23 (2,826)	
95 %-KI	[-2,243; 7,910]	[-8,827; 2,368]	
Veränderung zu Woche 20/21			
n/N (%)	26/72 (36)	18/59 (31)	LS MD 5,68 [-2,364; 13,726]
MW (SD)	5,34 (21,573)	-8,02 (24,641)	
LS MW (SE)	1,86 (2,624)	-3,82 (3,028)	
95 %-KI	[-3,340; 7,060]	[-9,806; 2,164]	
Veränderung zu Woche 24			
n/N (%)	22/69 (32)	15/54 (28)	LS MD 5,41 [-3,130; 13,956]
MW (SD)	6,06 (18,378)	-3,70 (23,256)	
LS MW (SE)	1,18 (2,737)	-4,23 (3,261)	
95 %-KI	[-4,237; 6,593]	[-10,670; 2,201]	
Veränderung zu Woche 36			
n/N (%)	31/60 (52)	16/48 (33)	LS MD 4,49 [-6,764; 15,752]
MW (SD)	1,97 (26,703)	-13,19 (32,259)	
LS MW (SE)	-1,16 (3,446)	-5,65 (4,433)	
95 %-KI	[-7,945; 5,627]	[-14,374; 3,067]	
Veränderung zu Woche 48			
n/N (%)	2/51 (4)	2/41 (5)	LS MD 3,57 [-11,261; 18,411]
MW (SD)	27,78 (7,857)	16,67 (23,570)	
LS MW (SE)	-3,50 (4,454)	-7,07 (5,904)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-12,255; 5,262]	[-18,678; 4,535]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Paclitaxel</b>			
Baseline			
n/N (%)	72/88 (82)	70/82 (85)	-
MW (SD)	45,99 (24,902)	44,76 (26,684)	
Absolute Werte zum Studienende			
n/N (%)	1/56 (2)	1/49 (2)	-
MW (SD)	11,11 (NA)	66,67 (NA)	
Effekt über Studiendauer			
n	72	70	LS MD 10,45 [4,873; 16,017] 0,0003  Hedges' g 0,62 [0,283; 0,957]
LS MW (SE)	7,34 (1,932)	-3,10 (2,048)	
95 %-KI	[3,519; 11,165]	[-7,152; 0,946]	
Veränderung zu Woche 3/4			
n/N (%)	53/87 (61)	46/81 (57)	LS MD 8,93 [2,731; 15,130]
MW (SD)	9,01 (20,097)	-1,21 (20,181)	
LS MW (SE)	8,41 (2,158)	-0,52 (2,288)	
95 %-KI	[4,156; 12,666]	[-5,027; 3,988]	
Veränderung zu Woche 8/9			
n/N (%)	61/86 (71)	55/79 (70)	LS MD 9,61 [3,916; 15,313]
MW (SD)	8,38 (23,276)	1,01 (18,052)	
LS MW (SE)	7,93 (1,993)	-1,69 (2,088)	
95 %-KI	[3,990; 11,866]	[-5,810; 2,437]	
Veränderung zu Woche 12			
n/N (%)	39/84 (46)	35/77 (45)	LS MD 10,09 [4,537; 15,651]
MW (SD)	12,54 (25,129)	-5,71 (17,333)	
LS MW (SE)	7,59 (1,938)	-2,50 (2,036)	
95 %-KI	[3,757; 11,423]	[-6,529; 1,521]	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	43/81 (53)	26/76 (34)	LS MD 10,57 [4,970; 16,175]
MW (SD)	9,82 (21,579)	-5,98 (20,423)	
LS MW (SE)	7,25 (1,938)	-3,32 (2,063)	
95 %-KI	[3,418; 11,086]	[-7,399; 0,758]	
Veränderung zu Woche 20/21			
n/N (%)	27/77 (35)	25/73 (34)	LS MD 11,26 [5,276; 17,238]
MW (SD)	3,70 (20,441)	-6,67 (18,144)	
LS MW (SE)	6,77 (2,033)	-4,49 (2,233)	
95 %-KI	[2,753; 10,786]	[-8,892; -0,083]	
Veränderung zu Woche 24			
n/N (%)	21/74 (28)	19/72 (26)	LS MD 11,74 [5,300; 18,172]
MW (SD)	6,88 (30,727)	-9,94 (19,207)	
LS MW (SE)	6,43 (2,159)	-5,30 (2,427)	
95 %-KI	[2,173; 10,690]	[-10,086; -0,524]	
Veränderung zu Woche 36			
n/N (%)	35/64 (55)	23/63 (37)	LS MD 13,38 [4,597; 22,160]
MW (SD)	8,57 (22,560)	-6,28 (27,793)	
LS MW (SE)	5,27 (2,849)	-8,11 (3,387)	
95 %-KI	[-0,329; 10,874]	[-14,763; -1,449]	
Veränderung zu Woche 48			
n/N (%)	1/56 (2)	1/49 (2)	LS MD 15,02 [3,266; 26,775]
MW (SD)	-11,11 (NA)	0,00 (NA)	
LS MW (SE)	4,11 (3,758)	-10,91 (4,571)	
95 %-KI	[-3,270; 11,497]	[-19,888; -1,926]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Topotecan</b>			
Baseline			
n/N (%)	37/50 (74)	32/49 (65)	-
MW (SD)	54,35 (29,255)	45,83 (29,967)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	6/33 (18)	2/20 (10)	-
MW (SD)	85,19 (15,181)	38,89 (39,284)	
Effekt über Studiendauer			
n	37	32	LS MD 8,66 [-0,865; 18,185] 0,0740  Hedges' g 0,43 [-0,044; 0,913]
LS MW (SE)	7,33 (3,148)	-1,33 (3,595)	
95 %-KI	[1,030; 13,622]	[-8,505; 5,837]	
Veränderung zu Woche 3/4			
n/N (%)	22/50 (44)	17/45 (38)	LS MD 1,10 [-9,189; 11,398]
MW (SD)	2,27 (25,925)	4,58 (17,150)	
LS MW (SE)	5,24 (3,406)	4,14 (3,909)	
95 %-KI	[-1,535; 12,014]	[-3,627; 11,898]	
Veränderung zu Woche 8/9			
n/N (%)	28/48 (58)	27/43 (63)	LS MD 4,28 [-5,393; 13,951]
MW (SD)	6,75 (23,684)	1,23 (25,099)	
LS MW (SE)	6,12 (3,219)	1,84 (3,634)	
95 %-KI	[-0,307; 12,540]	[-5,404; 9,079]	
Veränderung zu Woche 12			
n/N (%)	20/46 (43)	12/42 (29)	LS MD 6,50 [-2,988; 15,991]
MW (SD)	15,00 (27,043)	2,78 (13,505)	
LS MW (SE)	6,73 (3,154)	0,23 (3,562)	
95 %-KI	[0,425; 13,035]	[-6,879; 7,336]	
Veränderung zu Woche 15/16			
n/N (%)	16/44 (36)	8/40 (20)	LS MD 8,72 [-0,805; 18,253]
MW (SD)	13,89 (26,759)	-0,00 (10,287)	
LS MW (SE)	7,34 (3,149)	-1,38 (3,597)	
95 %-KI	[1,046; 13,641]	[-8,556; 5,795]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	11/41 (27)	7/33 (21)	LS MD 11,90 [1,937; 21,860]
MW (SD)	20,20 (19,763)	3,17 (24,607)	
LS MW (SE)	8,22 (3,244)	-3,68 (3,826)	
95 %-KI	[1,744; 14,697]	[-11,287; 3,931]	
Veränderung zu Woche 24			
n/N (%)	11/41 (27)	3/29 (10)	LS MD 14,12 [3,617; 24,626]
MW (SD)	18,18 (25,470)	0,00 (0,000)	
LS MW (SE)	8,83 (3,378)	-5,29 (4,093)	
95 %-KI	[2,106; 15,562]	[-13,409; 2,835]	
Veränderung zu Woche 36			
n/N (%)	15/36 (42)	8/23 (35)	LS MD 21,74 [8,256; 35,225]
MW (SD)	12,59 (26,182)	-11,11 (17,817)	
LS MW (SE)	10,94 (4,162)	-10,80 (5,465)	
95 %-KI	[2,707; 19,169]	[-21,591; -0,015]	
Veränderung zu Woche 48			
n/N (%)	5/33 (15)	2/20 (10)	LS MD 29,36 [11,882; 46,840]
MW (SD)	20,00 (38,809)	-27,78 (7,857)	
LS MW (SE)	13,04 (5,262)	-16,32 (7,212)	
95 %-KI	[2,663; 23,421]	[-30,539; -2,098]	
<p><i>Analysepopulation: ITT</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023</i></p> <p><i>Modell: Veränderung zu Baseline ~ Behandlung + Baseline-Wert * Zeit in Wochen + Behandlung * Zeit in Wochen + zufällige Effekte durch die Patientin</i></p> <p><i>Die Berechnung des LS-MWs erfolgt durch ein MMRM mit dem oben angegebenen Modell. Basierend hierauf werden KI und p-Wert ermittelt. Hedges' g basiert ebenfalls auf den LS-MW und ist somit auf das Modell angepasst.</i></p> <p><i>Es werden ausschließlich gemeinsame Analysezeitpunkte dargestellt.</i></p> <p><i>Ein LS MD und Hedges' g größer als Null bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

### 3.3 EORTC QLQ-OV28 periphere Neuropathie

#### EORTC QLQ-OV28 periphere Neuropathie: Subgruppenanalyse

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
<b>EORTC QLQ-OV28 periphere Neuropathie</b>			
<b>Alter: &lt; 65 Jahre</b>			
Baseline			
n/N (%)	90/115 (78)	91/119 (76)	-
MW (SD)	19,14 (21,136)	18,62 (21,459)	
Absolute Werte zum Studienende			
n/N (%)	4/73 (5)	4/64 (6)	-
MW (SD)	38,89 (33,333)	13,89 (21,033)	
Effekt über Studiendauer			
n	90	91	LS MD 1,90 [-4,277; 8,086] 0,5439
LS MW (SE)	14,68 (2,186)	12,77 (2,244)	
95 %-KI	[10,361; 18,995]	[8,345; 17,201]	Hedges' g 0,09 [-0,202; 0,381]
Veränderung zu Woche 3/4			
n/N (%)	57/113 (50)	60/115 (52)	LS MD 3,46 [-3,292; 10,214]
MW (SD)	0,78 (14,220)	7,13 (19,001)	
LS MW (SE)	11,55 (2,403)	8,09 (2,446)	
95 %-KI	[6,816; 16,283]	[3,271; 12,905]	
Veränderung zu Woche 8/9			
n/N (%)	73/112 (65)	72/108 (67)	LS MD 2,78 [-3,535; 9,087]
MW (SD)	19,25 (26,516)	10,42 (24,844)	
LS MW (SE)	12,93 (2,251)	10,15 (2,276)	
95 %-KI	[8,487; 17,366]	[5,663; 14,638]	
Veränderung zu Woche 12			
n/N (%)	45/110 (41)	40/105 (38)	
MW (SD)	18,02 (27,655)	17,64 (27,474)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	13,89 (2,196)	11,59 (2,231)	LS MD 2,30 [-3,880; 8,473]
95 %-KI	[9,556; 18,226]	[7,192; 15,996]	
Veränderung zu Woche 15/16			
n/N (%)	52/107 (49)	33/102 (32)	LS MD 1,82 [-4,380; 8,014]
MW (SD)	16,45 (31,695)	13,30 (20,969)	
LS MW (SE)	14,85 (2,189)	13,04 (2,253)	
95 %-KI	[10,533; 19,176]	[8,592; 17,483]	
Veränderung zu Woche 20/21			
n/N (%)	35/101 (35)	29/96 (30)	LS MD 1,13 [-5,357; 7,621]
MW (SD)	13,97 (28,050)	22,22 (28,015)	
LS MW (SE)	16,23 (2,260)	15,10 (2,396)	
95 %-KI	[11,773; 20,690]	[10,379; 19,821]	
Veränderung zu Woche 24			
n/N (%)	25/99 (25)	19/91 (21)	LS MD 0,65 [-6,208; 7,513]
MW (SD)	11,56 (27,495)	23,68 (31,418)	
LS MW (SE)	17,20 (2,363)	16,54 (2,562)	
95 %-KI	[12,538; 21,854]	[11,499; 21,588]	
Veränderung zu Woche 36			
n/N (%)	39/86 (45)	28/79 (35)	LS MD -0,99 [-9,877; 7,894]
MW (SD)	15,67 (32,215)	16,67 (27,962)	
LS MW (SE)	20,50 (2,969)	21,49 (3,417)	
95 %-KI	[14,666; 26,336]	[14,780; 28,206]	
Veränderung zu Woche 48			
n/N (%)	4/73 (5)	3/64 (5)	LS MD -2,64 [-14,210; 8,939]
MW (SD)	19,44 (13,981)	0,00 (11,111)	
LS MW (SE)	23,81 (3,809)	26,44 (4,506)	
95 %-KI	[16,326; 31,287]	[17,592; 35,292]	
<b>Alter: ≥ 65 Jahre</b>			
Baseline			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	79/103 (77)	65/88 (74)	-
MW (SD)	27,99 (25,574)	22,91 (23,966)	
Absolute Werte zum Studienende			
n/N (%)	6/67 (9)	2/46 (4)	-
MW (SD)	31,48 (21,564)	27,78 (7,857)	
Effekt über Studiendauer			
n	79	65	LS MD -1,24 [-8,137; 5,665] 0,7238  Hedges' g -0,06 [-0,388; 0,269]
LS MW (SE)	10,24 (2,294)	11,48 (2,621)	
95 %-KI	[5,704; 14,779]	[6,298; 16,657]	
Veränderung zu Woche 3/4			
n/N (%)	57/100 (57)	43/85 (51)	LS MD -0,34 [-7,750; 7,076]
MW (SD)	1,66 (18,721)	7,24 (21,535)	
LS MW (SE)	8,91 (2,475)	9,24 (2,818)	
95 %-KI	[4,024; 13,791]	[3,687; 14,802]	
Veränderung zu Woche 8/9			
n/N (%)	67/98 (68)	52/80 (65)	LS MD -0,73 [-7,737; 6,277]
MW (SD)	14,43 (25,312)	11,32 (23,233)	
LS MW (SE)	9,49 (2,346)	10,22 (2,649)	
95 %-KI	[4,853; 14,128]	[4,988; 15,453]	
Veränderung zu Woche 12			
n/N (%)	46/95 (48)	31/78 (40)	LS MD -1,00 [-7,894; 5,884]
MW (SD)	9,66 (21,925)	18,64 (23,551)	
LS MW (SE)	9,90 (2,301)	10,90 (2,606)	
95 %-KI	[5,347; 14,450]	[5,753; 16,054]	
Veränderung zu Woche 15/16			
n/N (%)	38/92 (41)	21/76 (28)	
MW (SD)	8,92 (19,225)	12,70 (29,873)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	10,31 (2,296)	11,59 (2,629)	LS MD -1,28 [-8,195; 5,635]
95 %-KI	[5,765; 14,848]	[6,392; 16,781]	
Veränderung zu Woche 20/21			
n/N (%)	29/89 (33)	21/69 (30)	LS MD -1,67 [-8,871; 5,526]
MW (SD)	10,15 (22,226)	25,93 (31,296)	
LS MW (SE)	10,89 (2,357)	12,56 (2,772)	
95 %-KI	[6,232; 15,547]	[7,092; 18,032]	
Veränderung zu Woche 24			
n/N (%)	28/85 (33)	18/64 (28)	LS MD -1,95 [-9,503; 5,608]
MW (SD)	9,33 (23,280)	27,78 (32,169)	
LS MW (SE)	11,30 (2,444)	13,25 (2,940)	
95 %-KI	[6,471; 16,124]	[7,449; 19,041]	
Veränderung zu Woche 36			
n/N (%)	40/74 (54)	19/55 (35)	LS MD -2,89 [-12,411; 6,631]
MW (SD)	8,19 (17,295)	12,87 (36,900)	
LS MW (SE)	12,70 (2,970)	15,59 (3,817)	
95 %-KI	[6,852; 18,541]	[8,083; 23,091]	
Veränderung zu Woche 48			
n/N (%)	4/67 (6)	2/46 (4)	LS MD -3,83 [-16,015; 8,349]
MW (SD)	2,78 (5,556)	-16,67 (54,997)	
LS MW (SE)	14,10 (3,719)	17,93 (4,956)	
95 %-KI	[6,787; 21,403]	[8,191; 27,666]	
<b>Region: USA</b>			
Baseline			
n/N (%)	47/65 (72)	33/51 (65)	-
MW (SD)	25,89 (24,907)	24,92 (26,648)	
Absolute Werte zum Studienende			
n/N (%)	2/39 (5)	3/27 (11)	-
MW (SD)	50,00 (23,570)	33,33 (11,111)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Effekt über Studiendauer			
n	47	33	LS MD 3,17 [-5,161; 11,510] 0,4505  Hedges' g 0,17 [-0,275; 0,617]
LS MW (SE)	13,27 (2,659)	10,09 (3,230)	
95 %-KI	[7,968; 18,567]	[3,662; 16,524]	
Veränderung zu Woche 3/4			
n/N (%)	32/64 (50)	19/49 (39)	LS MD 3,81 [-5,360; 12,977]
MW (SD)	-1,04 (17,479)	5,85 (18,654)	
LS MW (SE)	10,68 (2,915)	6,87 (3,593)	
95 %-KI	[4,897; 16,457]	[-0,250; 13,986]	
Veränderung zu Woche 8/9			
n/N (%)	41/62 (66)	30/46 (65)	LS MD 3,52 [-5,017; 12,064]
MW (SD)	18,56 (25,142)	10,00 (18,304)	
LS MW (SE)	11,84 (2,726)	8,32 (3,319)	
95 %-KI	[6,419; 17,264]	[1,721; 14,914]	
Veränderung zu Woche 12			
n/N (%)	25/59 (42)	16/45 (36)	LS MD 3,32 [-5,019; 11,667]
MW (SD)	14,67 (27,540)	9,03 (18,243)	
LS MW (SE)	12,66 (2,664)	9,33 (3,232)	
95 %-KI	[7,349; 17,965]	[2,898; 15,767]	
Veränderung zu Woche 15/16			
n/N (%)	19/56 (34)	11/44 (25)	LS MD 3,12 [-5,235; 11,484]
MW (SD)	16,37 (22,026)	16,16 (22,967)	
LS MW (SE)	13,47 (2,666)	10,35 (3,241)	
95 %-KI	[8,160; 18,784]	[3,895; 16,800]	
Veränderung zu Woche 20/21			
n/N (%)	12/54 (22)	9/40 (22)	
MW (SD)	11,11 (24,158)	25,93 (28,328)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	14,64 (2,777)	11,80 (3,418)	LS MD 2,84 [-5,912; 11,590]
95 %-KI	[9,115; 20,158]	[5,011; 18,584]	
Veränderung zu Woche 24			
n/N (%)	9/53 (17)	6/38 (16)	LS MD 2,64 [-6,619; 11,899]
MW (SD)	16,05 (26,124)	27,78 (28,760)	
LS MW (SE)	15,45 (2,924)	12,81 (3,642)	
95 %-KI	[9,651; 21,252]	[5,598; 20,027]	
Veränderung zu Woche 36			
n/N (%)	21/43 (49)	10/33 (30)	LS MD 1,96 [-10,110; 14,021]
MW (SD)	17,72 (24,192)	-1,11 (36,458)	
LS MW (SE)	18,25 (3,743)	16,29 (4,842)	
95 %-KI	[10,864; 25,631]	[6,747; 25,836]	
Veränderung zu Woche 48			
n/N (%)	2/39 (5)	3/27 (11)	LS MD 1,27 [-14,536; 17,078]
MW (SD)	11,11 (15,713)	-14,81 (39,021)	
LS MW (SE)	21,04 (4,847)	19,77 (6,402)	
95 %-KI	[11,498; 30,587]	[7,163; 32,379]	
<b>Region: Rest der Welt</b>			
Baseline			
n/N (%)	122/153 (80)	123/156 (79)	-
MW (SD)	22,27 (23,194)	19,20 (21,295)	
Absolute Werte zum Studienende			
n/N (%)	8/101 (8)	3/83 (4)	-
MW (SD)	30,56 (25,717)	3,70 (6,415)	
Effekt über Studiendauer			
n	122	123	LS MD -0,99 [-6,437; 4,448] 0,7192 Hedges' g
LS MW (SE)	12,17 (1,914)	13,17 (1,987)	
95 %-KI	[8,402; 15,944]	[9,256; 17,080]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
			-0,05 [-0,296; 0,205]
Veränderung zu Woche 3/4			
n/N (%)	82/149 (55)	84/151 (56)	LS MD 1,37 [-4,498; 7,241]
MW (SD)	2,10 (16,206)	7,47 (20,380)	
LS MW (SE)	10,11 (2,083)	8,74 (2,133)	
95 %-KI	[6,011; 14,207]	[4,542; 12,933]	
Veränderung zu Woche 8/9			
n/N (%)	99/148 (67)	94/142 (66)	LS MD 0,34 [-5,182; 5,864]
MW (SD)	16,27 (26,397)	11,05 (25,744)	
LS MW (SE)	11,01 (1,965)	10,67 (1,997)	
95 %-KI	[7,138; 14,878]	[6,734; 14,599]	
Veränderung zu Woche 12			
n/N (%)	66/146 (45)	55/138 (40)	LS MD -0,38 [-5,805; 5,045]
MW (SD)	13,47 (24,383)	20,71 (27,015)	
LS MW (SE)	11,64 (1,922)	12,02 (1,967)	
95 %-KI	[7,850; 15,425]	[8,143; 15,892]	
Veränderung zu Woche 15/16			
n/N (%)	71/143 (50)	43/134 (32)	LS MD -1,10 [-6,556; 4,354]
MW (SD)	12,44 (28,583)	12,27 (25,126)	
LS MW (SE)	12,27 (1,915)	13,37 (1,994)	
95 %-KI	[8,494; 16,040]	[9,441; 17,295]	
Veränderung zu Woche 20/21			
n/N (%)	52/136 (38)	41/125 (33)	LS MD -2,13 [-7,845; 3,582]
MW (SD)	12,50 (25,962)	23,31 (29,690)	
LS MW (SE)	13,17 (1,966)	15,30 (2,125)	
95 %-KI	[9,294; 17,037]	[11,115; 19,479]	
Veränderung zu Woche 24			
n/N (%)	44/131 (34)	31/117 (26)	
MW (SD)	9,22 (25,074)	25,27 (32,325)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	13,79 (2,042)	16,65 (2,274)	LS MD -2,85 [-8,883; 3,177]
95 %-KI	[9,776; 17,814]	[12,178; 21,118]	
Veränderung zu Woche 36			
n/N (%)	58/117 (50)	37/101 (37)	LS MD -5,33 [-13,061; 2,409]
MW (SD)	9,77 (26,333)	19,52 (29,093)	
LS MW (SE)	15,95 (2,502)	21,28 (3,019)	
95 %-KI	[11,036; 20,869]	[15,352; 27,205]	
Veränderung zu Woche 48			
n/N (%)	6/101 (6)	2/83 (2)	LS MD -7,80 [-17,795; 2,197]
MW (SD)	11,11 (14,055)	5,56 (7,857)	
LS MW (SE)	18,11 (3,158)	25,91 (3,962)	
95 %-KI	[11,911; 24,310]	[18,132; 33,686]	
<b>Stadium bei der Diagnose: I-III</b>			
Baseline			
n/N (%)	109/141 (77)	111/144 (77)	-
MW (SD)	22,38 (24,666)	20,37 (22,201)	
Absolute Werte zum Studienende			
n/N (%)	6/91 (7)	4/76 (5)	-
MW (SD)	27,78 (20,787)	27,78 (14,344)	
Effekt über Studiendauer			
n	109	111	LS MD 2,75 [-3,042; 8,545] 0,3502  Hedges' g 0,13 [-0,139; 0,390]
LS MW (SE)	14,34 (2,048)	11,59 (2,107)	
95 %-KI	[10,304; 18,380]	[7,438; 15,743]	
Veränderung zu Woche 3/4			
n/N (%)	72/137 (53)	74/138 (54)	LS MD 4,17 [-2,099; 10,434]
MW (SD)	1,77 (18,621)	6,08 (19,769)	
LS MW (SE)	11,43 (2,228)	7,26 (2,273)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[7,041; 15,811]	[2,787; 11,731]	
Veränderung zu Woche 8/9			
n/N (%)	92/136 (68)	88/129 (68)	LS MD 3,55 [-2,353; 9,459]
MW (SD)	17,39 (27,835)	9,41 (25,554)	
LS MW (SE)	12,69 (2,103)	9,14 (2,134)	
95 %-KI	[8,548; 16,836]	[4,935; 13,344]	
Veränderung zu Woche 12			
n/N (%)	59/133 (44)	49/128 (38)	LS MD 3,12 [-2,670; 8,915]
MW (SD)	12,81 (26,488)	19,39 (28,331)	
LS MW (SE)	13,58 (2,057)	10,46 (2,097)	
95 %-KI	[9,522; 17,634]	[6,323; 14,589]	
Veränderung zu Woche 15/16			
n/N (%)	62/130 (48)	35/125 (28)	LS MD 2,69 [-3,110; 8,494]
MW (SD)	16,04 (29,399)	14,44 (22,555)	
LS MW (SE)	14,46 (2,049)	11,77 (2,113)	
95 %-KI	[10,424; 18,505]	[7,610; 15,935]	
Veränderung zu Woche 20/21			
n/N (%)	45/123 (37)	33/116 (28)	LS MD 2,08 [-3,948; 8,102]
MW (SD)	16,17 (26,586)	26,26 (27,473)	
LS MW (SE)	15,73 (2,102)	13,65 (2,223)	
95 %-KI	[11,588; 19,873]	[9,277; 18,030]	
Veränderung zu Woche 24			
n/N (%)	35/121 (29)	26/109 (24)	LS MD 1,65 [-4,669; 7,963]
MW (SD)	13,81 (26,961)	28,85 (29,314)	
LS MW (SE)	16,62 (2,182)	14,97 (2,355)	
95 %-KI	[12,319; 20,914]	[10,337; 19,603]	
Veränderung zu Woche 36			
n/N (%)	52/105 (50)	35/92 (38)	
MW (SD)	13,25 (28,608)	15,24 (32,348)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	19,65 (2,668)	19,48 (3,050)	LS MD 0,17 [-7,780; 8,122]
95 %-KI	[14,413; 24,897]	[13,493; 25,474]	
Veränderung zu Woche 48			
n/N (%)	5/91 (5)	4/76 (5)	LS MD -1,30 [-11,485; 8,877]
MW (SD)	6,67 (9,938)	-8,33 (34,397)	
LS MW (SE)	22,69 (3,361)	24,00 (3,958)	
95 %-KI	[16,093; 29,293]	[16,226; 31,769]	
<b>Stadium bei der Diagnose: IV</b>			
Baseline			
n/N (%)	56/72 (78)	43/60 (72)	-
MW (SD)	24,70 (22,446)	20,67 (24,196)	
Absolute Werte zum Studienende			
n/N (%)	4/46 (9)	2/33 (6)	-
MW (SD)	44,44 (31,427)	0,00 (0,000)	
Effekt über Studiendauer			
n	56	43	LS MD -4,29 [-11,702; 3,116] 0,2529  Hedges' g -0,23 [-0,631; 0,166]
LS MW (SE)	9,06 (2,416)	13,35 (2,840)	
95 %-KI	[4,257; 13,857]	[7,715; 18,984]	
Veränderung zu Woche 3/4			
n/N (%)	38/71 (54)	27/59 (46)	LS MD -3,45 [-11,546; 4,639]
MW (SD)	0,88 (12,221)	8,23 (18,125)	
LS MW (SE)	8,00 (2,659)	11,46 (3,112)	
95 %-KI	[2,746; 13,263]	[5,307; 17,610]	
Veränderung zu Woche 8/9			
n/N (%)	44/69 (64)	34/56 (61)	LS MD -3,83 [-11,342; 3,687]
MW (SD)	15,03 (22,338)	14,38 (20,383)	
LS MW (SE)	8,47 (2,484)	12,30 (2,860)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[3,547; 13,400]	[6,631; 17,970]	
Veränderung zu Woche 12			
n/N (%)	28/67 (42)	21/52 (40)	LS MD -4,09 [-11,456; 3,278]
MW (SD)	15,48 (22,698)	15,34 (19,076)	
LS MW (SE)	8,80 (2,424)	12,89 (2,806)	
95 %-KI	[3,987; 13,615]	[7,321; 18,459]	
Veränderung zu Woche 15/16			
n/N (%)	26/64 (41)	17/50 (34)	LS MD -4,35 [-11,796; 3,096]
MW (SD)	8,12 (21,444)	8,50 (25,918)	
LS MW (SE)	9,13 (2,420)	13,48 (2,861)	
95 %-KI	[4,321; 13,937]	[7,804; 19,154]	
Veränderung zu Woche 20/21			
n/N (%)	17/62 (27)	16/46 (35)	LS MD -4,72 [-12,657; 3,210]
MW (SD)	3,27 (21,069)	18,75 (33,633)	
LS MW (SE)	9,60 (2,512)	14,32 (3,115)	
95 %-KI	[4,615; 14,581]	[8,159; 20,483]	
Veränderung zu Woche 24			
n/N (%)	17/59 (29)	10/44 (23)	LS MD -4,98 [-13,490; 3,521]
MW (SD)	3,92 (20,765)	14,44 (35,928)	
LS MW (SE)	9,93 (2,639)	14,91 (3,393)	
95 %-KI	[4,701; 15,150]	[8,211; 21,610]	
Veränderung zu Woche 36			
n/N (%)	26/52 (50)	11/41 (27)	LS MD -5,88 [-17,322; 5,559]
MW (SD)	10,04 (19,753)	10,10 (26,968)	
LS MW (SE)	11,05 (3,360)	16,93 (4,734)	
95 %-KI	[4,430; 17,671]	[7,614; 26,249]	
Veränderung zu Woche 48			
n/N (%)	3/46 (7)	1/33 (3)	
MW (SD)	18,52 (16,973)	0,00 (NA)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	12,17 (4,343)	18,95 (6,370)	LS MD -6,78 [-21,955; 8,400]
95 %-KI	[3,630; 20,720]	[6,421; 31,484]	
<b>BRCA Status: Positiv</b>			
Baseline			
n/N (%)	24/27 (89)	23/35 (66)	-
MW (SD)	23,61 (27,081)	22,71 (25,837)	
Absolute Werte zum Studienende			
n/N (%)	1/19 (5)	0/15 (0)	-
MW (SD)	66,67 (NA)	NA (NA)	
Effekt über Studiendauer			
n	24	23	LS MD -7,05 [-16,295; 2,192] 0,1312
LS MW (SE)	9,87 (3,089)	16,92 (3,401)	
95 %-KI	[3,615; 16,118]	[10,076; 23,759]	Hedges' g -0,44 [-1,021; 0,138]
Veränderung zu Woche 3/4			
n/N (%)	16/27 (59)	17/35 (49)	LS MD 1,11 [-9,181; 11,401]
MW (SD)	-1,39 (21,033)	8,50 (22,747)	
LS MW (SE)	10,11 (3,557)	9,00 (3,754)	
95 %-KI	[3,013; 17,216]	[1,523; 16,485]	
Veränderung zu Woche 8/9			
n/N (%)	21/26 (81)	20/30 (67)	LS MD -2,90 [-12,210; 6,407]
MW (SD)	13,49 (17,793)	8,89 (25,131)	
LS MW (SE)	9,99 (3,227)	12,89 (3,333)	
95 %-KI	[3,499; 16,486]	[6,191; 19,597]	
Veränderung zu Woche 12			
n/N (%)	14/26 (54)	11/30 (37)	LS MD -5,71 [-14,864; 3,445]
MW (SD)	15,08 (22,054)	31,31 (31,747)	
LS MW (SE)	9,91 (3,108)	15,62 (3,320)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[3,623; 16,191]	[8,927; 22,306]	
Veränderung zu Woche 15/16			
n/N (%)	10/26 (38)	7/29 (24)	LS MD -8,52 [-17,975; 0,940]
MW (SD)	8,89 (10,210)	12,70 (23,508)	
LS MW (SE)	9,82 (3,096)	18,34 (3,548)	
95 %-KI	[3,556; 16,088]	[11,222; 25,457]	
Veränderung zu Woche 20/21			
n/N (%)	10/25 (40)	4/25 (16)	LS MD -12,53 [-23,140; -1,919]
MW (SD)	5,56 (17,568)	25,00 (24,637)	
LS MW (SE)	9,70 (3,262)	22,23 (4,206)	
95 %-KI	[3,129; 16,270]	[13,861; 30,597]	
Veränderung zu Woche 24			
n/N (%)	8/25 (32)	4/24 (17)	LS MD -15,34 [-27,157; -3,518]
MW (SD)	5,56 (11,878)	33,33 (12,830)	
LS MW (SE)	9,61 (3,493)	24,95 (4,824)	
95 %-KI	[2,617; 16,611]	[15,389; 34,514]	
Veränderung zu Woche 36			
n/N (%)	9/21 (43)	5/20 (25)	LS MD -24,97 [-42,357; -7,574]
MW (SD)	4,94 (11,264)	26,67 (16,851)	
LS MW (SE)	9,32 (4,760)	34,29 (7,412)	
95 %-KI	[-0,104; 18,746]	[19,641; 48,933]	
Veränderung zu Woche 48			
n/N (%)	1/19 (5)	0/15 (0)	LS MD -34,59 [-58,531; -10,657]
MW (SD)	33,33 (NA)	NA (NA)	
LS MW (SE)	9,03 (6,405)	43,62 (10,297)	
95 %-KI	[-3,628; 21,684]	[23,275; 63,968]	
<b>BRCA Status: Negativ/Unbekannt</b>			
Baseline			
n/N (%)	145/191 (76)	133/172 (77)	-



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	23,22 (23,154)	20,01 (22,031)	
Absolute Werte zum Studienende			
n/N (%)	9/121 (7)	6/95 (6)	-
MW (SD)	30,86 (24,074)	18,52 (18,144)	
Effekt über Studiendauer			
n	145	133	LS MD 1,50 [-3,588; 6,593] 0,5616  Hedges' g 0,07 [-0,166; 0,305]
LS MW (SE)	13,14 (1,757)	11,63 (1,893)	
95 %-KI	[9,677; 16,595]	[7,907; 15,359]	
Veränderung zu Woche 3/4			
n/N (%)	98/186 (53)	86/165 (52)	LS MD 2,01 [-3,500; 7,520]
MW (SD)	1,64 (15,798)	6,91 (19,543)	
LS MW (SE)	10,37 (1,906)	8,36 (2,050)	
95 %-KI	[6,618; 14,116]	[4,328; 12,387]	
Veränderung zu Woche 8/9			
n/N (%)	119/184 (65)	104/158 (66)	LS MD 1,79 [-3,398; 6,981]
MW (SD)	17,55 (27,168)	11,16 (23,992)	
LS MW (SE)	11,56 (1,801)	9,77 (1,922)	
95 %-KI	[8,017; 15,105]	[5,988; 13,552]	
Veränderung zu Woche 12			
n/N (%)	77/179 (43)	60/153 (39)	LS MD 1,64 [-3,451; 6,727]
MW (SD)	13,56 (25,784)	15,65 (23,912)	
LS MW (SE)	12,40 (1,763)	10,76 (1,886)	
95 %-KI	[8,926; 15,868]	[7,046; 14,471]	
Veränderung zu Woche 15/16			
n/N (%)	80/173 (46)	47/149 (32)	LS MD 1,49 [-3,612; 6,582]
MW (SD)	13,82 (28,684)	13,12 (24,938)	
LS MW (SE)	13,23 (1,758)	11,75 (1,897)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[9,771; 16,694]	[8,014; 15,481]	
Veränderung zu Woche 20/21			
n/N (%)	54/165 (33)	46/140 (33)	LS MD 1,27 [-4,029; 6,562]
MW (SD)	13,48 (26,602)	23,67 (29,778)	
LS MW (SE)	14,43 (1,807)	13,16 (1,991)	
95 %-KI	[10,870; 17,983]	[9,244; 17,077]	
Veränderung zu Woche 24			
n/N (%)	45/159 (28)	33/131 (25)	LS MD 1,11 [-4,442; 6,668]
MW (SD)	11,23 (26,814)	24,75 (32,958)	
LS MW (SE)	15,26 (1,878)	14,15 (2,107)	
95 %-KI	[11,568; 18,957]	[10,008; 18,291]	
Veränderung zu Woche 36			
n/N (%)	70/139 (50)	42/114 (37)	LS MD 0,59 [-6,418; 7,594]
MW (SD)	12,78 (27,107)	13,76 (32,723)	
LS MW (SE)	18,13 (2,304)	17,54 (2,723)	
95 %-KI	[13,604; 22,652]	[12,194; 22,886]	
Veränderung zu Woche 48			
n/N (%)	7/121 (6)	5/95 (5)	LS MD 0,06 [-8,918; 9,044]
MW (SD)	7,94 (10,569)	-6,67 (30,021)	
LS MW (SE)	20,99 (2,906)	20,93 (3,534)	
95 %-KI	[15,290; 26,697]	[13,995; 27,865]	
<b>Baseline ECOG PS: 0</b>			
Baseline			
n/N (%)	98/128 (77)	94/113 (83)	-
MW (SD)	19,05 (21,568)	17,20 (19,790)	
Absolute Werte zum Studienende			
n/N (%)	7/87 (8)	3/72 (4)	-
MW (SD)	41,27 (20,998)	25,93 (23,130)	
Effekt über Studiendauer			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n	98	94	LS MD 3,63 [-2,249; 9,519] 0,2245  Hedges' g 0,18 [-0,108; 0,459]
LS MW (SE)	15,55 (2,051)	11,92 (2,166)	
95 %-KI	[11,505; 19,600]	[7,646; 16,190]	
Veränderung zu Woche 3/4			
n/N (%)	68/127 (54)	60/111 (54)	LS MD 3,74 [-2,743; 10,227]
MW (SD)	2,21 (14,530)	5,65 (18,510)	
LS MW (SE)	13,04 (2,258)	9,30 (2,397)	
95 %-KI	[8,591; 17,483]	[4,578; 14,013]	
Veränderung zu Woche 8/9			
n/N (%)	82/126 (65)	74/108 (69)	LS MD 3,70 [-2,344; 9,736]
MW (SD)	20,53 (26,445)	11,64 (23,157)	
LS MW (SE)	14,12 (2,114)	10,42 (2,216)	
95 %-KI	[9,950; 18,288]	[6,056; 14,791]	
Veränderung zu Woche 12			
n/N (%)	49/122 (40)	46/108 (43)	LS MD 3,66 [-2,229; 9,556]
MW (SD)	18,37 (27,269)	16,79 (24,469)	
LS MW (SE)	14,88 (2,062)	11,21 (2,161)	
95 %-KI	[10,809; 18,944]	[6,952; 15,474]	
Veränderung zu Woche 15/16			
n/N (%)	53/120 (44)	34/105 (32)	LS MD 3,63 [-2,260; 9,523]
MW (SD)	19,18 (30,440)	11,60 (24,172)	
LS MW (SE)	15,63 (2,052)	12,00 (2,170)	
95 %-KI	[11,584; 19,684]	[7,723; 16,282]	
Veränderung zu Woche 20/21			
n/N (%)	38/117 (32)	31/101 (31)	LS MD 3,59 [-2,558; 9,728]
MW (SD)	18,27 (27,670)	26,16 (30,839)	
LS MW (SE)	16,72 (2,113)	13,13 (2,293)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[12,548; 20,884]	[8,613; 17,648]	
Veränderung zu Woche 24			
n/N (%)	27/112 (24)	21/96 (22)	LS MD 3,55 [-2,927; 10,034]
MW (SD)	17,08 (26,551)	24,07 (34,486)	
LS MW (SE)	17,47 (2,206)	13,92 (2,446)	
95 %-KI	[13,127; 21,820]	[9,106; 18,735]	
Veränderung zu Woche 36			
n/N (%)	48/99 (48)	35/87 (40)	LS MD 3,44 [-4,929; 11,815]
MW (SD)	12,62 (28,042)	10,79 (34,033)	
LS MW (SE)	20,07 (2,757)	16,63 (3,258)	
95 %-KI	[14,653; 25,488]	[10,227; 23,028]	
Veränderung zu Woche 48			
n/N (%)	5/87 (6)	3/72 (4)	LS MD 3,33 [-7,584; 14,249]
MW (SD)	17,78 (12,669)	-22,22 (29,397)	
LS MW (SE)	22,67 (3,529)	19,33 (4,309)	
95 %-KI	[15,738; 29,597]	[10,874; 27,795]	
<b>Baseline ECOG PS: 1</b>			
Baseline			
n/N (%)	71/90 (79)	61/91 (67)	-
MW (SD)	29,11 (25,293)	25,50 (25,768)	
Absolute Werte zum Studienende			
n/N (%)	3/53 (6)	3/37 (8)	-
MW (SD)	18,52 (32,075)	11,11 (11,111)	
Effekt über Studiendauer			
n	71	61	LS MD -4,82 [-11,759; 2,126] 0,1723
LS MW (SE)	8,13 (2,330)	12,94 (2,619)	
95 %-KI	[3,514; 12,738]	[7,766; 18,119]	Hedges' g -0,24 [-0,583; 0,104]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	46/86 (53)	42/87 (48)	LS MD 1,45 [-5,920; 8,817]
MW (SD)	-0,24 (19,243)	7,94 (20,279)	
LS MW (SE)	6,60 (2,516)	5,15 (2,754)	
95 %-KI	[1,633; 11,567]	[-0,283; 10,586]	
Veränderung zu Woche 8/9			
n/N (%)	58/84 (69)	49/78 (63)	LS MD -1,38 [-8,354; 5,592]
MW (SD)	11,88 (24,614)	7,94 (23,130)	
LS MW (SE)	7,29 (2,381)	8,67 (2,600)	
95 %-KI	[2,580; 11,999]	[3,530; 13,811]	
Veränderung zu Woche 12			
n/N (%)	42/83 (51)	24/74 (32)	LS MD -3,36 [-10,255; 3,531]
MW (SD)	8,47 (21,507)	17,59 (24,719)	
LS MW (SE)	7,77 (2,335)	11,13 (2,583)	
95 %-KI	[3,149; 12,395]	[6,027; 16,241]	
Veränderung zu Woche 15/16			
n/N (%)	37/79 (47)	20/72 (28)	LS MD -5,34 [-12,326; 1,639]
MW (SD)	4,80 (19,341)	15,56 (25,592)	
LS MW (SE)	8,25 (2,333)	13,60 (2,642)	
95 %-KI	[3,635; 12,874]	[8,377; 18,819]	
Veränderung zu Woche 20/21			
n/N (%)	26/73 (36)	18/63 (29)	LS MD -8,17 [-15,563; -0,783]
MW (SD)	3,42 (19,057)	16,67 (23,260)	
LS MW (SE)	8,94 (2,404)	17,12 (2,848)	
95 %-KI	[4,188; 13,699]	[11,498; 22,736]	
Veränderung zu Woche 24			
n/N (%)	26/72 (36)	15/58 (26)	LS MD -10,15 [-18,003; -2,305]
MW (SD)	3,42 (21,947)	24,44 (25,268)	
LS MW (SE)	9,43 (2,503)	19,58 (3,064)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[4,482; 14,371]	[13,543; 25,618]	
Veränderung zu Woche 36			
n/N (%)	31/61 (51)	12/46 (26)	LS MD -16,95 [-27,135; -6,756]
MW (SD)	10,75 (22,495)	27,78 (18,653)	
LS MW (SE)	11,08 (3,077)	28,03 (4,098)	
95 %-KI	[5,025; 17,137]	[19,970; 36,084]	
Veränderung zu Woche 48			
n/N (%)	3/53 (6)	2/37 (5)	LS MD -23,74 [-36,945; -10,531]
MW (SD)	0,00 (0,000)	16,67 (7,857)	
LS MW (SE)	12,74 (3,881)	36,47 (5,376)	
95 %-KI	[5,107; 20,365]	[25,908; 47,038]	
<b>Anzahl vorheriger Therapielinien: 1</b>			
Baseline			
n/N (%)	24/31 (77)	21/29 (72)	-
MW (SD)	19,44 (22,283)	16,67 (19,405)	
Absolute Werte zum Studienende			
n/N (%)	1/22 (5)	0/14 (0)	-
MW (SD)	44,44 (NA)	NA (NA)	
Effekt über Studiendauer			
n	24	21	LS MD 7,51 [-3,368; 18,397] 0,1707  Hedges' g 0,41 [-0,182; 1,003]
LS MW (SE)	14,84 (3,629)	7,33 (3,977)	
95 %-KI	[7,507; 22,181]	[-0,694; 15,353]	
Veränderung zu Woche 3/4			
n/N (%)	16/31 (52)	13/29 (45)	LS MD 8,94 [-3,122; 20,993]
MW (SD)	2,78 (12,505)	-2,14 (23,520)	
LS MW (SE)	10,81 (4,037)	1,87 (4,478)	
95 %-KI	[2,732; 18,886]	[-7,065; 10,812]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	20/31 (65)	16/26 (62)	LS MD 8,35 [-2,884; 19,574]
MW (SD)	18,33 (19,505)	7,29 (14,729)	
LS MW (SE)	12,48 (3,776)	4,14 (4,107)	
95 %-KI	[4,886; 20,083]	[-4,113; 12,391]	
Veränderung zu Woche 12			
n/N (%)	14/31 (45)	12/24 (50)	LS MD 7,93 [-2,999; 18,863]
MW (SD)	12,70 (22,586)	11,57 (14,691)	
LS MW (SE)	13,66 (3,668)	5,72 (3,980)	
95 %-KI	[6,251; 21,063]	[-2,300; 13,750]	
Veränderung zu Woche 15/16			
n/N (%)	15/31 (48)	11/22 (50)	LS MD 7,52 [-3,362; 18,401]
MW (SD)	19,26 (27,688)	0,51 (14,154)	
LS MW (SE)	14,83 (3,629)	7,31 (3,977)	
95 %-KI	[7,493; 22,167]	[-0,711; 15,333]	
Veränderung zu Woche 20/21			
n/N (%)	11/30 (37)	9/22 (41)	LS MD 6,93 [-4,313; 18,171]
MW (SD)	17,17 (28,702)	7,41 (18,426)	
LS MW (SE)	16,51 (3,696)	9,58 (4,183)	
95 %-KI	[9,048; 23,962]	[1,173; 17,979]	
Veränderung zu Woche 24			
n/N (%)	9/30 (30)	10/20 (50)	LS MD 6,52 [-5,264; 18,296]
MW (SD)	11,11 (17,568)	3,89 (17,382)	
LS MW (SE)	17,68 (3,825)	11,16 (4,458)	
95 %-KI	[9,988; 25,368]	[2,245; 20,079]	
Veränderung zu Woche 36			
n/N (%)	15/26 (58)	6/18 (33)	LS MD 5,10 [-9,922; 20,121]
MW (SD)	17,78 (27,794)	16,67 (23,040)	
LS MW (SE)	21,70 (4,678)	16,60 (5,965)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[12,410; 30,987]	[4,789; 28,409]	
Veränderung zu Woche 48			
n/N (%)	0/22 (0)	0/14 (0)	LS MD 3,68 [-15,879; 23,246]
MW (SD)	NA (NA)	NA (NA)	
LS MW (SE)	25,72 (5,933)	22,04 (7,935)	
95 %-KI	[13,995; 37,444]	[6,366; 37,706]	
<b>Anzahl vorheriger Therapielinien: 2</b>			
Baseline			
n/N (%)	73/89 (82)	65/83 (78)	-
MW (SD)	22,75 (22,834)	18,80 (21,599)	
Absolute Werte zum Studienende			
n/N (%)	4/59 (7)	2/50 (4)	-
MW (SD)	38,89 (26,450)	11,11 (15,713)	
Effekt über Studiendauer			
n	73	65	LS MD -2,39 [-9,261; 4,479] 0,4925  Hedges' g -0,12 [-0,452; 0,217]
LS MW (SE)	11,19 (2,322)	13,58 (2,579)	
95 %-KI	[6,591; 15,783]	[8,480; 18,676]	
Veränderung zu Woche 3/4			
n/N (%)	50/86 (58)	43/80 (54)	LS MD 1,48 [-5,894; 8,858]
MW (SD)	2,89 (16,313)	10,85 (20,066)	
LS MW (SE)	10,01 (2,510)	8,53 (2,763)	
95 %-KI	[5,056; 14,966]	[3,078; 13,980]	
Veränderung zu Woche 8/9			
n/N (%)	61/85 (72)	52/77 (68)	LS MD -0,25 [-7,208; 6,699]
MW (SD)	13,39 (25,728)	9,83 (20,950)	
LS MW (SE)	10,54 (2,376)	10,79 (2,588)	
95 %-KI	[5,840; 15,237]	[5,679; 15,908]	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	38/83 (46)	30/75 (40)	LS MD -1,47 [-8,315; 5,374]
MW (SD)	13,16 (19,986)	18,15 (26,820)	
LS MW (SE)	10,91 (2,330)	12,38 (2,554)	
95 %-KI	[6,297; 15,518]	[7,329; 17,427]	
Veränderung zu Woche 15/16			
n/N (%)	37/80 (46)	19/74 (26)	LS MD -2,69 [-9,584; 4,211]
MW (SD)	11,41 (24,635)	17,54 (26,531)	
LS MW (SE)	11,28 (2,325)	13,96 (2,596)	
95 %-KI	[6,676; 15,878]	[8,832; 19,094]	
Veränderung zu Woche 20/21			
n/N (%)	31/78 (40)	20/68 (29)	LS MD -4,42 [-11,671; 2,824]
MW (SD)	8,96 (20,371)	22,22 (29,945)	
LS MW (SE)	11,80 (2,390)	16,23 (2,782)	
95 %-KI	[7,078; 16,530]	[10,738; 21,717]	
Veränderung zu Woche 24			
n/N (%)	25/74 (34)	13/65 (20)	LS MD -5,64 [-13,303; 2,024]
MW (SD)	5,78 (23,377)	28,21 (31,628)	
LS MW (SE)	12,17 (2,483)	17,81 (2,987)	
95 %-KI	[7,269; 17,077]	[11,928; 23,698]	
Veränderung zu Woche 36			
n/N (%)	33/65 (51)	18/58 (31)	LS MD -9,81 [-19,677; 0,060]
MW (SD)	9,60 (19,899)	16,67 (36,004)	
LS MW (SE)	13,44 (3,034)	23,25 (3,996)	
95 %-KI	[7,467; 19,411]	[15,392; 31,102]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	1/50 (2)	LS MD -13,98 [-26,747; -1,207]
MW (SD)	16,67 (14,344)	22,22 (NA)	
LS MW (SE)	14,70 (3,815)	28,68 (5,259)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[7,207; 22,202]	[18,347; 39,016]	
<b>Anzahl vorheriger Therapielinien: 3</b>			
Baseline			
n/N (%)	72/98 (73)	70/95 (74)	-
MW (SD)	25,08 (25,037)	23,02 (24,249)	
Absolute Werte zum Studienende			
n/N (%)	5/59 (8)	4/46 (9)	-
MW (SD)	28,89 (28,974)	22,22 (20,286)	
Effekt über Studiendauer			
n	72	70	LS MD 1,12 [-6,254; 8,492] 0,7645  Hedges' g 0,05 [-0,279; 0,379]
LS MW (SE)	13,48 (2,585)	12,36 (2,683)	
95 %-KI	[8,370; 18,597]	[7,060; 17,669]	
Veränderung zu Woche 3/4			
n/N (%)	48/96 (50)	47/91 (52)	LS MD 0,55 [-7,449; 8,549]
MW (SD)	-1,04 (17,962)	6,38 (18,352)	
LS MW (SE)	10,70 (2,822)	10,15 (2,911)	
95 %-KI	[5,133; 16,268]	[4,410; 15,891]	
Veränderung zu Woche 8/9			
n/N (%)	59/94 (63)	56/85 (66)	LS MD 0,80 [-6,713; 8,312]
MW (SD)	20,15 (27,967)	12,70 (28,696)	
LS MW (SE)	11,92 (2,649)	11,12 (2,725)	
95 %-KI	[6,685; 17,155]	[5,738; 16,504]	
Veränderung zu Woche 12			
n/N (%)	39/91 (43)	29/84 (35)	LS MD 0,97 [-6,392; 8,340]
MW (SD)	14,81 (30,518)	20,69 (28,129)	
LS MW (SE)	12,77 (2,591)	11,80 (2,674)	
95 %-KI	[7,650; 17,898]	[6,515; 17,085]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	38/88 (43)	24/82 (29)	LS MD 1,15 [-6,240; 8,538]
MW (SD)	12,72 (29,817)	15,28 (25,551)	
LS MW (SE)	13,63 (2,589)	12,48 (2,691)	
95 %-KI	[8,508; 18,749]	[7,160; 17,799]	
Veränderung zu Woche 20/21			
n/N (%)	22/82 (27)	21/75 (28)	LS MD 1,40 [-6,314; 9,111]
MW (SD)	14,39 (30,413)	32,28 (30,001)	
LS MW (SE)	14,85 (2,683)	13,45 (2,834)	
95 %-KI	[9,547; 20,149]	[7,856; 19,044]	
Veränderung zu Woche 24			
n/N (%)	19/80 (24)	14/70 (20)	LS MD 1,57 [-6,551; 9,696]
MW (SD)	16,08 (29,912)	38,89 (32,247)	
LS MW (SE)	15,70 (2,811)	14,13 (3,005)	
95 %-KI	[10,155; 21,250]	[8,203; 20,055]	
Veränderung zu Woche 36			
n/N (%)	31/69 (45)	23/58 (40)	LS MD 2,17 [-8,217; 12,560]
MW (SD)	11,47 (30,562)	13,53 (30,879)	
LS MW (SE)	18,63 (3,542)	16,46 (3,913)	
95 %-KI	[11,661; 25,599]	[8,763; 24,153]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	4/46 (9)	LS MD 2,77 [-10,659; 16,200]
MW (SD)	5,56 (11,111)	-13,89 (29,222)	
LS MW (SE)	21,56 (4,545)	18,79 (5,098)	
95 %-KI	[12,626; 30,490]	[8,769; 28,806]	
<b>Vorherige Verabreichung von Bevacizumab: Ja</b>			
Baseline			
n/N (%)	98/134 (73)	97/132 (73)	-
MW (SD)	21,20 (21,982)	20,73 (22,546)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	3/79 (4)	3/62 (5)	-
MW (SD)	37,04 (16,973)	22,22 (22,222)	
Effekt über Studiendauer			
n	98	97	LS MD 0,66 [-5,131; 6,461] 0,8213  Hedges' g 0,03 [-0,248; 0,313]
LS MW (SE)	14,29 (2,023)	13,63 (2,134)	
95 %-KI	[10,298; 18,283]	[9,417; 17,835]	
Veränderung zu Woche 3/4			
n/N (%)	62/130 (48)	64/127 (50)	LS MD 0,95 [-5,356; 7,250]
MW (SD)	1,34 (12,430)	8,68 (19,242)	
LS MW (SE)	11,70 (2,219)	10,75 (2,312)	
95 %-KI	[7,331; 16,071]	[6,203; 15,306]	
Veränderung zu Woche 8/9			
n/N (%)	81/130 (62)	74/119 (62)	LS MD 0,82 [-5,060; 6,693]
MW (SD)	18,93 (26,971)	13,21 (24,097)	
LS MW (SE)	12,90 (2,078)	12,08 (2,141)	
95 %-KI	[8,798; 16,995]	[7,860; 16,300]	
Veränderung zu Woche 12			
n/N (%)	49/126 (39)	37/114 (32)	LS MD 0,73 [-5,046; 6,497]
MW (SD)	20,86 (21,592)	17,72 (24,068)	
LS MW (SE)	13,73 (2,030)	13,01 (2,111)	
95 %-KI	[9,728; 17,740]	[8,846; 17,171]	
Veränderung zu Woche 15/16			
n/N (%)	54/122 (44)	31/112 (28)	LS MD 0,63 [-5,203; 6,471]
MW (SD)	15,53 (24,453)	16,13 (27,192)	
LS MW (SE)	14,57 (2,027)	13,94 (2,159)	
95 %-KI	[10,570; 18,571]	[9,680; 18,193]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	36/114 (32)	28/103 (27)	LS MD 0,50 [-5,708; 6,715]
MW (SD)	17,13 (18,179)	24,21 (30,699)	
LS MW (SE)	15,77 (2,102)	15,26 (2,353)	
95 %-KI	[11,622; 19,910]	[10,629; 19,895]	
Veränderung zu Woche 24			
n/N (%)	28/109 (26)	17/95 (18)	LS MD 0,41 [-6,233; 7,058]
MW (SD)	16,87 (21,462)	29,41 (35,992)	
LS MW (SE)	16,60 (2,204)	16,19 (2,561)	
95 %-KI	[12,261; 20,945]	[11,153; 21,227]	
Veränderung zu Woche 36			
n/N (%)	43/93 (46)	21/79 (27)	LS MD 0,10 [-8,764; 8,964]
MW (SD)	16,15 (23,282)	11,64 (29,497)	
LS MW (SE)	19,47 (2,789)	19,37 (3,549)	
95 %-KI	[13,990; 24,954]	[12,402; 26,343]	
Veränderung zu Woche 48			
n/N (%)	3/79 (4)	2/62 (3)	LS MD -0,21 [-11,902; 11,477]
MW (SD)	7,41 (12,830)	5,56 (23,570)	
LS MW (SE)	22,34 (3,591)	22,55 (4,750)	
95 %-KI	[15,290; 29,393]	[13,226; 31,883]	
<b>Vorherige Verabreichung von Bevacizumab: Nein</b>			
Baseline			
n/N (%)	71/84 (85)	59/75 (79)	-
MW (SD)	26,13 (25,690)	19,87 (22,771)	
Absolute Werte zum Studienende			
n/N (%)	7/61 (11)	3/48 (6)	-
MW (SD)	33,33 (29,397)	14,81 (16,973)	
Effekt über Studiendauer			
n	71	59	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	10,51 (2,500)	9,39 (2,792)	LS MD 1,12 [-6,329; 8,562] 0,7672  Hedges' g 0,05 [-0,293; 0,398]
95 %-KI	[5,556; 15,456]	[3,866; 14,914]	
Veränderung zu Woche 3/4			
n/N (%)	52/83 (63)	39/73 (53)	LS MD 3,80 [-4,268; 11,870]
MW (SD)	1,07 (20,554)	4,70 (21,195)	
LS MW (SE)	8,62 (2,709)	4,82 (3,039)	
95 %-KI	[3,275; 13,974]	[-1,174; 10,822]	
Veränderung zu Woche 8/9			
n/N (%)	59/80 (74)	50/69 (72)	LS MD 2,69 [-4,936; 10,321]
MW (SD)	14,22 (24,484)	7,22 (23,869)	
LS MW (SE)	9,40 (2,565)	6,71 (2,861)	
95 %-KI	[4,328; 14,474]	[1,054; 12,364]	
Veränderung zu Woche 12			
n/N (%)	42/79 (53)	34/69 (49)	LS MD 1,92 [-5,553; 9,387]
MW (SD)	5,56 (26,686)	18,46 (27,650)	
LS MW (SE)	9,94 (2,512)	8,03 (2,798)	
95 %-KI	[4,974; 14,916]	[2,493; 13,564]	
Veränderung zu Woche 15/16			
n/N (%)	36/77 (47)	23/66 (35)	LS MD 1,14 [-6,303; 8,585]
MW (SD)	9,88 (31,063)	8,94 (20,291)	
LS MW (SE)	10,49 (2,500)	9,35 (2,791)	
95 %-KI	[5,539; 15,438]	[3,825; 14,870]	
Veränderung zu Woche 20/21			
n/N (%)	28/76 (37)	22/62 (35)	LS MD 0,03 [-7,606; 7,671]
MW (SD)	5,95 (31,786)	23,23 (27,838)	
LS MW (SE)	11,27 (2,557)	11,23 (2,878)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[6,207; 16,323]	[5,544; 16,921]	
Veränderung zu Woche 24			
n/N (%)	25/75 (33)	20/60 (33)	LS MD -0,74 [-8,670; 7,185]
MW (SD)	3,11 (27,315)	22,50 (27,482)	
LS MW (SE)	11,81 (2,646)	12,55 (3,001)	
95 %-KI	[6,581; 17,037]	[6,626; 18,478]	
Veränderung zu Woche 36			
n/N (%)	36/67 (54)	26/55 (47)	LS MD -3,40 [-13,085; 6,280]
MW (SD)	6,79 (28,144)	17,95 (33,419)	
LS MW (SE)	13,67 (3,195)	17,08 (3,727)	
95 %-KI	[7,383; 19,963]	[9,742; 24,410]	
Veränderung zu Woche 48			
n/N (%)	5/61 (8)	3/48 (6)	LS MD -6,06 [-18,263; 6,139]
MW (SD)	13,33 (14,487)	-14,81 (35,717)	
LS MW (SE)	15,54 (3,991)	21,60 (4,742)	
95 %-KI	[7,692; 23,382]	[12,281; 30,918]	
<b>Letztes Platin-freies Intervall: ≤ 3 Monate</b>			
Baseline			
n/N (%)	63/83 (76)	62/91 (68)	-
MW (SD)	18,78 (20,701)	24,91 (25,184)	
Absolute Werte zum Studienende			
n/N (%)	3/55 (5)	5/39 (13)	-
MW (SD)	22,22 (22,222)	20,00 (19,876)	
Effekt über Studiendauer			
n	63	62	LS MD -2,98 [-10,720; 4,754] 0,4467
LS MW (SE)	13,13 (2,677)	16,11 (2,827)	
95 %-KI	[7,823; 18,433]	[10,516; 21,705]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	46/82 (56)	44/86 (51)	LS MD -2,41 [-10,759; 5,938]
MW (SD)	1,93 (18,637)	7,07 (21,176)	
LS MW (SE)	10,52 (2,923)	12,93 (3,031)	
95 %-KI	[4,746; 16,291]	[6,946; 18,912]	
Veränderung zu Woche 8/9			
n/N (%)	50/81 (62)	46/80 (57)	LS MD -2,67 [-10,512; 5,174]
MW (SD)	22,56 (30,209)	11,35 (27,366)	
LS MW (SE)	11,70 (2,738)	14,37 (2,844)	
95 %-KI	[6,276; 17,116]	[8,740; 19,990]	
Veränderung zu Woche 12			
n/N (%)	31/78 (40)	25/78 (32)	LS MD -2,85 [-10,560; 4,861]
MW (SD)	13,98 (28,396)	27,56 (26,859)	
LS MW (SE)	12,52 (2,680)	15,37 (2,805)	
95 %-KI	[7,211; 17,831]	[9,819; 20,922]	
Veränderung zu Woche 15/16			
n/N (%)	33/76 (43)	13/75 (17)	LS MD -3,03 [-10,802; 4,741]
MW (SD)	11,11 (30,807)	18,80 (31,225)	
LS MW (SE)	13,35 (2,685)	16,38 (2,846)	
95 %-KI	[8,026; 18,665]	[10,746; 22,006]	
Veränderung zu Woche 20/21			
n/N (%)	21/72 (29)	14/67 (21)	LS MD -3,29 [-11,471; 4,893]
MW (SD)	11,11 (28,545)	41,27 (33,878)	
LS MW (SE)	14,52 (2,799)	17,81 (3,034)	
95 %-KI	[8,985; 20,062]	[11,819; 23,806]	
Veränderung zu Woche 24			
n/N (%)	15/72 (21)	12/62 (19)	LS MD -3,47 [-12,143; 5,203]
MW (SD)	15,56 (29,337)	43,52 (30,871)	
LS MW (SE)	15,35 (2,948)	18,82 (3,245)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[9,524; 21,172]	[12,417; 25,219]	
Veränderung zu Woche 36			
n/N (%)	28/63 (44)	18/50 (36)	LS MD -4,09 [-15,354; 7,174]
MW (SD)	15,28 (28,232)	16,67 (31,020)	
LS MW (SE)	18,18 (3,770)	22,27 (4,300)	
95 %-KI	[10,757; 25,595]	[13,808; 30,724]	
Veränderung zu Woche 48			
n/N (%)	2/55 (4)	4/39 (10)	LS MD -4,71 [-19,367; 9,947]
MW (SD)	11,11 (15,713)	-11,11 (32,710)	
LS MW (SE)	21,00 (4,873)	25,71 (5,634)	
95 %-KI	[11,423; 30,583]	[14,637; 36,789]	
<b>Letztes Platin-freies Intervall: &gt; 3 Monate</b>			
Baseline			
n/N (%)	106/135 (79)	94/116 (81)	-
MW (SD)	25,94 (24,972)	17,43 (20,247)	
Absolute Werte zum Studienende			
n/N (%)	7/85 (8)	1/71 (1)	-
MW (SD)	39,68 (26,338)	11,11 (NA)	
Effekt über Studiendauer			
n	106	94	LS MD 1,61 [-4,073; 7,287] 0,5775  Hedges' g 0,08 [-0,198; 0,357]
LS MW (SE)	11,76 (1,935)	10,16 (2,103)	
95 %-KI	[7,944; 15,580]	[6,009; 14,302]	
Veränderung zu Woche 3/4			
n/N (%)	68/131 (52)	59/114 (52)	LS MD 3,72 [-2,495; 9,939]
MW (SD)	0,74 (15,113)	7,25 (19,252)	
LS MW (SE)	9,70 (2,115)	5,98 (2,310)	
95 %-KI	[5,540; 13,868]	[1,436; 10,528]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	90/129 (70)	78/108 (72)	LS MD 2,81 [-3,011; 8,628]
MW (SD)	13,83 (22,872)	10,47 (22,113)	
LS MW (SE)	10,59 (1,993)	7,78 (2,145)	
95 %-KI	[6,664; 14,523]	[3,558; 12,011]	
Veränderung zu Woche 12			
n/N (%)	60/127 (47)	46/105 (44)	LS MD 2,17 [-3,519; 7,857]
MW (SD)	13,70 (23,536)	12,92 (23,717)	
LS MW (SE)	11,22 (1,947)	9,05 (2,096)	
95 %-KI	[7,375; 15,056]	[4,914; 13,180]	
Veränderung zu Woche 15/16			
n/N (%)	57/123 (46)	41/103 (40)	LS MD 1,53 [-4,158; 7,216]
MW (SD)	14,52 (25,192)	11,25 (22,170)	
LS MW (SE)	11,84 (1,936)	10,31 (2,108)	
95 %-KI	[8,019; 15,657]	[6,153; 14,464]	
Veränderung zu Woche 20/21			
n/N (%)	43/118 (36)	36/98 (37)	LS MD 0,62 [-5,295; 6,526]
MW (SD)	12,79 (24,141)	16,98 (24,414)	
LS MW (SE)	12,73 (1,981)	12,11 (2,225)	
95 %-KI	[8,821; 16,632]	[7,728; 16,495]	
Veränderung zu Woche 24			
n/N (%)	38/112 (34)	25/93 (27)	LS MD -0,02 [-6,235; 6,187]
MW (SD)	8,33 (23,384)	17,11 (28,415)	
LS MW (SE)	13,35 (2,053)	13,37 (2,370)	
95 %-KI	[9,305; 17,394]	[8,708; 18,038]	
Veränderung zu Woche 36			
n/N (%)	51/97 (53)	29/84 (35)	LS MD -2,22 [-10,131; 5,698]
MW (SD)	10,02 (24,571)	14,18 (32,380)	
LS MW (SE)	15,48 (2,500)	17,70 (3,136)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[10,569; 20,397]	[11,539; 23,860]	
Veränderung zu Woche 48			
n/N (%)	6/85 (7)	1/71 (1)	LS MD -4,41 [-14,640; 5,822]
MW (SD)	11,11 (14,055)	11,11 (NA)	
LS MW (SE)	17,62 (3,147)	22,03 (4,129)	
95 %-KI	[11,437; 23,796]	[13,920; 30,132]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Pegyliertes liposomales Doxorubicin</b>			
Baseline			
n/N (%)	60/80 (75)	54/76 (71)	-
MW (SD)	24,81 (25,987)	20,68 (25,273)	
Absolute Werte zum Studienende			
n/N (%)	3/51 (6)	3/41 (7)	-
MW (SD)	40,74 (27,962)	18,52 (16,973)	
Effekt über Studiendauer			
n	60	54	LS MD 7,21 [-0,779; 15,205] 0,0764  Hedges' g 0,33 [-0,036; 0,705]
LS MW (SE)	15,01 (2,714)	7,80 (2,975)	
95 %-KI	[9,631; 20,394]	[1,906; 13,693]	
Veränderung zu Woche 3/4			
n/N (%)	39/76 (51)	37/74 (50)	LS MD 6,39 [-2,269; 15,048]
MW (SD)	-1,42 (17,509)	2,55 (19,711)	
LS MW (SE)	11,61 (2,978)	5,22 (3,206)	
95 %-KI	[5,729; 17,498]	[-1,109; 11,557]	
Veränderung zu Woche 8/9			
n/N (%)	50/76 (66)	42/66 (64)	LS MD 6,74 [-1,403; 14,886]
MW (SD)	18,00 (30,358)	8,60 (21,260)	
LS MW (SE)	13,07 (2,803)	6,32 (3,003)	
95 %-KI	[7,515; 18,617]	[0,380; 12,269]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	32/75 (43)	23/64 (36)	LS MD 6,99 [-0,997; 14,972]
MW (SD)	13,89 (30,787)	14,73 (17,376)	
LS MW (SE)	14,08 (2,735)	7,10 (2,952)	
95 %-KI	[8,662; 19,504]	[1,247; 12,943]	
Veränderung zu Woche 15/16			
n/N (%)	31/74 (42)	19/62 (31)	LS MD 7,23 [-0,766; 15,234]
MW (SD)	19,00 (33,603)	3,22 (20,228)	
LS MW (SE)	15,10 (2,714)	7,87 (2,981)	
95 %-KI	[9,718; 20,482]	[1,961; 13,770]	
Veränderung zu Woche 20/21			
n/N (%)	26/72 (36)	18/59 (31)	LS MD 7,59 [-0,736; 15,909]
MW (SD)	18,38 (30,298)	13,58 (26,828)	
LS MW (SE)	16,55 (2,770)	8,97 (3,156)	
95 %-KI	[11,065; 22,041]	[2,727; 15,206]	
Veränderung zu Woche 24			
n/N (%)	22/69 (32)	15/54 (28)	LS MD 7,83 [-0,909; 16,574]
MW (SD)	14,65 (27,727)	7,78 (18,991)	
LS MW (SE)	17,57 (2,865)	9,74 (3,360)	
95 %-KI	[11,899; 23,240]	[3,104; 16,370]	
Veränderung zu Woche 36			
n/N (%)	30/60 (50)	16/48 (33)	LS MD 8,68 [-2,409; 19,764]
MW (SD)	15,93 (29,133)	11,81 (32,828)	
LS MW (SE)	21,06 (3,478)	12,38 (4,412)	
95 %-KI	[14,203; 27,909]	[3,698; 21,059]	
Veränderung zu Woche 48			
n/N (%)	2/51 (4)	2/41 (5)	LS MD 9,52 [-4,751; 23,795]
MW (SD)	22,22 (15,713)	-16,67 (54,997)	
LS MW (SE)	24,54 (4,375)	15,02 (5,765)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[15,939; 33,146]	[3,685; 26,355]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Paclitaxel</b>			
Baseline			
n/N (%)	72/88 (82)	70/82 (85)	-
MW (SD)	22,69 (23,676)	19,68 (21,164)	
Absolute Werte zum Studienende			
n/N (%)	1/56 (2)	1/49 (2)	-
MW (SD)	22,22 (NA)	0,00 (NA)	
Effekt über Studiendauer			
n	72	70	LS MD -7,86 [-14,309; -1,418] 0,0172  Hedges' g -0,40 [-0,736; -0,071]
LS MW (SE)	12,80 (2,245)	20,66 (2,354)	
95 %-KI	[8,355; 17,238]	[16,007; 25,312]	
Veränderung zu Woche 3/4			
n/N (%)	53/87 (61)	49/81 (60)	LS MD -5,37 [-12,507; 1,764]
MW (SD)	1,99 (13,743)	10,20 (21,497)	
LS MW (SE)	9,65 (2,497)	15,02 (2,617)	
95 %-KI	[4,728; 14,575]	[9,866; 20,181]	
Veränderung zu Woche 8/9			
n/N (%)	61/86 (71)	55/79 (70)	LS MD -6,51 [-13,091; 0,074]
MW (SD)	17,58 (23,618)	20,00 (25,337)	
LS MW (SE)	11,09 (2,311)	17,59 (2,396)	
95 %-KI	[6,520; 15,653]	[12,862; 22,328]	
Veränderung zu Woche 12			
n/N (%)	39/84 (46)	37/77 (48)	LS MD -7,30 [-13,733; -0,875]
MW (SD)	13,96 (21,131)	26,73 (28,744)	
LS MW (SE)	12,09 (2,250)	19,40 (2,340)	
95 %-KI	[7,640; 16,542]	[14,769; 24,021]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	43/81 (53)	27/76 (36)	LS MD -8,10 [-14,584; -1,616]
MW (SD)	14,08 (23,393)	23,46 (26,209)	
LS MW (SE)	13,10 (2,252)	21,20 (2,373)	
95 %-KI	[8,639; 17,551]	[16,506; 25,885]	
Veränderung zu Woche 20/21			
n/N (%)	27/77 (35)	25/73 (34)	LS MD -9,24 [-16,149; -2,325]
MW (SD)	14,20 (19,752)	35,11 (29,863)	
LS MW (SE)	14,53 (2,363)	23,77 (2,564)	
95 %-KI	[9,861; 19,199]	[18,708; 28,826]	
Veränderung zu Woche 24			
n/N (%)	20/74 (27)	19/72 (26)	LS MD -10,03 [-17,456; -2,610]
MW (SD)	14,72 (22,242)	43,86 (31,092)	
LS MW (SE)	15,53 (2,508)	25,57 (2,784)	
95 %-KI	[10,586; 20,483]	[20,083; 31,051]	
Veränderung zu Woche 36			
n/N (%)	34/64 (53)	23/63 (37)	LS MD -12,76 [-22,825; -2,698]
MW (SD)	12,91 (25,540)	23,67 (31,123)	
LS MW (SE)	18,98 (3,301)	31,74 (3,867)	
95 %-KI	[12,488; 25,467]	[24,140; 39,338]	
Veränderung zu Woche 48			
n/N (%)	1/56 (2)	1/49 (2)	LS MD -15,49 [-28,911; -2,069]
MW (SD)	22,22 (NA)	0,00 (NA)	
LS MW (SE)	22,42 (4,344)	37,91 (5,204)	
95 %-KI	[13,886; 30,955]	[27,687; 48,135]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Topotecan</b>			
Baseline			
n/N (%)	37/50 (74)	32/49 (65)	-
MW (SD)	21,92 (19,857)	21,53 (21,296)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	6/33 (18)	2/20 (10)	-
MW (SD)	33,33 (28,109)	27,78 (23,570)	
Effekt über Studiendauer			
n	37	32	LS MD 8,73 [-0,471; 17,925] 0,0626  Hedges' g 0,45 [-0,027; 0,931]
LS MW (SE)	8,52 (3,099)	-0,21 (3,422)	
95 %-KI	[2,326; 14,714]	[-7,034; 6,620]	
Veränderung zu Woche 3/4			
n/N (%)	22/50 (44)	17/45 (38)	LS MD 10,95 [1,277; 20,620]
MW (SD)	4,04 (20,729)	8,50 (14,449)	
LS MW (SE)	9,87 (3,255)	-1,08 (3,613)	
95 %-KI	[3,391; 16,355]	[-8,260; 6,109]	
Veränderung zu Woche 8/9			
n/N (%)	29/48 (60)	27/43 (63)	LS MD 10,01 [0,727; 19,301]
MW (SD)	13,79 (22,936)	-4,53 (16,382)	
LS MW (SE)	9,30 (3,139)	-0,71 (3,448)	
95 %-KI	[3,038; 15,570]	[-7,585; 6,165]	
Veränderung zu Woche 12			
n/N (%)	20/46 (43)	11/42 (26)	LS MD 9,36 [0,183; 18,536]
MW (SD)	13,33 (23,529)	-4,04 (11,410)	
LS MW (SE)	8,91 (3,101)	-0,45 (3,405)	
95 %-KI	[2,709; 15,102]	[-7,248; 6,340]	
Veränderung zu Woche 15/16			
n/N (%)	16/44 (36)	8/40 (20)	LS MD 8,71 [-0,495; 17,906]
MW (SD)	0,00 (19,030)	1,39 (11,011)	
LS MW (SE)	8,51 (3,100)	-0,20 (3,424)	
95 %-KI	[2,312; 14,702]	[-7,029; 6,632]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	11/41 (27)	7/33 (21)	LS MD 7,77 [-1,697; 17,238]
MW (SD)	-7,07 (15,926)	9,52 (16,265)	
LS MW (SE)	7,94 (3,163)	0,17 (3,556)	
95 %-KI	[1,624; 14,252]	[-6,912; 7,247]	
Veränderung zu Woche 24			
n/N (%)	11/41 (27)	3/29 (10)	LS MD 7,12 [-2,691; 16,924]
MW (SD)	-6,06 (18,832)	0,00 (0,000)	
LS MW (SE)	7,54 (3,251)	0,42 (3,716)	
95 %-KI	[1,062; 14,017]	[-6,960; 7,806]	
Veränderung zu Woche 36			
n/N (%)	15/36 (42)	8/23 (35)	LS MD 4,87 [-6,887; 16,633]
MW (SD)	1,48 (16,728)	-2,78 (23,570)	
LS MW (SE)	6,17 (3,776)	1,30 (4,586)	
95 %-KI	[-1,305; 13,651]	[-7,761; 10,361]	
Veränderung zu Woche 48			
n/N (%)	5/33 (15)	2/20 (10)	LS MD 2,63 [-11,906; 17,167]
MW (SD)	4,44 (9,938)	0,00 (15,713)	
LS MW (SE)	4,81 (4,549)	2,18 (5,767)	
95 %-KI	[-4,171; 13,785]	[-9,196; 13,550]	
<p><i>Analysepopulation: ITT</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023</i></p> <p><i>Modell: Veränderung zu Baseline ~ Behandlung + Baseline-Wert * Zeit in Wochen + Behandlung * Zeit in Wochen + zufällige Effekte durch die Patientin</i></p> <p><i>Die Berechnung des LS-MW's erfolgt durch ein MMRM mit dem oben angegebenen Modell. Basierend hierauf werden KI und p-Wert ermittelt. Hedges' g basiert ebenfalls auf den LS-MW und ist somit auf das Modell angepasst.</i></p> <p><i>Es werden ausschließlich gemeinsame Analysezeitpunkte dargestellt.</i></p> <p><i>Ein LS MD und Hedges' g kleiner als Null bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			



### 3.4 EORTC QLQ-OV28 Sexualität

#### EORTC QLQ-OV28 Sexualität: Subgruppenanalyse

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
<b>EORTC QLQ-OV28 Sexualität</b>			
<b>Alter: &lt; 65 Jahre</b>			
Baseline			
n/N (%)	91/115 (79)	89/119 (75)	-
MW (SD)	12,91 (20,908)	16,20 (22,274)	
Absolute Werte zum Studienende			
n/N (%)	4/73 (5)	4/64 (6)	-
MW (SD)	18,75 (21,916)	6,25 (12,500)	
Effekt über Studiendauer			
n	91	89	LS MD 0,65 [-2,718; 4,018] 0,7038
LS MW (SE)	-3,83 (1,171)	-4,48 (1,240)	
95 %-KI	[-6,146; -1,522]	[-6,930; -2,038]	Hedges' g 0,06 [-0,236; 0,349]
Veränderung zu Woche 3/4			
n/N (%)	58/113 (51)	59/115 (51)	LS MD 2,15 [-1,692; 5,986]
MW (SD)	-0,86 (11,753)	-5,08 (15,630)	
LS MW (SE)	-2,20 (1,350)	-4,34 (1,407)	
95 %-KI	[-4,855; 0,461]	[-7,113; -1,575]	
Veränderung zu Woche 8/9			
n/N (%)	72/112 (64)	70/108 (65)	LS MD 1,49 [-1,992; 4,977]
MW (SD)	-3,24 (16,344)	-4,05 (21,269)	
LS MW (SE)	-2,91 (1,228)	-4,41 (1,270)	
95 %-KI	[-5,334; -0,491]	[-6,908; -1,902]	
Veränderung zu Woche 12			
n/N (%)	46/110 (42)	38/105 (36)	
MW (SD)	-2,36 (18,059)	-4,17 (16,863)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-3,41 (1,181)	-4,45 (1,231)	LS MD 1,03 [-2,335; 4,404]
95 %-KI	[-5,746; -1,081]	[-6,877; -2,019]	
Veränderung zu Woche 15/16			
n/N (%)	53/107 (50)	31/102 (30)	LS MD 0,58 [-2,801; 3,954]
MW (SD)	-3,14 (13,889)	-4,03 (18,865)	
LS MW (SE)	-3,91 (1,172)	-4,49 (1,245)	
95 %-KI	[-6,228; -1,600]	[-6,948; -2,033]	
Veränderung zu Woche 20/21			
n/N (%)	36/101 (36)	29/96 (30)	LS MD -0,08 [-3,676; 3,519]
MW (SD)	-3,47 (12,500)	-10,34 (22,784)	
LS MW (SE)	-4,63 (1,223)	-4,55 (1,354)	
95 %-KI	[-7,043; -2,217]	[-7,219; -1,885]	
Veränderung zu Woche 24			
n/N (%)	25/99 (25)	19/91 (21)	LS MD -0,54 [-4,415; 3,342]
MW (SD)	-8,00 (17,260)	-1,75 (9,452)	
LS MW (SE)	-5,13 (1,300)	-4,59 (1,480)	
95 %-KI	[-7,692; -2,570]	[-7,507; -1,682]	
Veränderung zu Woche 36			
n/N (%)	41/86 (48)	27/79 (34)	LS MD -2,11 [-7,466; 3,251]
MW (SD)	-5,28 (13,662)	-4,63 (21,599)	
LS MW (SE)	-6,85 (1,741)	-4,74 (2,102)	
95 %-KI	[-10,270; -3,427]	[-8,871; -0,611]	
Veränderung zu Woche 48			
n/N (%)	4/73 (5)	3/64 (5)	LS MD -3,68 [-10,920; 3,563]
MW (SD)	-6,25 (12,500)	-19,44 (26,788)	
LS MW (SE)	-8,57 (2,329)	-4,89 (2,865)	
95 %-KI	[-13,140; -3,992]	[-10,514; 0,739]	
<b>Alter: ≥ 65 Jahre</b>			
Baseline			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	78/103 (76)	64/88 (73)	-
MW (SD)	6,52 (16,484)	8,98 (19,603)	
Absolute Werte zum Studienende			
n/N (%)	6/67 (9)	2/46 (4)	-
MW (SD)	0,00 (0,000)	0,00 (0,000)	
Effekt über Studiendauer			
n	78	64	LS MD -0,32 [-3,453; 2,805] 0,8381  Hedges' g -0,03 [-0,365; 0,296]
LS MW (SE)	-1,82 (1,038)	-1,50 (1,196)	
95 %-KI	[-3,875; 0,232]	[-3,861; 0,866]	
Veränderung zu Woche 3/4			
n/N (%)	57/100 (57)	43/85 (51)	LS MD -1,15 [-4,549; 2,258]
MW (SD)	-1,75 (14,497)	2,52 (14,265)	
LS MW (SE)	-0,76 (1,141)	0,39 (1,296)	
95 %-KI	[-3,006; 1,494]	[-2,167; 2,946]	
Veränderung zu Woche 8/9			
n/N (%)	62/98 (63)	50/80 (62)	LS MD -0,78 [-3,965; 2,397]
MW (SD)	-1,21 (6,890)	-3,33 (19,048)	
LS MW (SE)	-1,22 (1,068)	-0,44 (1,206)	
95 %-KI	[-3,335; 0,885]	[-2,822; 1,941]	
Veränderung zu Woche 12			
n/N (%)	44/95 (46)	32/78 (41)	LS MD -0,53 [-3,650; 2,588]
MW (SD)	-1,89 (13,905)	2,34 (9,039)	
LS MW (SE)	-1,55 (1,042)	-1,02 (1,185)	
95 %-KI	[-3,614; 0,508]	[-3,364; 1,320]	
Veränderung zu Woche 15/16			
n/N (%)	39/92 (42)	20/76 (26)	
MW (SD)	-2,14 (10,767)	-2,92 (16,284)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-1,88 (1,039)	-1,60 (1,201)	LS MD -0,28 [-3,416; 2,861]
95 %-KI	[-3,937; 0,175]	[-3,977; 0,772]	
Veränderung zu Woche 20/21			
n/N (%)	28/89 (31)	21/69 (30)	LS MD 0,08 [-3,222; 3,389]
MW (SD)	-1,79 (11,421)	-5,95 (24,741)	
LS MW (SE)	-2,35 (1,075)	-2,43 (1,287)	
95 %-KI	[-4,474; -0,225]	[-4,972; 0,106]	
Veränderung zu Woche 24			
n/N (%)	28/85 (33)	18/64 (28)	LS MD 0,34 [-3,172; 3,845]
MW (SD)	-3,57 (10,499)	-4,17 (12,211)	
LS MW (SE)	-2,68 (1,126)	-3,01 (1,383)	
95 %-KI	[-4,900; -0,456]	[-5,741; -0,288]	
Veränderung zu Woche 36			
n/N (%)	38/74 (51)	18/55 (33)	LS MD 1,20 [-3,385; 5,793]
MW (SD)	-2,85 (10,661)	-1,39 (10,790)	
LS MW (SE)	-3,80 (1,420)	-5,01 (1,866)	
95 %-KI	[-6,597; -1,009]	[-8,674; -1,340]	
Veränderung zu Woche 48			
n/N (%)	4/67 (6)	2/46 (4)	LS MD 2,07 [-3,931; 8,075]
MW (SD)	0,00 (0,000)	0,00 (0,000)	
LS MW (SE)	-4,93 (1,826)	-7,00 (2,470)	
95 %-KI	[-8,516; -1,339]	[-11,853; -2,146]	
<b>Region: USA</b>			
Baseline			
n/N (%)	46/65 (71)	33/51 (65)	-
MW (SD)	14,13 (22,144)	10,61 (22,173)	
Absolute Werte zum Studienende			
n/N (%)	2/39 (5)	3/27 (11)	-
MW (SD)	16,67 (23,570)	8,33 (14,434)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Effekt über Studiendauer			
n	46	33	LS MD -1,01 [-7,155; 5,143] 0,7453  Hedges' g -0,07 [-0,522; 0,373]
LS MW (SE)	-2,63 (1,948)	-1,62 (2,374)	
95 %-KI	[-6,514; 1,254]	[-6,354; 3,106]	
Veränderung zu Woche 3/4			
n/N (%)	32/64 (50)	19/49 (39)	LS MD -0,70 [-7,518; 6,123]
MW (SD)	-1,56 (17,638)	3,95 (11,577)	
LS MW (SE)	-2,18 (2,155)	-1,48 (2,658)	
95 %-KI	[-6,454; 2,092]	[-6,749; 3,782]	
Veränderung zu Woche 8/9			
n/N (%)	39/62 (63)	30/46 (65)	LS MD -0,84 [-7,147; 5,471]
MW (SD)	-5,56 (16,812)	-0,56 (25,327)	
LS MW (SE)	-2,39 (2,000)	-1,55 (2,443)	
95 %-KI	[-6,365; 1,595]	[-6,403; 3,309]	
Veränderung zu Woche 12			
n/N (%)	25/59 (42)	16/45 (36)	LS MD -0,94 [-7,088; 5,215]
MW (SD)	-4,33 (18,021)	3,12 (8,539)	
LS MW (SE)	-2,53 (1,951)	-1,59 (2,376)	
95 %-KI	[-6,416; 1,360]	[-6,323; 3,139]	
Veränderung zu Woche 15/16			
n/N (%)	20/56 (36)	11/44 (25)	LS MD -1,03 [-7,208; 5,140]
MW (SD)	-3,75 (21,710)	-0,00 (12,910)	
LS MW (SE)	-2,67 (1,955)	-1,64 (2,385)	
95 %-KI	[-6,567; 1,225]	[-6,386; 3,114]	
Veränderung zu Woche 20/21			
n/N (%)	12/54 (22)	9/40 (22)	
MW (SD)	-4,17 (14,865)	-13,89 (31,180)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-2,87 (2,051)	-1,70 (2,528)	LS MD -1,17 [-7,685; 5,336]
95 %-KI	[-6,953; 1,203]	[-6,722; 3,322]	
Veränderung zu Woche 24			
n/N (%)	9/53 (17)	6/38 (16)	LS MD -1,27 [-8,210; 5,664]
MW (SD)	-4,63 (16,197)	-5,56 (13,608)	
LS MW (SE)	-3,02 (2,175)	-1,74 (2,708)	
95 %-KI	[-7,332; 1,297]	[-7,109; 3,620]	
Veränderung zu Woche 36			
n/N (%)	20/43 (47)	9/33 (27)	LS MD -1,61 [-10,848; 7,629]
MW (SD)	-2,92 (14,377)	10,19 (18,530)	
LS MW (SE)	-3,51 (2,851)	-1,90 (3,653)	
95 %-KI	[-9,129; 2,115]	[-9,099; 5,305]	
Veränderung zu Woche 48			
n/N (%)	2/39 (5)	3/27 (11)	LS MD -1,95 [-14,193; 10,300]
MW (SD)	4,17 (5,893)	-2,78 (4,811)	
LS MW (SE)	-4,00 (3,741)	-2,05 (4,868)	
95 %-KI	[-11,364; 3,372]	[-11,636; 7,536]	
<b>Region: Rest der Welt</b>			
Baseline			
n/N (%)	123/153 (80)	120/156 (77)	-
MW (SD)	8,40 (17,838)	13,89 (21,262)	
Absolute Werte zum Studienende			
n/N (%)	8/101 (8)	3/83 (4)	-
MW (SD)	5,21 (14,731)	0,00 (0,000)	
Effekt über Studiendauer			
n	123	120	LS MD 0,60 [-1,820; 3,015] 0,6268 Hedges' g
LS MW (SE)	-3,02 (0,834)	-3,62 (0,894)	
95 %-KI	[-4,664; -1,374]	[-5,376; -1,856]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
			0,06 [-0,189; 0,314]
Veränderung zu Woche 3/4			
n/N (%)	83/149 (56)	83/151 (55)	LS MD 1,48 [-1,246; 4,214]
MW (SD)	-1,20 (11,053)	-3,21 (15,984)	
LS MW (SE)	-1,26 (0,956)	-2,74 (1,001)	
95 %-KI	[-3,139; 0,621]	[-4,712; -0,774]	
Veränderung zu Woche 8/9			
n/N (%)	95/148 (64)	90/142 (63)	LS MD 1,10 [-1,389; 3,588]
MW (SD)	-0,96 (10,657)	-4,81 (18,359)	
LS MW (SE)	-2,02 (0,874)	-3,12 (0,908)	
95 %-KI	[-3,743; -0,302]	[-4,909; -1,335]	
Veränderung zu Woche 12			
n/N (%)	65/146 (45)	54/138 (39)	LS MD 0,83 [-1,583; 3,244]
MW (SD)	-1,28 (15,326)	-2,47 (15,240)	
LS MW (SE)	-2,56 (0,842)	-3,39 (0,884)	
95 %-KI	[-4,216; -0,897]	[-5,128; -1,646]	
Veränderung zu Woche 15/16			
n/N (%)	72/143 (50)	40/134 (30)	LS MD 0,56 [-1,863; 2,985]
MW (SD)	-2,43 (8,783)	-4,58 (18,867)	
LS MW (SE)	-3,09 (0,835)	-3,65 (0,898)	
95 %-KI	[-4,736; -1,445]	[-5,420; -1,884]	
Veränderung zu Woche 20/21			
n/N (%)	52/136 (38)	41/125 (33)	LS MD 0,18 [-2,408; 2,761]
MW (SD)	-2,40 (11,354)	-7,32 (21,746)	
LS MW (SE)	-3,85 (0,867)	-4,03 (0,979)	
95 %-KI	[-5,563; -2,145]	[-5,957; -2,105]	
Veränderung zu Woche 24			
n/N (%)	44/131 (34)	31/117 (26)	
MW (SD)	-5,87 (13,872)	-2,42 (10,362)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-4,39 (0,918)	-4,30 (1,071)	LS MD -0,09 [-2,878; 2,692]
95 %-KI	[-6,195; -2,582]	[-6,401; -2,191]	
Veränderung zu Woche 36			
n/N (%)	59/117 (50)	36/101 (36)	LS MD -1,02 [-4,846; 2,814]
MW (SD)	-4,52 (11,613)	-6,71 (16,405)	
LS MW (SE)	-6,22 (1,213)	-5,20 (1,519)	
95 %-KI	[-8,602; -3,839]	[-8,187; -2,223]	
Veränderung zu Woche 48			
n/N (%)	6/101 (6)	2/83 (2)	LS MD -1,94 [-7,096; 3,218]
MW (SD)	-5,56 (8,607)	-25,00 (35,355)	
LS MW (SE)	-8,05 (1,611)	-6,11 (2,065)	
95 %-KI	[-11,214; -4,891]	[-10,166; -2,061]	
<b>Stadium bei der Diagnose: I-III</b>			
Baseline			
n/N (%)	110/141 (78)	110/144 (76)	-
MW (SD)	9,24 (18,526)	12,88 (20,495)	
Absolute Werte zum Studienende			
n/N (%)	6/91 (7)	4/76 (5)	-
MW (SD)	6,94 (17,010)	6,25 (12,500)	
Effekt über Studiendauer			
n	110	110	LS MD -0,93 [-3,482; 1,626] 0,4747
LS MW (SE)	-2,72 (0,888)	-1,79 (0,942)	
95 %-KI	[-4,474; -0,971]	[-3,652; 0,062]	Hedges' g -0,10 [-0,361; 0,168]
Veränderung zu Woche 3/4			
n/N (%)	73/137 (53)	75/138 (54)	LS MD -0,59 [-3,502; 2,326]
MW (SD)	-1,26 (14,479)	-0,89 (15,534)	
LS MW (SE)	-1,90 (1,029)	-1,31 (1,065)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,921; 0,128]	[-3,403; 0,786]	
Veränderung zu Woche 8/9			
n/N (%)	89/136 (65)	87/129 (67)	LS MD -0,74 [-3,381; 1,908]
MW (SD)	-2,53 (11,195)	-2,68 (15,117)	
LS MW (SE)	-2,26 (0,934)	-1,52 (0,963)	
95 %-KI	[-4,098; -0,418]	[-3,419; 0,376]	
Veränderung zu Woche 12			
n/N (%)	60/133 (45)	48/128 (38)	LS MD -0,84 [-3,397; 1,716]
MW (SD)	-1,81 (13,027)	-0,87 (14,712)	
LS MW (SE)	-2,51 (0,897)	-1,67 (0,935)	
95 %-KI	[-4,280; -0,742]	[-3,514; 0,173]	
Veränderung zu Woche 15/16			
n/N (%)	63/130 (48)	34/125 (27)	LS MD -0,94 [-3,507; 1,617]
MW (SD)	-3,04 (13,159)	-0,25 (13,987)	
LS MW (SE)	-2,76 (0,889)	-1,82 (0,947)	
95 %-KI	[-4,517; -1,011]	[-3,685; 0,047]	
Veränderung zu Woche 20/21			
n/N (%)	46/123 (37)	33/116 (28)	LS MD -1,09 [-3,821; 1,634]
MW (SD)	-3,08 (13,189)	-5,30 (18,613)	
LS MW (SE)	-3,13 (0,927)	-2,03 (1,028)	
95 %-KI	[-4,952; -1,299]	[-4,056; -0,008]	
Veränderung zu Woche 24			
n/N (%)	34/121 (28)	26/109 (24)	LS MD -1,20 [-4,138; 1,743]
MW (SD)	-5,64 (14,611)	-1,28 (8,060)	
LS MW (SE)	-3,38 (0,985)	-2,18 (1,123)	
95 %-KI	[-5,319; -1,439]	[-4,389; 0,027]	
Veränderung zu Woche 36			
n/N (%)	52/105 (50)	33/92 (36)	
MW (SD)	-3,53 (11,113)	-2,02 (17,925)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-4,25 (1,323)	-2,69 (1,589)	LS MD -1,55 [-5,617; 2,508]
95 %-KI	[-6,846; -1,647]	[-5,812; 0,429]	
Veränderung zu Woche 48			
n/N (%)	5/91 (5)	4/76 (5)	LS MD -1,91 [-7,401; 3,579]
MW (SD)	-3,33 (7,454)	-2,08 (4,167)	
LS MW (SE)	-5,11 (1,774)	-3,20 (2,161)	
95 %-KI	[-8,596; -1,631]	[-7,445; 1,041]	
<b>Stadium bei der Diagnose: IV</b>			
Baseline			
n/N (%)	55/72 (76)	41/60 (68)	-
MW (SD)	10,61 (19,737)	13,62 (23,990)	
Absolute Werte zum Studienende			
n/N (%)	4/46 (9)	2/33 (6)	-
MW (SD)	8,33 (16,667)	0,00 (0,000)	
Effekt über Studiendauer			
n	55	41	LS MD 2,28 [-2,721; 7,279] 0,3677  Hedges' g 0,19 [-0,219; 0,592]
LS MW (SE)	-3,94 (1,616)	-6,22 (1,927)	
95 %-KI	[-7,154; -0,728]	[-10,044; -2,395]	
Veränderung zu Woche 3/4			
n/N (%)	38/71 (54)	25/59 (42)	LS MD 3,37 [-2,144; 8,883]
MW (SD)	-1,54 (11,105)	-5,00 (15,775)	
LS MW (SE)	-1,65 (1,792)	-5,02 (2,135)	
95 %-KI	[-5,193; 1,896]	[-9,238; -0,799]	
Veränderung zu Woche 8/9			
n/N (%)	41/69 (59)	31/56 (55)	LS MD 2,89 [-2,196; 7,983]
MW (SD)	-2,24 (16,460)	-6,72 (31,063)	
LS MW (SE)	-2,65 (1,666)	-5,54 (1,950)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-5,956; 0,657]	[-9,409; -1,677]	
Veränderung zu Woche 12			
n/N (%)	27/67 (40)	21/52 (40)	LS MD 2,56 [-2,413; 7,533]
MW (SD)	-3,09 (22,307)	-1,98 (13,412)	
LS MW (SE)	-3,35 (1,622)	-5,91 (1,905)	
95 %-KI	[-6,574; -0,126]	[-9,692; -2,127]	
Veränderung zu Woche 15/16			
n/N (%)	27/64 (42)	15/50 (30)	LS MD 2,23 [-2,791; 7,244]
MW (SD)	-1,54 (11,565)	-10,00 (23,612)	
LS MW (SE)	-4,05 (1,618)	-6,28 (1,937)	
95 %-KI	[-7,267; -0,833]	[-10,121; -2,433]	
Veränderung zu Woche 20/21			
n/N (%)	16/62 (26)	16/46 (35)	LS MD 1,75 [-3,597; 7,098]
MW (SD)	-1,04 (7,979)	-15,62 (31,310)	
LS MW (SE)	-5,05 (1,681)	-6,80 (2,106)	
95 %-KI	[-8,388; -1,714]	[-10,969; -2,633]	
Veränderung zu Woche 24			
n/N (%)	18/59 (31)	10/44 (23)	LS MD 1,42 [-4,325; 7,159]
MW (SD)	-5,09 (13,749)	-7,50 (15,933)	
LS MW (SE)	-5,75 (1,769)	-7,17 (2,296)	
95 %-KI	[-9,257; -2,246]	[-11,702; -2,633]	
Veränderung zu Woche 36			
n/N (%)	26/52 (50)	11/41 (27)	LS MD 0,27 [-7,510; 8,057]
MW (SD)	-5,45 (14,709)	-7,58 (19,168)	
LS MW (SE)	-8,15 (2,274)	-8,43 (3,220)	
95 %-KI	[-12,634; -3,671]	[-14,765; -2,087]	
Veränderung zu Woche 48			
n/N (%)	3/46 (7)	1/33 (3)	
MW (SD)	-2,78 (12,729)	-50,00 (NA)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-10,55 (2,959)	-9,68 (4,351)	LS MD -0,87 [-11,252; 9,512]
95 %-KI	[-16,376; -4,732]	[-18,244; -1,124]	
<b>BRCA Status: Positiv</b>			
Baseline			
n/N (%)	24/27 (89)	22/35 (63)	-
MW (SD)	7,99 (18,631)	6,06 (16,098)	
Absolute Werte zum Studienende			
n/N (%)	1/19 (5)	0/15 (0)	-
MW (SD)	0,00 (NA)	NA (NA)	
Effekt über Studiendauer			
n	24	22	LS MD 0,13 [-4,538; 4,800] 0,9552  Hedges' g 0,02 [-0,562; 0,595]
LS MW (SE)	-1,66 (1,541)	-1,79 (1,712)	
95 %-KI	[-4,778; 1,453]	[-5,234; 1,648]	
Veränderung zu Woche 3/4			
n/N (%)	16/27 (59)	16/35 (46)	LS MD -0,45 [-5,402; 4,494]
MW (SD)	-3,65 (14,583)	2,08 (5,693)	
LS MW (SE)	-0,95 (1,693)	-0,50 (1,803)	
95 %-KI	[-4,343; 2,438]	[-4,102; 3,106]	
Veränderung zu Woche 8/9			
n/N (%)	20/26 (77)	18/30 (60)	LS MD -0,17 [-4,808; 4,468]
MW (SD)	-0,83 (12,653)	-2,31 (9,821)	
LS MW (SE)	-1,30 (1,582)	-1,13 (1,668)	
95 %-KI	[-4,485; 1,889]	[-4,485; 2,229]	
Veränderung zu Woche 12			
n/N (%)	13/26 (50)	10/30 (33)	LS MD 0,03 [-4,587; 4,646]
MW (SD)	0,00 (15,215)	0,00 (0,000)	
LS MW (SE)	-1,54 (1,545)	-1,57 (1,675)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-4,662; 1,583]	[-4,942; 1,804]	
Veränderung zu Woche 15/16			
n/N (%)	12/26 (46)	6/29 (21)	LS MD 0,23 [-4,530; 4,988]
MW (SD)	-0,69 (2,406)	0,00 (0,000)	
LS MW (SE)	-1,78 (1,546)	-2,01 (1,767)	
95 %-KI	[-4,906; 1,344]	[-5,553; 1,534]	
Veränderung zu Woche 20/21			
n/N (%)	10/25 (40)	4/25 (16)	LS MD 0,51 [-4,709; 5,735]
MW (SD)	-3,33 (10,541)	0,00 (0,000)	
LS MW (SE)	-2,13 (1,612)	-2,64 (2,019)	
95 %-KI	[-5,371; 1,118]	[-6,659; 1,380]	
Veränderung zu Woche 24			
n/N (%)	7/25 (28)	4/24 (17)	LS MD 0,71 [-4,986; 6,410]
MW (SD)	-4,76 (12,599)	0,00 (0,000)	
LS MW (SE)	-2,37 (1,698)	-3,08 (2,257)	
95 %-KI	[-5,772; 1,036]	[-7,559; 1,398]	
Veränderung zu Woche 36			
n/N (%)	9/21 (43)	5/20 (25)	LS MD 1,40 [-6,533; 9,324]
MW (SD)	-5,56 (8,333)	0,00 (0,000)	
LS MW (SE)	-3,20 (2,180)	-4,59 (3,286)	
95 %-KI	[-7,520; 1,126]	[-11,088; 1,904]	
Veränderung zu Woche 48			
n/N (%)	1/19 (5)	0/15 (0)	LS MD 2,08 [-8,539; 12,695]
MW (SD)	-16,67 (NA)	NA (NA)	
LS MW (SE)	-4,03 (2,828)	-6,10 (4,463)	
95 %-KI	[-9,616; 1,564]	[-14,927; 2,719]	
<b>BRCA Status: Negativ/Unbekannt</b>			
Baseline			
n/N (%)	145/191 (76)	131/172 (76)	-

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	10,29 (19,345)	14,38 (22,025)	
Absolute Werte zum Studienende			
n/N (%)	9/121 (7)	6/95 (6)	-
MW (SD)	8,33 (16,667)	4,17 (10,206)	
Effekt über Studiendauer			
n	145	131	LS MD 0,05 [-2,566; 2,663] 0,9706  Hedges' g 0,00 [-0,232; 0,241]
LS MW (SE)	-3,21 (0,893)	-3,26 (0,980)	
95 %-KI	[-4,971; -1,453]	[-5,191; -1,331]	
Veränderung zu Woche 3/4			
n/N (%)	99/186 (53)	86/165 (52)	LS MD 0,75 [-2,188; 3,686]
MW (SD)	-0,93 (12,926)	-2,62 (16,581)	
LS MW (SE)	-1,76 (1,011)	-2,51 (1,099)	
95 %-KI	[-3,749; 0,226]	[-4,670; -0,351]	
Veränderung zu Woche 8/9			
n/N (%)	114/184 (62)	102/158 (65)	LS MD 0,45 [-2,247; 3,141]
MW (SD)	-2,56 (12,935)	-4,00 (21,646)	
LS MW (SE)	-2,39 (0,930)	-2,83 (1,003)	
95 %-KI	[-4,217; -0,558]	[-4,808; -0,861]	
Veränderung zu Woche 12			
n/N (%)	77/179 (43)	60/153 (39)	LS MD 0,24 [-2,380; 2,850]
MW (SD)	-2,49 (16,282)	-1,39 (15,279)	
LS MW (SE)	-2,83 (0,899)	-3,06 (0,975)	
95 %-KI	[-4,597; -1,055]	[-4,981; -1,142]	
Veränderung zu Woche 15/16			
n/N (%)	80/173 (46)	45/149 (30)	LS MD 0,02 [-2,596; 2,643]
MW (SD)	-3,02 (13,473)	-4,07 (18,855)	
LS MW (SE)	-3,26 (0,894)	-3,29 (0,983)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-5,024; -1,504]	[-5,224; -1,352]	
Veränderung zu Woche 20/21			
n/N (%)	54/165 (33)	46/140 (33)	LS MD -0,28 [-3,047; 2,490]
MW (SD)	-2,62 (12,310)	-9,24 (24,358)	
LS MW (SE)	-3,89 (0,929)	-3,61 (1,055)	
95 %-KI	[-5,719; -2,062]	[-5,686; -1,538]	
Veränderung zu Woche 24			
n/N (%)	46/159 (29)	33/131 (25)	LS MD -0,49 [-3,451; 2,471]
MW (SD)	-5,80 (14,473)	-3,28 (11,399)	
LS MW (SE)	-4,33 (0,981)	-3,84 (1,140)	
95 %-KI	[-6,258; -2,399]	[-6,080; -1,598]	
Veränderung zu Woche 36			
n/N (%)	70/139 (50)	40/114 (35)	LS MD -1,22 [-5,208; 2,778]
MW (SD)	-3,93 (12,747)	-3,75 (19,054)	
LS MW (SE)	-5,83 (1,284)	-4,62 (1,575)	
95 %-KI	[-8,352; -3,311]	[-7,708; -1,524]	
Veränderung zu Woche 48			
n/N (%)	7/121 (6)	5/95 (5)	LS MD -1,94 [-7,269; 3,388]
MW (SD)	-1,19 (7,498)	-11,67 (21,731)	
LS MW (SE)	-7,33 (1,693)	-5,39 (2,120)	
95 %-KI	[-10,657; -4,012]	[-9,554; -1,233]	
<b>Baseline ECOG PS: 0</b>			
Baseline			
n/N (%)	98/128 (77)	92/113 (81)	-
MW (SD)	11,05 (19,907)	15,94 (22,499)	
Absolute Werte zum Studienende			
n/N (%)	7/87 (8)	3/72 (4)	-
MW (SD)	10,71 (18,456)	8,33 (14,434)	
Effekt über Studiendauer			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n	98	92	LS MD 0,09 [-3,284; 3,470] 0,9569  Hedges' g 0,01 [-0,277; 0,292]
LS MW (SE)	-3,76 (1,167)	-3,85 (1,248)	
95 %-KI	[-6,062; -1,458]	[-6,314; -1,392]	
Veränderung zu Woche 3/4			
n/N (%)	69/127 (54)	60/111 (54)	LS MD 1,41 [-2,313; 5,133]
MW (SD)	0,24 (13,328)	-1,11 (16,343)	
LS MW (SE)	-1,73 (1,291)	-3,14 (1,377)	
95 %-KI	[-4,271; 0,815]	[-5,849; -0,426]	
Veränderung zu Woche 8/9			
n/N (%)	79/126 (63)	71/108 (66)	LS MD 0,84 [-2,621; 4,305]
MW (SD)	-2,22 (12,639)	-7,04 (23,259)	
LS MW (SE)	-2,60 (1,205)	-3,45 (1,273)	
95 %-KI	[-4,981; -0,227]	[-5,956; -0,936]	
Veränderung zu Woche 12			
n/N (%)	50/122 (41)	44/108 (41)	LS MD 0,44 [-2,934; 3,823]
MW (SD)	-3,33 (15,338)	-1,70 (16,430)	
LS MW (SE)	-3,22 (1,173)	-3,66 (1,243)	
95 %-KI	[-5,533; -0,902]	[-6,113; -1,211]	
Veränderung zu Woche 15/16			
n/N (%)	54/120 (45)	32/105 (30)	LS MD 0,05 [-3,335; 3,428]
MW (SD)	-4,01 (14,088)	-6,77 (21,107)	
LS MW (SE)	-3,83 (1,167)	-3,88 (1,251)	
95 %-KI	[-6,135; -1,528]	[-6,345; -1,411]	
Veränderung zu Woche 20/21			
n/N (%)	39/117 (33)	31/101 (31)	LS MD -0,52 [-4,059; 3,016]
MW (SD)	-3,42 (14,142)	-9,95 (27,590)	
LS MW (SE)	-4,71 (1,203)	-4,19 (1,326)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-7,081; -2,334]	[-6,800; -1,573]	
Veränderung zu Woche 24			
n/N (%)	27/112 (24)	21/96 (22)	LS MD -0,92 [-4,660; 2,822]
MW (SD)	-8,02 (16,744)	-4,37 (11,672)	
LS MW (SE)	-5,32 (1,258)	-4,40 (1,419)	
95 %-KI	[-7,801; -2,842]	[-7,195; -1,609]	
Veränderung zu Woche 36			
n/N (%)	48/99 (48)	33/87 (38)	LS MD -2,28 [-7,152; 2,586]
MW (SD)	-5,21 (12,470)	-4,04 (20,846)	
LS MW (SE)	-7,42 (1,584)	-5,14 (1,901)	
95 %-KI	[-10,539; -4,311]	[-8,876; -1,408]	
Veränderung zu Woche 48			
n/N (%)	5/87 (6)	3/72 (4)	LS MD -3,65 [-10,018; 2,726]
MW (SD)	-5,00 (11,180)	-19,44 (26,788)	
LS MW (SE)	-9,53 (2,040)	-5,88 (2,519)	
95 %-KI	[-13,534; -5,523]	[-10,829; -0,937]	
<b>Baseline ECOG PS: 1</b>			
Baseline			
n/N (%)	71/90 (79)	60/91 (66)	-
MW (SD)	8,45 (18,230)	8,33 (18,539)	
Absolute Werte zum Studienende			
n/N (%)	3/53 (6)	3/37 (8)	-
MW (SD)	0,00 (0,000)	0,00 (0,000)	
Effekt über Studiendauer			
n	71	60	LS MD -0,31 [-3,220; 2,598] 0,8329
LS MW (SE)	-1,63 (0,951)	-1,32 (1,120)	
95 %-KI	[-3,519; 0,250]	[-3,539; 0,892]	Hedges' g -0,04 [-0,381; 0,307]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	46/86 (53)	41/87 (47)	LS MD -0,17 [-3,586; 3,242]
MW (SD)	-3,62 (12,626)	-2,85 (14,387)	
LS MW (SE)	-1,36 (1,153)	-1,18 (1,292)	
95 %-KI	[-3,627; 0,916]	[-3,729; 1,361]	
Veränderung zu Woche 8/9			
n/N (%)	55/84 (65)	48/78 (62)	LS MD -0,23 [-3,241; 2,772]
MW (SD)	-2,42 (13,290)	1,04 (14,031)	
LS MW (SE)	-1,48 (1,015)	-1,25 (1,133)	
95 %-KI	[-3,488; 0,526]	[-3,484; 0,991]	
Veränderung zu Woche 12			
n/N (%)	40/83 (48)	25/74 (34)	LS MD -0,28 [-3,169; 2,613]
MW (SD)	-0,63 (17,025)	-0,00 (9,317)	
LS MW (SE)	-1,57 (0,963)	-1,29 (1,098)	
95 %-KI	[-3,475; 0,338]	[-3,463; 0,882]	
Veränderung zu Woche 15/16			
n/N (%)	38/79 (48)	19/72 (26)	LS MD -0,32 [-3,256; 2,613]
MW (SD)	-0,88 (10,028)	1,75 (7,647)	
LS MW (SE)	-1,66 (0,952)	-1,33 (1,136)	
95 %-KI	[-3,544; 0,232]	[-3,581; 0,912]	
Veränderung zu Woche 20/21			
n/N (%)	25/73 (34)	18/63 (29)	LS MD -0,38 [-3,639; 2,871]
MW (SD)	-1,67 (7,607)	-4,63 (13,774)	
LS MW (SE)	-1,78 (1,014)	-1,40 (1,300)	
95 %-KI	[-3,787; 0,225]	[-3,961; 1,166]	
Veränderung zu Woche 24			
n/N (%)	26/72 (36)	15/58 (26)	LS MD -0,43 [-4,052; 3,196]
MW (SD)	-3,21 (10,561)	1,11 (4,303)	
LS MW (SE)	-1,87 (1,103)	-1,44 (1,470)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-4,046; 0,309]	[-4,337; 1,455]	
Veränderung zu Woche 36			
n/N (%)	31/61 (51)	12/46 (26)	LS MD -0,58 [-5,971; 4,816]
MW (SD)	-2,42 (12,017)	-1,39 (4,811)	
LS MW (SE)	-2,17 (1,585)	-1,59 (2,237)	
95 %-KI	[-5,286; 0,948]	[-5,989; 2,806]	
Veränderung zu Woche 48			
n/N (%)	3/53 (6)	2/37 (5)	LS MD -0,73 [-8,228; 6,774]
MW (SD)	0,00 (0,000)	0,00 (0,000)	
LS MW (SE)	-2,47 (2,194)	-1,74 (3,119)	
95 %-KI	[-6,781; 1,843]	[-7,873; 4,389]	
<b>Anzahl vorheriger Therapielinien: 1</b>			
Baseline			
n/N (%)	24/31 (77)	21/29 (72)	-
MW (SD)	6,60 (20,111)	9,52 (18,872)	
Absolute Werte zum Studienende			
n/N (%)	1/22 (5)	0/14 (0)	-
MW (SD)	0,00 (NA)	NA (NA)	
Effekt über Studiendauer			
n	24	21	LS MD 1,37 [-3,396; 6,141] 0,5641  Hedges' g 0,17 [-0,416; 0,758]
LS MW (SE)	-0,48 (1,584)	-1,85 (1,747)	
95 %-KI	[-3,681; 2,730]	[-5,374; 1,678]	
Veränderung zu Woche 3/4			
n/N (%)	16/31 (52)	13/29 (45)	LS MD 1,02 [-4,437; 6,483]
MW (SD)	2,08 (10,758)	-3,85 (17,218)	
LS MW (SE)	1,64 (1,830)	0,62 (2,035)	
95 %-KI	[-2,010; 5,295]	[-3,435; 4,674]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	20/31 (65)	16/26 (62)	LS MD 1,17 [-3,812; 6,148]
MW (SD)	2,50 (11,180)	1,56 (13,340)	
LS MW (SE)	0,76 (1,675)	-0,41 (1,824)	
95 %-KI	[-2,603; 4,129]	[-4,066; 3,255]	
Veränderung zu Woche 12			
n/N (%)	14/31 (45)	12/24 (50)	LS MD 1,27 [-3,533; 6,072]
MW (SD)	-2,98 (11,136)	2,78 (7,397)	
LS MW (SE)	0,15 (1,609)	-1,12 (1,750)	
95 %-KI	[-3,101; 3,396]	[-4,650; 2,405]	
Veränderung zu Woche 15/16			
n/N (%)	15/31 (48)	11/22 (50)	LS MD 1,37 [-3,397; 6,139]
MW (SD)	-1,11 (6,948)	-3,03 (14,080)	
LS MW (SE)	-0,47 (1,584)	-1,84 (1,747)	
95 %-KI	[-3,674; 2,737]	[-5,364; 1,685]	
Veränderung zu Woche 20/21			
n/N (%)	11/30 (37)	9/22 (41)	LS MD 1,52 [-3,452; 6,484]
MW (SD)	-2,27 (10,601)	-3,70 (11,111)	
LS MW (SE)	-1,35 (1,623)	-2,86 (1,864)	
95 %-KI	[-4,623; 1,928]	[-6,607; 0,879]	
Veränderung zu Woche 24			
n/N (%)	9/30 (30)	10/20 (50)	LS MD 1,62 [-3,652; 6,888]
MW (SD)	-3,70 (7,349)	-3,33 (10,541)	
LS MW (SE)	-1,96 (1,699)	-3,58 (2,020)	
95 %-KI	[-5,377; 1,450]	[-7,616; 0,454]	
Veränderung zu Woche 36			
n/N (%)	15/26 (58)	6/18 (33)	LS MD 1,97 [-5,084; 9,016]
MW (SD)	-2,22 (5,864)	0,00 (0,000)	
LS MW (SE)	-4,07 (2,189)	-6,04 (2,841)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-8,413; 0,265]	[-11,660; -0,421]	
Veränderung zu Woche 48			
n/N (%)	0/22 (0)	0/14 (0)	LS MD 2,31 [-7,141; 11,769]
MW (SD)	NA (NA)	NA (NA)	
LS MW (SE)	-6,19 (2,881)	-8,50 (3,877)	
95 %-KI	[-11,875; -0,495]	[-16,154; -0,844]	
<b>Anzahl vorheriger Therapielinien: 2</b>			
Baseline			
n/N (%)	73/89 (82)	65/83 (78)	-
MW (SD)	7,65 (16,123)	12,05 (20,731)	
Absolute Werte zum Studienende			
n/N (%)	4/59 (7)	2/50 (4)	-
MW (SD)	10,42 (20,833)	0,00 (0,000)	
Effekt über Studiendauer			
n	73	65	LS MD -3,19 [-6,640; 0,253] 0,0690  Hedges' g -0,31 [-0,649; 0,024]
LS MW (SE)	-2,42 (1,141)	0,77 (1,315)	
95 %-KI	[-4,685; -0,165]	[-1,831; 3,368]	
Veränderung zu Woche 3/4			
n/N (%)	50/86 (58)	44/80 (55)	LS MD -1,55 [-5,471; 2,366]
MW (SD)	0,17 (12,081)	-0,38 (16,855)	
LS MW (SE)	-0,94 (1,328)	0,61 (1,477)	
95 %-KI	[-3,559; 1,679]	[-2,297; 3,522]	
Veränderung zu Woche 8/9			
n/N (%)	58/85 (68)	51/77 (66)	LS MD -2,29 [-5,818; 1,230]
MW (SD)	-3,02 (12,061)	-0,49 (20,643)	
LS MW (SE)	-1,61 (1,200)	0,68 (1,318)	
95 %-KI	[-3,983; 0,762]	[-1,920; 3,286]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	36/83 (43)	31/75 (41)	LS MD -2,81 [-6,234; 0,609]
MW (SD)	-1,16 (20,330)	0,27 (15,736)	
LS MW (SE)	-2,08 (1,152)	0,73 (1,289)	
95 %-KI	[-4,361; 0,200]	[-1,816; 3,281]	
Veränderung zu Woche 15/16			
n/N (%)	39/80 (49)	17/74 (23)	LS MD -3,33 [-6,808; 0,145]
MW (SD)	-2,99 (10,897)	0,98 (19,738)	
LS MW (SE)	-2,55 (1,143)	0,78 (1,334)	
95 %-KI	[-4,813; -0,287]	[-1,855; 3,418]	
Veränderung zu Woche 20/21			
n/N (%)	31/78 (40)	20/68 (29)	LS MD -4,07 [-7,884; -0,261]
MW (SD)	-1,61 (10,633)	0,83 (18,712)	
LS MW (SE)	-3,22 (1,198)	0,85 (1,512)	
95 %-KI	[-5,590; -0,850]	[-2,129; 3,833]	
Veränderung zu Woche 24			
n/N (%)	25/74 (34)	13/65 (20)	LS MD -4,59 [-8,785; -0,398]
MW (SD)	-3,67 (11,805)	1,28 (4,623)	
LS MW (SE)	-3,69 (1,281)	0,90 (1,696)	
95 %-KI	[-6,218; -1,161]	[-2,437; 4,241]	
Veränderung zu Woche 36			
n/N (%)	33/65 (51)	16/58 (28)	LS MD -6,37 [-12,417; -0,323]
MW (SD)	-4,80 (11,973)	0,52 (6,433)	
LS MW (SE)	-5,30 (1,745)	1,07 (2,525)	
95 %-KI	[-8,730; -1,867]	[-3,891; 6,033]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	1/50 (2)	LS MD -8,15 [-16,438; 0,141]
MW (SD)	-8,33 (9,623)	0,00 (NA)	
LS MW (SE)	-6,91 (2,354)	1,24 (3,486)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-11,533; -2,283]	[-5,610; 8,091]	
<b>Anzahl vorheriger Therapielinien: 3</b>			
Baseline			
n/N (%)	72/98 (73)	67/95 (71)	-
MW (SD)	13,43 (21,375)	15,42 (22,856)	
Absolute Werte zum Studienende			
n/N (%)	5/59 (8)	4/46 (9)	-
MW (SD)	6,67 (14,907)	6,25 (12,500)	
Effekt über Studiendauer			
n	72	67	LS MD 2,69 [-1,187; 6,568] 0,1723  Hedges' g 0,23 [-0,102; 0,566]
LS MW (SE)	-4,32 (1,341)	-7,01 (1,429)	
95 %-KI	[-6,975; -1,668]	[-9,837; -4,186]	
Veränderung zu Woche 3/4			
n/N (%)	49/96 (51)	45/91 (49)	LS MD 2,87 [-1,400; 7,149]
MW (SD)	-3,91 (14,544)	-2,78 (13,647)	
LS MW (SE)	-3,33 (1,490)	-6,20 (1,574)	
95 %-KI	[-6,269; -0,391]	[-9,308; -3,101]	
Veränderung zu Woche 8/9			
n/N (%)	56/94 (60)	53/85 (62)	LS MD 2,79 [-1,176; 6,765]
MW (SD)	-3,27 (14,006)	-8,49 (20,961)	
LS MW (SE)	-3,76 (1,382)	-6,56 (1,458)	
95 %-KI	[-6,493; -1,029]	[-9,436; -3,675]	
Veränderung zu Woche 12			
n/N (%)	40/91 (44)	27/84 (32)	LS MD 2,74 [-1,137; 6,614]
MW (SD)	-2,71 (13,262)	-4,63 (14,122)	
LS MW (SE)	-4,06 (1,345)	-6,80 (1,424)	
95 %-KI	[-6,724; -1,402]	[-9,617; -3,985]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	38/88 (43)	23/82 (28)	LS MD 2,68 [-1,203; 6,567]
MW (SD)	-3,07 (15,790)	-7,25 (17,643)	
LS MW (SE)	-4,36 (1,343)	-7,05 (1,433)	
95 %-KI	[-7,022; -1,708]	[-9,880; -4,214]	
Veränderung zu Woche 20/21			
n/N (%)	22/82 (27)	21/75 (28)	LS MD 2,60 [-1,476; 6,680]
MW (SD)	-4,55 (14,486)	-19,44 (27,301)	
LS MW (SE)	-4,80 (1,399)	-7,40 (1,516)	
95 %-KI	[-7,561; -2,031]	[-10,391; -4,404]	
Veränderung zu Woche 24			
n/N (%)	19/80 (24)	14/70 (20)	LS MD 2,55 [-1,780; 6,871]
MW (SD)	-9,21 (18,612)	-6,55 (13,936)	
LS MW (SE)	-5,10 (1,477)	-7,64 (1,618)	
95 %-KI	[-8,012; -2,183]	[-10,835; -4,452]	
Veränderung zu Woche 36			
n/N (%)	31/69 (45)	23/58 (40)	LS MD 2,35 [-3,322; 8,028]
MW (SD)	-4,30 (14,887)	-6,88 (24,315)	
LS MW (SE)	-6,13 (1,914)	-8,49 (2,155)	
95 %-KI	[-9,898; -2,368]	[-12,722; -4,249]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	4/46 (9)	LS MD 2,16 [-5,297; 9,618]
MW (SD)	2,08 (4,167)	-14,58 (23,936)	
LS MW (SE)	-7,17 (2,502)	-9,33 (2,846)	
95 %-KI	[-12,084; -2,251]	[-14,921; -3,736]	
<b>Vorherige Verabreichung von Bevacizumab: Ja</b>			
Baseline			
n/N (%)	99/134 (74)	94/132 (71)	-
MW (SD)	11,53 (19,910)	15,34 (23,293)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	3/79 (4)	3/62 (5)	-
MW (SD)	13,89 (24,056)	8,33 (14,434)	
Effekt über Studiendauer			
n	99	94	LS MD -0,54 [-3,849; 2,769] 0,7478  Hedges' g -0,05 [-0,329; 0,236]
LS MW (SE)	-4,22 (1,140)	-3,68 (1,229)	
95 %-KI	[-6,470; -1,971]	[-6,104; -1,256]	
Veränderung zu Woche 3/4			
n/N (%)	63/130 (48)	63/127 (50)	LS MD -0,16 [-3,829; 3,509]
MW (SD)	-2,51 (12,668)	-2,12 (15,978)	
LS MW (SE)	-3,41 (1,279)	-3,25 (1,354)	
95 %-KI	[-5,924; -0,889]	[-5,910; -0,582]	
Veränderung zu Woche 8/9			
n/N (%)	78/130 (60)	71/119 (60)	LS MD -0,33 [-3,705; 3,038]
MW (SD)	-4,49 (15,117)	-4,81 (19,953)	
LS MW (SE)	-3,78 (1,180)	-3,44 (1,236)	
95 %-KI	[-6,106; -1,451]	[-5,881; -1,009]	
Veränderung zu Woche 12			
n/N (%)	48/126 (38)	36/114 (32)	LS MD -0,46 [-3,750; 2,839]
MW (SD)	-2,95 (18,712)	-1,39 (16,962)	
LS MW (SE)	-4,04 (1,145)	-3,58 (1,213)	
95 %-KI	[-6,300; -1,779]	[-5,977; -1,191]	
Veränderung zu Woche 15/16			
n/N (%)	54/122 (44)	30/112 (27)	LS MD -0,58 [-3,911; 2,756]
MW (SD)	-4,48 (14,633)	-1,67 (16,724)	
LS MW (SE)	-4,30 (1,142)	-3,72 (1,244)	
95 %-KI	[-6,554; -2,046]	[-6,176; -1,270]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	37/114 (32)	28/103 (27)	LS MD -0,75 [-4,334; 2,831]
MW (SD)	-4,73 (13,543)	-10,71 (25,037)	
LS MW (SE)	-4,67 (1,191)	-3,92 (1,372)	
95 %-KI	[-7,021; -2,324]	[-6,623; -1,220]	
Veränderung zu Woche 24			
n/N (%)	29/109 (27)	17/95 (18)	LS MD -0,87 [-4,744; 2,999]
MW (SD)	-7,18 (15,060)	-1,96 (8,085)	
LS MW (SE)	-4,93 (1,260)	-4,06 (1,509)	
95 %-KI	[-7,414; -2,452]	[-7,027; -1,093]	
Veränderung zu Woche 36			
n/N (%)	44/93 (47)	21/79 (27)	LS MD -1,29 [-6,616; 4,036]
MW (SD)	-4,55 (13,140)	-0,00 (16,667)	
LS MW (SE)	-5,83 (1,648)	-4,54 (2,149)	
95 %-KI	[-9,065; -2,588]	[-8,757; -0,316]	
Veränderung zu Woche 48			
n/N (%)	3/79 (4)	2/62 (3)	LS MD -1,71 [-8,851; 5,436]
MW (SD)	-5,56 (9,623)	-4,17 (5,893)	
LS MW (SE)	-6,72 (2,168)	-5,01 (2,915)	
95 %-KI	[-10,979; -2,462]	[-10,737; 0,711]	
<b>Vorherige Verabreichung von Bevacizumab: Nein</b>			
Baseline			
n/N (%)	70/84 (83)	59/75 (79)	-
MW (SD)	7,74 (18,076)	9,75 (17,722)	
Absolute Werte zum Studienende			
n/N (%)	7/61 (11)	3/48 (6)	-
MW (SD)	4,76 (12,599)	0,00 (0,000)	
Effekt über Studiendauer			
n	70	59	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-1,34 (1,059)	-2,19 (1,198)	LS MD 0,85 [-2,316; 4,017] 0,5958  Hedges' g 0,09 [-0,253; 0,440]
95 %-KI	[-3,439; 0,755]	[-4,563; 0,177]	
Veränderung zu Woche 3/4			
n/N (%)	52/83 (63)	39/73 (53)	LS MD 1,85 [-1,785; 5,476]
MW (SD)	0,16 (13,657)	-1,50 (14,793)	
LS MW (SE)	0,71 (1,222)	-1,13 (1,376)	
95 %-KI	[-1,698; 3,123]	[-3,845; 1,580]	
Veränderung zu Woche 8/9			
n/N (%)	56/80 (70)	49/69 (71)	LS MD 1,43 [-1,869; 4,731]
MW (SD)	0,74 (7,989)	-2,21 (20,887)	
LS MW (SE)	-0,14 (1,112)	-1,57 (1,245)	
95 %-KI	[-2,342; 2,056]	[-4,034; 0,886]	
Veränderung zu Woche 12			
n/N (%)	42/79 (53)	34/69 (49)	LS MD 1,14 [-2,040; 4,322]
MW (SD)	-1,19 (12,560)	-0,98 (10,613)	
LS MW (SE)	-0,74 (1,069)	-1,88 (1,199)	
95 %-KI	[-2,859; 1,375]	[-4,256; 0,490]	
Veränderung zu Woche 15/16			
n/N (%)	38/77 (49)	21/66 (32)	LS MD 0,85 [-2,315; 4,018]
MW (SD)	-0,22 (8,553)	-6,35 (19,168)	
LS MW (SE)	-1,34 (1,059)	-2,19 (1,197)	
95 %-KI	[-3,437; 0,757]	[-4,562; 0,178]	
Veränderung zu Woche 20/21			
n/N (%)	27/76 (36)	22/62 (35)	LS MD 0,44 [-2,889; 3,764]
MW (SD)	0,00 (8,951)	-5,68 (21,576)	
LS MW (SE)	-2,20 (1,100)	-2,63 (1,270)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-4,373; -0,019]	[-5,142; -0,124]	
Veränderung zu Woche 24			
n/N (%)	24/75 (32)	20/60 (33)	LS MD 0,15 [-3,406; 3,700]
MW (SD)	-3,82 (12,998)	-3,75 (12,818)	
LS MW (SE)	-2,79 (1,166)	-2,94 (1,366)	
95 %-KI	[-5,098; -0,491]	[-5,637; -0,247]	
Veränderung zu Woche 36			
n/N (%)	35/67 (52)	24/55 (44)	LS MD -0,85 [-5,664; 3,970]
MW (SD)	-3,57 (11,305)	-6,25 (18,915)	
LS MW (SE)	-4,85 (1,552)	-4,00 (1,883)	
95 %-KI	[-7,900; -1,795]	[-7,702; -0,299]	
Veränderung zu Woche 48			
n/N (%)	5/61 (8)	3/48 (6)	LS MD -1,84 [-8,317; 4,636]
MW (SD)	-1,67 (9,129)	-16,67 (28,868)	
LS MW (SE)	-6,90 (2,070)	-5,06 (2,544)	
95 %-KI	[-10,969; -2,831]	[-10,059; -0,060]	
<b>Letztes Platin-freies Intervall: ≤ 3 Monate</b>			
Baseline			
n/N (%)	62/83 (75)	60/91 (66)	-
MW (SD)	10,62 (18,243)	13,19 (23,233)	
Absolute Werte zum Studienende			
n/N (%)	3/55 (5)	5/39 (13)	-
MW (SD)	13,89 (24,056)	5,00 (11,180)	
Effekt über Studiendauer			
n	62	60	LS MD -0,64 [-4,271; 2,985] 0,7260
LS MW (SE)	-4,41 (1,246)	-3,76 (1,343)	
95 %-KI	[-6,877; -1,937]	[-6,422; -1,105]	Hedges' g -0,06 [-0,418; 0,292]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	46/82 (56)	42/86 (49)	LS MD 0,42 [-3,597; 4,440]
MW (SD)	-1,09 (12,122)	-1,59 (14,166)	
LS MW (SE)	-2,74 (1,401)	-3,16 (1,479)	
95 %-KI	[-5,504; 0,026]	[-6,077; -0,243]	
Veränderung zu Woche 8/9			
n/N (%)	48/81 (59)	43/80 (54)	LS MD -0,05 [-3,756; 3,648]
MW (SD)	-4,17 (15,084)	-6,01 (18,032)	
LS MW (SE)	-3,48 (1,284)	-3,43 (1,361)	
95 %-KI	[-6,026; -0,941]	[-6,120; -0,739]	
Veränderung zu Woche 12			
n/N (%)	31/78 (40)	24/78 (31)	LS MD -0,39 [-4,002; 3,227]
MW (SD)	-5,11 (18,089)	0,35 (4,584)	
LS MW (SE)	-4,01 (1,247)	-3,62 (1,332)	
95 %-KI	[-6,478; -1,534]	[-6,255; -0,982]	
Veränderung zu Woche 15/16			
n/N (%)	34/76 (45)	12/75 (16)	LS MD -0,72 [-4,366; 2,926]
MW (SD)	-5,39 (12,956)	-7,64 (17,929)	
LS MW (SE)	-4,53 (1,250)	-3,81 (1,352)	
95 %-KI	[-7,006; -2,049]	[-6,482; -1,132]	
Veränderung zu Woche 20/21			
n/N (%)	20/72 (28)	14/67 (21)	LS MD -1,20 [-5,085; 2,693]
MW (SD)	-1,25 (11,870)	-14,29 (29,313)	
LS MW (SE)	-5,27 (1,323)	-4,08 (1,459)	
95 %-KI	[-7,891; -2,654]	[-6,959; -1,194]	
Veränderung zu Woche 24			
n/N (%)	16/72 (22)	12/62 (19)	LS MD -1,53 [-5,709; 2,651]
MW (SD)	-8,33 (19,003)	-7,64 (14,847)	
LS MW (SE)	-5,79 (1,416)	-4,27 (1,580)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-8,592; -2,996]	[-7,382; -1,148]	
Veränderung zu Woche 36			
n/N (%)	27/63 (43)	18/50 (36)	LS MD -2,67 [-8,353; 3,011]
MW (SD)	-8,02 (16,093)	-4,17 (22,002)	
LS MW (SE)	-7,58 (1,913)	-4,91 (2,179)	
95 %-KI	[-11,346; -3,819]	[-9,198; -0,626]	
Veränderung zu Woche 48			
n/N (%)	2/55 (4)	4/39 (10)	LS MD -3,81 [-11,402; 3,776]
MW (SD)	-8,33 (11,785)	-14,58 (23,936)	
LS MW (SE)	-9,37 (2,552)	-5,56 (2,919)	
95 %-KI	[-14,389; -4,354]	[-11,299; 0,181]	
<b>Letztes Platin-freies Intervall: &gt; 3 Monate</b>			
Baseline			
n/N (%)	107/135 (79)	93/116 (80)	-
MW (SD)	9,58 (19,820)	13,17 (20,313)	
Absolute Werte zum Studienende			
n/N (%)	7/85 (8)	1/71 (1)	-
MW (SD)	4,76 (12,599)	0,00 (NA)	
Effekt über Studiendauer			
n	107	93	LS MD 0,62 [-2,382; 3,627] 0,6832
LS MW (SE)	-2,10 (1,017)	-2,72 (1,133)	
95 %-KI	[-4,103; -0,090]	[-4,953; -0,485]	Hedges' g 0,06 [-0,220; 0,336]
Veränderung zu Woche 3/4			
n/N (%)	69/131 (53)	60/114 (53)	LS MD 0,69 [-2,714; 4,090]
MW (SD)	-1,45 (13,853)	-2,08 (16,427)	
LS MW (SE)	-1,16 (1,159)	-1,85 (1,283)	
95 %-KI	[-3,444; 1,117]	[-4,375; 0,672]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	86/129 (67)	77/108 (71)	LS MD 0,66 [-2,443; 3,762]
MW (SD)	-1,26 (11,399)	-2,49 (21,463)	
LS MW (SE)	-1,57 (1,064)	-2,23 (1,160)	
95 %-KI	[-3,665; 0,528]	[-4,513; 0,057]	
Veränderung zu Woche 12			
n/N (%)	59/127 (46)	46/105 (44)	LS MD 0,64 [-2,366; 3,645]
MW (SD)	-0,56 (14,832)	-1,99 (17,140)	
LS MW (SE)	-1,85 (1,027)	-2,49 (1,125)	
95 %-KI	[-3,877; 0,173]	[-4,710; -0,274]	
Veränderung zu Woche 15/16			
n/N (%)	58/123 (47)	39/103 (38)	LS MD 0,62 [-2,392; 3,632]
MW (SD)	-1,15 (12,236)	-2,35 (17,724)	
LS MW (SE)	-2,14 (1,017)	-2,76 (1,138)	
95 %-KI	[-4,142; -0,128]	[-4,998; -0,512]	
Veränderung zu Woche 20/21			
n/N (%)	44/118 (37)	36/98 (37)	LS MD 0,59 [-2,605; 3,788]
MW (SD)	-3,41 (12,099)	-6,25 (20,833)	
LS MW (SE)	-2,54 (1,052)	-3,13 (1,234)	
95 %-KI	[-4,615; -0,466]	[-5,562; -0,701]	
Veränderung zu Woche 24			
n/N (%)	37/112 (33)	25/93 (27)	LS MD 0,57 [-2,862; 4,006]
MW (SD)	-4,50 (11,553)	-0,67 (7,577)	
LS MW (SE)	-2,82 (1,108)	-3,40 (1,347)	
95 %-KI	[-5,007; -0,641]	[-6,045; -0,745]	
Veränderung zu Woche 36			
n/N (%)	52/97 (54)	27/84 (32)	LS MD 0,50 [-4,192; 5,198]
MW (SD)	-2,08 (9,317)	-2,78 (15,156)	
LS MW (SE)	-3,80 (1,444)	-4,30 (1,907)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,632; -0,959]	[-8,044; -0,554]	
Veränderung zu Woche 48			
n/N (%)	6/85 (7)	1/71 (1)	LS MD 0,44 [-5,876; 6,746]
MW (SD)	-1,39 (8,193)	0,00 (NA)	
LS MW (SE)	-4,77 (1,903)	-5,20 (2,595)	
95 %-KI	[-8,505; -1,031]	[-10,297; -0,109]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Pegyliertes liposomales Doxorubicin</b>			
Baseline			
n/N (%)	60/80 (75)	53/76 (70)	-
MW (SD)	10,14 (19,773)	11,01 (18,689)	
Absolute Werte zum Studienende			
n/N (%)	3/51 (6)	3/41 (7)	-
MW (SD)	0,00 (0,000)	0,00 (0,000)	
Effekt über Studiendauer			
n	60	53	LS MD -0,05 [-4,068; 3,971] 0,9810  Hedges' g -0,00 [-0,374; 0,365]
LS MW (SE)	-2,65 (1,365)	-2,60 (1,501)	
95 %-KI	[-5,358; 0,055]	[-5,577; 0,370]	
Veränderung zu Woche 3/4			
n/N (%)	39/76 (51)	37/74 (50)	LS MD -0,06 [-4,425; 4,301]
MW (SD)	-1,28 (15,711)	-2,25 (19,509)	
LS MW (SE)	-1,13 (1,505)	-1,06 (1,618)	
95 %-KI	[-4,100; 1,847]	[-4,260; 2,131]	
Veränderung zu Woche 8/9			
n/N (%)	47/76 (62)	41/66 (62)	LS MD -0,06 [-4,156; 4,044]
MW (SD)	-3,01 (13,947)	-2,64 (18,582)	
LS MW (SE)	-1,78 (1,413)	-1,72 (1,516)	
95 %-KI	[-4,573; 1,021]	[-4,720; 1,280]	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	32/75 (43)	23/64 (36)	LS MD -0,05 [-4,069; 3,965]
MW (SD)	-2,60 (12,600)	-2,54 (15,166)	
LS MW (SE)	-2,23 (1,376)	-2,18 (1,490)	
95 %-KI	[-4,959; 0,497]	[-5,130; 0,772]	
Veränderung zu Woche 15/16			
n/N (%)	33/74 (45)	18/62 (29)	LS MD -0,05 [-4,071; 3,975]
MW (SD)	-2,27 (11,078)	-5,09 (18,109)	
LS MW (SE)	-2,69 (1,365)	-2,64 (1,503)	
95 %-KI	[-5,392; 0,021]	[-5,616; 0,341]	
Veränderung zu Woche 20/21			
n/N (%)	26/72 (36)	18/59 (31)	LS MD -0,04 [-4,225; 4,140]
MW (SD)	-2,88 (12,005)	-4,63 (13,774)	
LS MW (SE)	-3,34 (1,393)	-3,29 (1,590)	
95 %-KI	[-6,096; -0,574]	[-6,437; -0,149]	
Veränderung zu Woche 24			
n/N (%)	21/69 (30)	15/54 (28)	LS MD -0,04 [-4,431; 4,354]
MW (SD)	-7,54 (14,411)	-3,33 (9,344)	
LS MW (SE)	-3,79 (1,443)	-3,75 (1,692)	
95 %-KI	[-6,646; -0,934]	[-7,091; -0,412]	
Veränderung zu Woche 36			
n/N (%)	30/60 (50)	16/48 (33)	LS MD -0,02 [-5,597; 5,548]
MW (SD)	-6,39 (11,091)	-3,65 (10,958)	
LS MW (SE)	-5,35 (1,762)	-5,32 (2,217)	
95 %-KI	[-8,821; -1,877]	[-9,687; -0,962]	
Veränderung zu Woche 48			
n/N (%)	2/51 (4)	2/41 (5)	LS MD -0,01 [-7,190; 7,169]
MW (SD)	-8,33 (11,785)	0,00 (0,000)	
LS MW (SE)	-6,91 (2,227)	-6,90 (2,895)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-11,288; -2,528]	[-12,589; -1,206]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Paclitaxel</b>			
Baseline			
n/N (%)	73/88 (83)	68/82 (83)	-
MW (SD)	11,19 (19,306)	12,75 (22,234)	
Absolute Werte zum Studienende			
n/N (%)	1/56 (2)	1/49 (2)	-
MW (SD)	41,67 (NA)	0,00 (NA)	
Effekt über Studiendauer			
n	73	68	LS MD 1,19 [-2,527; 4,900] 0,5284  Hedges' g 0,11 [-0,224; 0,437]
LS MW (SE)	-3,16 (1,280)	-4,35 (1,373)	
95 %-KI	[-5,698; -0,630]	[-7,066; -1,635]	
Veränderung zu Woche 3/4			
n/N (%)	54/87 (62)	48/81 (59)	LS MD 1,04 [-3,144; 5,231]
MW (SD)	-2,01 (12,842)	-1,56 (13,388)	
LS MW (SE)	-2,38 (1,451)	-3,43 (1,552)	
95 %-KI	[-5,244; 0,479]	[-6,485; -0,368]	
Veränderung zu Woche 8/9			
n/N (%)	60/86 (70)	52/79 (66)	LS MD 1,11 [-2,711; 4,928]
MW (SD)	-2,78 (11,240)	-4,97 (23,758)	
LS MW (SE)	-2,74 (1,327)	-3,85 (1,406)	
95 %-KI	[-5,361; -0,114]	[-6,622; -1,070]	
Veränderung zu Woche 12			
n/N (%)	38/84 (45)	35/77 (45)	LS MD 1,15 [-2,555; 4,864]
MW (SD)	-1,97 (20,082)	0,48 (14,283)	
LS MW (SE)	-2,99 (1,285)	-4,14 (1,366)	
95 %-KI	[-5,529; -0,443]	[-6,841; -1,439]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	43/81 (53)	25/76 (33)	LS MD 1,20 [-2,535; 4,934]
MW (SD)	-3,88 (12,380)	-2,00 (18,832)	
LS MW (SE)	-3,23 (1,284)	-4,43 (1,385)	
95 %-KI	[-5,776; -0,693]	[-7,171; -1,697]	
Veränderung zu Woche 20/21			
n/N (%)	27/77 (35)	25/73 (34)	LS MD 1,26 [-2,730; 5,260]
MW (SD)	-3,40 (13,127)	-9,00 (28,960)	
LS MW (SE)	-3,59 (1,354)	-4,85 (1,506)	
95 %-KI	[-6,264; -0,914]	[-7,826; -1,882]	
Veränderung zu Woche 24			
n/N (%)	21/74 (28)	19/72 (26)	LS MD 1,31 [-3,003; 5,624]
MW (SD)	-3,97 (12,807)	-3,07 (12,793)	
LS MW (SE)	-3,84 (1,446)	-5,15 (1,646)	
95 %-KI	[-6,691; -0,984]	[-8,391; -1,905]	
Veränderung zu Woche 36			
n/N (%)	35/64 (55)	22/63 (35)	LS MD 1,47 [-4,492; 7,425]
MW (SD)	-4,05 (14,201)	-5,30 (19,167)	
LS MW (SE)	-4,69 (1,949)	-6,16 (2,332)	
95 %-KI	[-8,520; -0,858]	[-10,739; -1,572]	
Veränderung zu Woche 48			
n/N (%)	1/56 (2)	1/49 (2)	LS MD 1,62 [-6,411; 9,657]
MW (SD)	-16,67 (NA)	-50,00 (NA)	
LS MW (SE)	-5,54 (2,602)	-7,16 (3,171)	
95 %-KI	[-10,652; -0,429]	[-13,394; -0,934]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Topotecan</b>			
Baseline			
n/N (%)	36/50 (72)	32/49 (65)	-
MW (SD)	7,18 (18,274)	17,71 (23,830)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	6/33 (18)	2/20 (10)	-
MW (SD)	5,56 (13,608)	12,50 (17,678)	
Effekt über Studiendauer			
n	36	32	LS MD -1,83 [-6,761; 3,109] 0,4622  Hedges' g -0,18 [-0,657; 0,297]
LS MW (SE)	-2,62 (1,591)	-0,79 (1,860)	
95 %-KI	[-5,805; 0,573]	[-4,504; 2,923]	
Veränderung zu Woche 3/4			
n/N (%)	22/50 (44)	17/45 (38)	LS MD 2,25 [-3,249; 7,757]
MW (SD)	0,38 (8,324)	-1,96 (11,230)	
LS MW (SE)	-0,11 (1,818)	-2,37 (2,069)	
95 %-KI	[-3,722; 3,497]	[-6,470; 1,737]	
Veränderung zu Woche 8/9			
n/N (%)	27/48 (56)	27/43 (63)	LS MD 0,51 [-4,515; 5,545]
MW (SD)	-0,00 (14,434)	-3,09 (15,530)	
LS MW (SE)	-1,18 (1,657)	-1,69 (1,877)	
95 %-KI	[-4,488; 2,128]	[-5,436; 2,047]	
Veränderung zu Woche 12			
n/N (%)	20/46 (43)	12/42 (29)	LS MD -0,70 [-5,601; 4,196]
MW (SD)	-1,67 (12,853)	-3,47 (12,028)	
LS MW (SE)	-1,93 (1,599)	-1,22 (1,832)	
95 %-KI	[-5,129; 1,275]	[-4,882; 2,433]	
Veränderung zu Woche 15/16			
n/N (%)	16/44 (36)	8/40 (20)	LS MD -1,92 [-6,864; 3,025]
MW (SD)	-0,52 (16,236)	-5,21 (14,731)	
LS MW (SE)	-2,67 (1,593)	-0,75 (1,866)	
95 %-KI	[-5,865; 0,518]	[-4,478; 2,970]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	11/41 (27)	7/33 (21)	LS MD -3,66 [-8,966; 1,649]
MW (SD)	-0,76 (9,468)	-16,67 (22,048)	
LS MW (SE)	-3,74 (1,672)	-0,08 (2,043)	
95 %-KI	[-7,082; -0,400]	[-4,144; 3,980]	
Veränderung zu Woche 24			
n/N (%)	11/41 (27)	3/29 (10)	LS MD -4,88 [-10,616; 0,865]
MW (SD)	-5,30 (16,780)	0,00 (0,000)	
LS MW (SE)	-4,49 (1,783)	0,39 (2,240)	
95 %-KI	[-8,039; -0,937]	[-4,053; 4,828]	
Veränderung zu Woche 36			
n/N (%)	14/36 (39)	7/23 (30)	LS MD -9,05 [-17,009; -1,090]
MW (SD)	0,60 (8,310)	3,57 (26,726)	
LS MW (SE)	-7,05 (2,400)	2,00 (3,186)	
95 %-KI	[-11,790; -2,307]	[-4,286; 8,287]	
Veränderung zu Woche 48			
n/N (%)	5/33 (15)	2/20 (10)	LS MD -13,22 [-23,971; -2,474]
MW (SD)	1,67 (3,727)	-4,17 (5,893)	
LS MW (SE)	-9,61 (3,209)	3,61 (4,331)	
95 %-KI	[-15,939; -3,281]	[-4,927; 12,152]	
<p><i>Analysepopulation: ITT</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023</i></p> <p><i>Modell: Veränderung zu Baseline ~ Behandlung + Baseline-Wert * Zeit in Wochen + Behandlung * Zeit in Wochen + zufällige Effekte durch die Patientin</i></p> <p><i>Die Berechnung des LS-MWs erfolgt durch ein MMRM mit dem oben angegebenen Modell. Basierend hierauf werden KI und p-Wert ermittelt. Hedges' g basiert ebenfalls auf den LS-MW und ist somit auf das Modell angepasst.</i></p> <p><i>Es werden ausschließlich gemeinsame Analysezeitpunkte dargestellt.</i></p> <p><i>Ein LS MD und Hedges' g größer als Null bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

### 3.5 EORTC QLQ-OV28 Körperbild

#### EORTC QLQ-OV28 Körperbild: Subgruppenanalyse

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
<b>EORTC QLQ-OV28 Körperbild</b>			
<b>Alter: &lt; 65 Jahre</b>			
Baseline			
n/N (%)	91/115 (79)	91/119 (76)	-
MW (SD)	35,53 (30,953)	31,68 (29,612)	
Absolute Werte zum Studienende			
n/N (%)	4/73 (5)	4/64 (6)	-
MW (SD)	37,50 (43,833)	33,33 (0,000)	
Effekt über Studiendauer			
n	91	91	LS MD -6,25 [-12,470; -0,038] 0,0486  Hedges' g -0,29 [-0,586; -0,001]
LS MW (SE)	-4,08 (2,185)	2,17 (2,263)	
95 %-KI	[-8,396; 0,229]	[-2,293; 6,634]	
Veränderung zu Woche 3/4			
n/N (%)	57/113 (50)	60/115 (52)	LS MD -6,51 [-13,296; 0,270]
MW (SD)	-7,60 (26,553)	1,67 (24,873)	
LS MW (SE)	-4,72 (2,403)	1,79 (2,461)	
95 %-KI	[-9,458; 0,011]	[-3,057; 6,636]	
Veränderung zu Woche 8/9			
n/N (%)	73/112 (65)	71/108 (66)	LS MD -6,40 [-12,739; -0,060]
MW (SD)	-4,34 (26,647)	3,99 (25,738)	
LS MW (SE)	-4,44 (2,251)	1,96 (2,289)	
95 %-KI	[-8,882; -0,003]	[-2,556; 6,471]	
Veränderung zu Woche 12			
n/N (%)	44/110 (40)	39/105 (37)	
MW (SD)	-4,55 (31,615)	7,69 (23,522)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-4,25 (2,195)	2,07 (2,246)	LS MD -6,32 [-12,526; -0,113]
95 %-KI	[-8,578; 0,088]	[-2,357; 6,506]	
Veränderung zu Woche 15/16			
n/N (%)	53/107 (50)	31/102 (30)	LS MD -6,24 [-12,472; -0,008]
MW (SD)	-3,46 (32,581)	4,30 (31,905)	
LS MW (SE)	-4,05 (2,186)	2,19 (2,272)	
95 %-KI	[-8,365; 0,268]	[-2,291; 6,674]	
Veränderung zu Woche 20/21			
n/N (%)	36/101 (36)	28/96 (29)	LS MD -6,13 [-12,660; 0,409]
MW (SD)	-6,48 (27,968)	-2,38 (32,620)	
LS MW (SE)	-3,77 (2,255)	2,36 (2,424)	
95 %-KI	[-8,215; 0,682]	[-2,417; 7,135]	
Veränderung zu Woche 24			
n/N (%)	25/99 (25)	19/91 (21)	LS MD -6,05 [-12,961; 0,869]
MW (SD)	-8,00 (29,705)	4,39 (21,403)	
LS MW (SE)	-3,57 (2,356)	2,48 (2,599)	
95 %-KI	[-8,213; 1,073]	[-2,639; 7,591]	
Veränderung zu Woche 36			
n/N (%)	41/86 (48)	25/79 (32)	LS MD -5,77 [-14,748; 3,203]
MW (SD)	-7,32 (31,191)	-7,33 (28,900)	
LS MW (SE)	-2,89 (2,952)	2,88 (3,484)	
95 %-KI	[-8,697; 2,908]	[-3,966; 9,722]	
Veränderung zu Woche 48			
n/N (%)	4/73 (5)	3/64 (5)	LS MD -5,50 [-17,201; 6,204]
MW (SD)	-8,33 (28,868)	-16,67 (50,000)	
LS MW (SE)	-2,22 (3,783)	3,28 (4,603)	
95 %-KI	[-9,650; 5,212]	[-5,761; 12,320]	
<b>Alter: ≥ 65 Jahre</b>			
Baseline			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	78/103 (76)	64/88 (73)	-
MW (SD)	26,07 (25,424)	25,00 (26,891)	
Absolute Werte zum Studienende			
n/N (%)	6/67 (9)	2/46 (4)	-
MW (SD)	16,67 (14,907)	0,00 (0,000)	
Effekt über Studiendauer			
n	78	64	LS MD -8,22 [-14,766; -1,670] 0,0143  Hedges' g -0,42 [-0,751; -0,083]
LS MW (SE)	-1,32 (2,182)	6,90 (2,497)	
95 %-KI	[-5,636; 3,000]	[1,965; 11,835]	
Veränderung zu Woche 3/4			
n/N (%)	55/100 (55)	43/85 (51)	LS MD -9,21 [-16,341; -2,087]
MW (SD)	-5,15 (23,542)	7,36 (26,553)	
LS MW (SE)	-2,14 (2,392)	7,07 (2,712)	
95 %-KI	[-6,863; 2,575]	[1,722; 12,417]	
Veränderung zu Woche 8/9			
n/N (%)	64/98 (65)	51/80 (64)	LS MD -8,78 [-15,443; -2,114]
MW (SD)	1,04 (23,547)	4,90 (25,450)	
LS MW (SE)	-1,78 (2,244)	7,00 (2,520)	
95 %-KI	[-6,218; 2,652]	[2,018; 11,973]	
Veränderung zu Woche 12			
n/N (%)	47/95 (49)	32/78 (41)	LS MD -8,47 [-15,004; -1,943]
MW (SD)	-0,35 (22,918)	8,85 (26,769)	
LS MW (SE)	-1,53 (2,191)	6,94 (2,475)	
95 %-KI	[-5,864; 2,805]	[2,053; 11,835]	
Veränderung zu Woche 15/16			
n/N (%)	40/92 (43)	21/76 (28)	
MW (SD)	-2,08 (18,174)	5,56 (23,174)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-1,28 (2,184)	6,89 (2,508)	LS MD -8,17 [-14,733; -1,604]
95 %-KI	[-5,599; 3,045]	[1,936; 11,848]	
Veränderung zu Woche 20/21			
n/N (%)	29/89 (33)	21/69 (30)	LS MD -7,73 [-14,630; -0,836]
MW (SD)	-8,05 (23,830)	11,90 (23,654)	
LS MW (SE)	-0,92 (2,255)	6,82 (2,685)	
95 %-KI	[-5,372; 3,541]	[1,521; 12,115]	
Veränderung zu Woche 24			
n/N (%)	27/85 (32)	18/64 (28)	LS MD -7,43 [-14,736; -0,121]
MW (SD)	-9,88 (19,204)	12,04 (23,435)	
LS MW (SE)	-0,66 (2,355)	6,77 (2,886)	
95 %-KI	[-5,313; 3,988]	[1,079; 12,453]	
Veränderung zu Woche 36			
n/N (%)	40/74 (54)	18/55 (33)	LS MD -6,38 [-15,898; 3,131]
MW (SD)	-1,25 (20,109)	3,70 (21,047)	
LS MW (SE)	0,20 (2,948)	6,59 (3,893)	
95 %-KI	[-5,595; 6,005]	[-1,063; 14,240]	
Veränderung zu Woche 48			
n/N (%)	4/67 (6)	2/46 (4)	LS MD -5,34 [-17,758; 7,081]
MW (SD)	8,33 (9,623)	-8,33 (11,785)	
LS MW (SE)	1,07 (3,772)	6,41 (5,157)	
95 %-KI	[-6,340; 8,485]	[-3,722; 16,544]	
<b>Region: USA</b>			
Baseline			
n/N (%)	47/65 (72)	33/51 (65)	-
MW (SD)	29,08 (28,119)	34,34 (31,716)	
Absolute Werte zum Studienende			
n/N (%)	2/39 (5)	3/27 (11)	-
MW (SD)	8,33 (11,785)	11,11 (19,245)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Effekt über Studiendauer			
n	47	33	LS MD -4,72 [-13,256; 3,811] 0,2738  Hedges' g -0,25 [-0,696; 0,198]
LS MW (SE)	-1,40 (2,718)	3,32 (3,305)	
95 %-KI	[-6,815; 4,017]	[-3,259; 9,907]	
Veränderung zu Woche 3/4			
n/N (%)	31/64 (48)	19/49 (39)	LS MD -4,80 [-14,224; 4,625]
MW (SD)	-3,23 (28,356)	2,63 (24,383)	
LS MW (SE)	-1,13 (3,003)	3,67 (3,686)	
95 %-KI	[-7,079; 4,828]	[-3,629; 10,978]	
Veränderung zu Woche 8/9			
n/N (%)	39/62 (63)	29/46 (63)	LS MD -4,77 [-13,536; 4,006]
MW (SD)	-2,56 (23,113)	2,30 (27,359)	
LS MW (SE)	-1,25 (2,795)	3,52 (3,409)	
95 %-KI	[-6,807; 4,313]	[-3,258; 10,294]	
Veränderung zu Woche 12			
n/N (%)	24/59 (41)	16/45 (36)	LS MD -4,74 [-13,295; 3,813]
MW (SD)	4,86 (21,127)	8,33 (22,771)	
LS MW (SE)	-1,33 (2,725)	3,41 (3,315)	
95 %-KI	[-6,762; 4,097]	[-3,191; 10,009]	
Veränderung zu Woche 15/16			
n/N (%)	20/56 (36)	11/44 (25)	LS MD -4,72 [-13,269; 3,834]
MW (SD)	-1,67 (24,122)	15,15 (27,340)	
LS MW (SE)	-1,42 (2,723)	3,30 (3,313)	
95 %-KI	[-6,844; 4,009]	[-3,297; 9,897]	
Veränderung zu Woche 20/21			
n/N (%)	12/54 (22)	9/40 (22)	
MW (SD)	-9,72 (26,071)	5,56 (26,352)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-1,54 (2,838)	3,14 (3,467)	LS MD -4,68 [-13,599; 4,232]
95 %-KI	[-7,182; 4,104]	[-3,746; 10,034]	
Veränderung zu Woche 24			
n/N (%)	9/53 (17)	6/38 (16)	LS MD -4,66 [-14,067; 4,747]
MW (SD)	-5,56 (30,046)	8,33 (13,944)	
LS MW (SE)	-1,62 (2,993)	3,04 (3,675)	
95 %-KI	[-7,562; 4,312]	[-4,251; 10,321]	
Veränderung zu Woche 36			
n/N (%)	21/43 (49)	10/33 (30)	LS MD -4,58 [-16,765; 7,609]
MW (SD)	-1,59 (28,822)	-8,33 (16,197)	
LS MW (SE)	-1,92 (3,861)	2,66 (4,823)	
95 %-KI	[-9,533; 5,699]	[-6,850; 12,172]	
Veränderung zu Woche 48			
n/N (%)	2/39 (5)	3/27 (11)	LS MD -4,50 [-20,436; 11,443]
MW (SD)	-16,67 (47,140)	-11,11 (9,623)	
LS MW (SE)	-2,21 (5,029)	2,29 (6,345)	
95 %-KI	[-12,114; 7,695]	[-10,209; 14,783]	
<b>Region: Rest der Welt</b>			
Baseline			
n/N (%)	122/153 (80)	122/156 (78)	-
MW (SD)	31,97 (29,191)	27,46 (27,684)	
Absolute Werte zum Studienende			
n/N (%)	8/101 (8)	3/83 (4)	-
MW (SD)	29,17 (31,810)	33,33 (0,000)	
Effekt über Studiendauer			
n	122	122	LS MD -8,14 [-13,508; -2,766] 0,0031  Hedges' g
LS MW (SE)	-3,66 (1,883)	4,48 (1,964)	
95 %-KI	[-7,366; 0,055]	[0,615; 8,349]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
			-0,38 [-0,635; -0,129]
Veränderung zu Woche 3/4			
n/N (%)	81/149 (54)	84/151 (56)	LS MD -9,00 [-14,812; -3,179]
MW (SD)	-7,61 (23,724)	4,37 (26,016)	
LS MW (SE)	-4,40 (2,064)	4,60 (2,113)	
95 %-KI	[-8,457; -0,337]	[0,443; 8,753]	
Veränderung zu Woche 8/9			
n/N (%)	98/148 (66)	93/142 (65)	LS MD -8,62 [-14,073; -3,168]
MW (SD)	-1,53 (26,226)	5,02 (25,034)	
LS MW (SE)	-4,07 (1,939)	4,55 (1,970)	
95 %-KI	[-7,893; -0,254]	[0,668; 8,426]	
Veränderung zu Woche 12			
n/N (%)	67/146 (46)	55/138 (40)	LS MD -8,36 [-13,709; -3,006]
MW (SD)	-4,98 (29,015)	8,18 (25,634)	
LS MW (SE)	-3,85 (1,893)	4,51 (1,941)	
95 %-KI	[-7,577; -0,116]	[0,689; 8,334]	
Veränderung zu Woche 15/16			
n/N (%)	73/143 (51)	41/134 (31)	LS MD -8,10 [-13,480; -2,710]
MW (SD)	-3,20 (28,144)	2,03 (28,430)	
LS MW (SE)	-3,62 (1,884)	4,48 (1,973)	
95 %-KI	[-7,332; 0,093]	[0,591; 8,361]	
Veränderung zu Woche 20/21			
n/N (%)	53/136 (39)	40/125 (32)	LS MD -7,72 [-13,381; -2,060]
MW (SD)	-6,60 (26,218)	3,33 (30,709)	
LS MW (SE)	-3,30 (1,935)	4,43 (2,118)	
95 %-KI	[-7,107; 0,516]	[0,258; 8,592]	
Veränderung zu Woche 24			
n/N (%)	43/131 (33)	31/117 (26)	
MW (SD)	-9,69 (23,635)	8,06 (23,910)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-3,07 (2,013)	4,39 (2,279)	LS MD -7,46 [-13,453; -1,463]
95 %-KI	[-7,031; 0,894]	[-0,092; 8,870]	
Veränderung zu Woche 36			
n/N (%)	60/117 (51)	33/101 (33)	LS MD -6,56 [-14,336; 1,220]
MW (SD)	-5,28 (25,580)	-1,01 (28,547)	
LS MW (SE)	-2,29 (2,486)	4,27 (3,074)	
95 %-KI	[-7,174; 2,592]	[-1,767; 10,302]	
Veränderung zu Woche 48			
n/N (%)	6/101 (6)	2/83 (2)	LS MD -5,66 [-15,778; 4,461]
MW (SD)	5,56 (8,607)	-16,67 (70,711)	
LS MW (SE)	-1,51 (3,157)	4,15 (4,065)	
95 %-KI	[-7,710; 4,684]	[-3,834; 12,124]	
<b>Stadium bei der Diagnose: I-III</b>			
Baseline			
n/N (%)	109/141 (77)	110/144 (76)	-
MW (SD)	30,58 (29,962)	26,21 (27,600)	
Absolute Werte zum Studienende			
n/N (%)	6/91 (7)	4/76 (5)	-
MW (SD)	30,56 (28,707)	16,67 (19,245)	
Effekt über Studiendauer			
n	109	110	LS MD -7,16 [-12,732; -1,580] 0,0121
LS MW (SE)	-1,38 (1,960)	5,78 (2,032)	
95 %-KI	[-5,242; 2,487]	[1,773; 9,783]	Hedges' g -0,34 [-0,608; -0,074]
Veränderung zu Woche 3/4			
n/N (%)	71/137 (52)	74/138 (54)	LS MD -8,36 [-14,428; -2,284]
MW (SD)	-7,75 (25,484)	4,73 (23,002)	
LS MW (SE)	-3,58 (2,152)	4,78 (2,201)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-7,815; 0,656]	[0,446; 9,107]	
Veränderung zu Woche 8/9			
n/N (%)	90/136 (66)	86/129 (67)	LS MD -7,83 [-13,522; -2,142]
MW (SD)	-1,11 (25,940)	6,98 (26,130)	
LS MW (SE)	-2,62 (2,020)	5,21 (2,055)	
95 %-KI	[-6,599; 1,362]	[1,165; 9,262]	
Veränderung zu Woche 12			
n/N (%)	60/133 (45)	48/128 (38)	LS MD -7,47 [-13,038; -1,893]
MW (SD)	-3,61 (29,447)	11,11 (26,705)	
LS MW (SE)	-1,95 (1,971)	5,52 (2,019)	
95 %-KI	[-5,832; 1,941]	[1,542; 9,498]	
Veränderung zu Woche 15/16			
n/N (%)	64/130 (49)	33/125 (26)	LS MD -7,10 [-12,686; -1,511]
MW (SD)	0,52 (29,242)	9,60 (24,306)	
LS MW (SE)	-1,27 (1,961)	5,83 (2,040)	
95 %-KI	[-5,139; 2,594]	[1,808; 9,844]	
Veränderung zu Woche 20/21			
n/N (%)	46/123 (37)	32/116 (28)	LS MD -6,57 [-12,410; -0,740]
MW (SD)	-5,80 (25,390)	10,94 (26,643)	
LS MW (SE)	-0,31 (2,014)	6,26 (2,165)	
95 %-KI	[-4,281; 3,658]	[2,001; 10,525]	
Veränderung zu Woche 24			
n/N (%)	33/121 (27)	26/109 (24)	LS MD -6,21 [-12,360; -0,056]
MW (SD)	-4,55 (25,095)	8,33 (24,152)	
LS MW (SE)	0,36 (2,097)	6,57 (2,311)	
95 %-KI	[-3,768; 4,490]	[2,023; 11,115]	
Veränderung zu Woche 36			
n/N (%)	53/105 (50)	31/92 (34)	
MW (SD)	-0,63 (27,144)	-0,54 (19,946)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	2,67 (2,595)	7,62 (3,060)	LS MD -4,95 [-12,847; 2,946]
95 %-KI	[-2,432; 7,768]	[1,610; 13,628]	
Veränderung zu Woche 48			
n/N (%)	5/91 (5)	4/76 (5)	LS MD -3,69 [-13,924; 6,537]
MW (SD)	10,00 (9,129)	-0,00 (23,570)	
LS MW (SE)	4,98 (3,303)	8,67 (4,017)	
95 %-KI	[-1,509; 11,459]	[0,782; 16,555]	
<b>Stadium bei der Diagnose: IV</b>			
Baseline			
n/N (%)	56/72 (78)	43/60 (72)	-
MW (SD)	32,74 (27,333)	36,43 (30,485)	
Absolute Werte zum Studienende			
n/N (%)	4/46 (9)	2/33 (6)	-
MW (SD)	16,67 (33,333)	33,33 (0,000)	
Effekt über Studiendauer			
n	56	43	LS MD -8,01 [-16,204; 0,194] 0,0556  Hedges' g -0,39 [-0,793; 0,010]
LS MW (SE)	-7,34 (2,686)	0,67 (3,136)	
95 %-KI	[-12,676; -2,003]	[-5,557; 6,888]	
Veränderung zu Woche 3/4			
n/N (%)	37/71 (52)	27/59 (46)	LS MD -6,06 [-14,926; 2,803]
MW (SD)	-6,31 (24,009)	-1,23 (26,524)	
LS MW (SE)	-4,69 (2,913)	1,38 (3,396)	
95 %-KI	[-10,452; 1,079]	[-5,340; 8,091]	
Veränderung zu Woche 8/9			
n/N (%)	43/69 (62)	34/56 (61)	LS MD -6,92 [-15,228; 1,397]
MW (SD)	-5,04 (23,720)	-1,96 (23,842)	
LS MW (SE)	-5,85 (2,751)	1,06 (3,158)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-11,309; -0,395]	[-5,198; 7,325]	
Veränderung zu Woche 12			
n/N (%)	27/67 (40)	22/52 (42)	LS MD -7,51 [-15,678; 0,651]
MW (SD)	-0,62 (22,872)	2,27 (20,116)	
LS MW (SE)	-6,67 (2,694)	0,85 (3,104)	
95 %-KI	[-12,019; -1,317]	[-5,316; 7,007]	
Veränderung zu Woche 15/16			
n/N (%)	27/64 (42)	17/50 (34)	LS MD -8,11 [-16,336; 0,114]
MW (SD)	-9,88 (20,806)	-3,92 (35,614)	
LS MW (SE)	-7,48 (2,689)	0,63 (3,151)	
95 %-KI	[-12,826; -2,143]	[-5,625; 6,879]	
Veränderung zu Woche 20/21			
n/N (%)	17/62 (27)	16/46 (35)	LS MD -8,97 [-17,627; -0,304]
MW (SD)	-8,82 (27,712)	-10,42 (32,131)	
LS MW (SE)	-8,65 (2,770)	0,32 (3,382)	
95 %-KI	[-14,146; -3,155]	[-6,378; 7,009]	
Veränderung zu Woche 24			
n/N (%)	18/59 (31)	10/44 (23)	LS MD -9,56 [-18,750; -0,376]
MW (SD)	-15,74 (22,486)	8,33 (19,642)	
LS MW (SE)	-9,47 (2,884)	0,10 (3,640)	
95 %-KI	[-15,180; -3,753]	[-7,094; 7,288]	
Veränderung zu Woche 36			
n/N (%)	27/52 (52)	11/41 (27)	LS MD -11,61 [-23,587; 0,361]
MW (SD)	-11,73 (23,937)	-9,09 (40,390)	
LS MW (SE)	-12,26 (3,556)	-0,65 (4,923)	
95 %-KI	[-19,275; -5,255]	[-10,342; 9,039]	
Veränderung zu Woche 48			
n/N (%)	3/46 (7)	1/33 (3)	
MW (SD)	-16,67 (28,868)	-66,67 (NA)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-15,06 (4,499)	-1,40 (6,526)	LS MD -13,66 [-29,288; 1,961]
95 %-KI	[-23,917; -6,209]	[-14,238; 11,439]	
<b>BRCA Status: Positiv</b>			
Baseline			
n/N (%)	24/27 (89)	23/35 (66)	-
MW (SD)	35,42 (31,589)	28,99 (27,624)	
Absolute Werte zum Studienende			
n/N (%)	1/19 (5)	0/15 (0)	-
MW (SD)	66,67 (NA)	NA (NA)	
Effekt über Studiendauer			
n	24	23	LS MD -6,53 [-19,924; 6,866] 0,3313  Hedges' g -0,28 [-0,858; 0,292]
LS MW (SE)	-1,83 (4,500)	4,70 (4,873)	
95 %-KI	[-10,925; 7,263]	[-5,101; 14,497]	
Veränderung zu Woche 3/4			
n/N (%)	16/27 (59)	17/35 (49)	LS MD -5,64 [-20,000; 8,728]
MW (SD)	-8,33 (33,884)	4,90 (24,836)	
LS MW (SE)	-1,97 (4,961)	3,67 (5,187)	
95 %-KI	[-11,898; 7,957]	[-6,697; 14,027]	
Veränderung zu Woche 8/9			
n/N (%)	21/26 (81)	20/30 (67)	LS MD -6,07 [-19,487; 7,347]
MW (SD)	-5,56 (34,694)	0,83 (20,573)	
LS MW (SE)	-1,90 (4,633)	4,17 (4,776)	
95 %-KI	[-11,231; 7,426]	[-5,444; 13,779]	
Veränderung zu Woche 12			
n/N (%)	13/26 (50)	11/30 (37)	LS MD -6,37 [-19,662; 6,913]
MW (SD)	5,13 (24,893)	7,58 (25,126)	
LS MW (SE)	-1,86 (4,518)	4,52 (4,778)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-10,981; 7,270]	[-5,103; 14,142]	
Veränderung zu Woche 15/16			
n/N (%)	12/26 (46)	7/29 (24)	LS MD -6,68 [-20,287; 6,930]
MW (SD)	0,00 (42,640)	-2,38 (29,547)	
LS MW (SE)	-1,81 (4,508)	4,87 (5,022)	
95 %-KI	[-10,918; 7,303]	[-5,204; 14,946]	
Veränderung zu Woche 20/21			
n/N (%)	10/25 (40)	4/25 (16)	LS MD -7,11 [-21,910; 7,683]
MW (SD)	0,00 (22,222)	-8,33 (28,868)	
LS MW (SE)	-1,74 (4,673)	5,37 (5,723)	
95 %-KI	[-11,152; 7,672]	[-6,022; 16,769]	
Veränderung zu Woche 24			
n/N (%)	7/25 (28)	4/24 (17)	LS MD -7,42 [-23,481; 8,646]
MW (SD)	-2,38 (26,227)	-4,17 (20,972)	
LS MW (SE)	-1,69 (4,905)	5,73 (6,396)	
95 %-KI	[-11,530; 8,146]	[-6,962; 18,413]	
Veränderung zu Woche 36			
n/N (%)	10/21 (48)	5/20 (25)	LS MD -8,46 [-30,638; 13,717]
MW (SD)	-5,00 (26,117)	3,33 (13,944)	
LS MW (SE)	-1,53 (6,236)	6,93 (9,320)	
95 %-KI	[-13,897; 10,839]	[-11,483; 25,346]	
Veränderung zu Woche 48			
n/N (%)	1/19 (5)	0/15 (0)	LS MD -9,50 [-39,171; 20,163]
MW (SD)	0,00 (NA)	NA (NA)	
LS MW (SE)	-1,37 (8,057)	8,14 (12,676)	
95 %-KI	[-17,292; 14,559]	[-16,910; 33,185]	
<b>BRCA Status: Negativ/Unbekannt</b>			
Baseline			
n/N (%)	145/191 (76)	132/172 (77)	-

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	30,46 (28,419)	28,91 (28,894)	
Absolute Werte zum Studienende			
n/N (%)	9/121 (7)	6/95 (6)	-
MW (SD)	20,37 (27,358)	22,22 (17,213)	
Effekt über Studiendauer			
n	145	132	LS MD -7,31 [-12,126; -2,494] 0,0031  Hedges' g -0,36 [-0,597; -0,121]
LS MW (SE)	-3,19 (1,660)	4,12 (1,796)	
95 %-KI	[-6,457; 0,080]	[0,586; 7,657]	
Veränderung zu Woche 3/4			
n/N (%)	96/186 (52)	86/165 (52)	LS MD -8,18 [-13,434; -2,919]
MW (SD)	-6,08 (23,461)	3,88 (25,905)	
LS MW (SE)	-3,76 (1,821)	4,42 (1,957)	
95 %-KI	[-7,339; -0,176]	[0,571; 8,266]	
Veränderung zu Woche 8/9			
n/N (%)	116/184 (63)	102/158 (65)	LS MD -7,80 [-12,721; -2,884]
MW (SD)	-1,15 (23,336)	5,07 (26,409)	
LS MW (SE)	-3,51 (1,709)	4,29 (1,823)	
95 %-KI	[-6,875; -0,149]	[0,703; 7,878]	
Veränderung zu Woche 12			
n/N (%)	78/179 (44)	60/153 (39)	LS MD -7,54 [-12,353; -2,728]
MW (SD)	-3,63 (27,739)	8,33 (25,024)	
LS MW (SE)	-3,34 (1,668)	4,20 (1,786)	
95 %-KI	[-6,624; -0,056]	[0,684; 7,717]	
Veränderung zu Woche 15/16			
n/N (%)	81/173 (47)	45/149 (30)	LS MD -7,28 [-12,103; -2,455]
MW (SD)	-3,29 (24,498)	5,93 (28,461)	
LS MW (SE)	-3,17 (1,661)	4,11 (1,801)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,438; 0,102]	[0,567; 7,655]	
Veränderung zu Woche 20/21			
n/N (%)	55/165 (33)	45/140 (32)	LS MD -6,91 [-11,945; -1,865]
MW (SD)	-8,48 (26,619)	4,81 (29,861)	
LS MW (SE)	-2,92 (1,710)	3,98 (1,906)	
95 %-KI	[-6,288; 0,443]	[0,234; 7,732]	
Veränderung zu Woche 24			
n/N (%)	45/159 (28)	33/131 (25)	LS MD -6,64 [-11,961; -1,326]
MW (SD)	-10,00 (24,464)	9,60 (22,450)	
LS MW (SE)	-2,75 (1,783)	3,89 (2,032)	
95 %-KI	[-6,257; 0,756]	[-0,101; 7,887]	
Veränderung zu Woche 36			
n/N (%)	71/139 (51)	38/114 (33)	LS MD -5,75 [-12,592; 1,100]
MW (SD)	-4,23 (26,535)	-3,51 (27,443)	
LS MW (SE)	-2,16 (2,219)	3,59 (2,687)	
95 %-KI	[-6,518; 2,197]	[-1,690; 8,860]	
Veränderung zu Woche 48			
n/N (%)	7/121 (6)	5/95 (5)	LS MD -4,85 [-13,738; 4,040]
MW (SD)	0,00 (23,570)	-13,33 (36,132)	
LS MW (SE)	-1,57 (2,832)	3,28 (3,531)	
95 %-KI	[-7,129; 3,986]	[-3,651; 10,206]	
<b>Baseline ECOG PS: 0</b>			
Baseline			
n/N (%)	99/128 (77)	94/113 (83)	-
MW (SD)	27,95 (27,749)	28,01 (27,130)	
Absolute Werte zum Studienende			
n/N (%)	7/87 (8)	3/72 (4)	-
MW (SD)	28,57 (34,311)	22,22 (19,245)	
Effekt über Studiendauer			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n	99	94	LS MD -3,09 [-8,869; 2,688] 0,2927  Hedges' g -0,15 [-0,434; 0,131]
LS MW (SE)	-0,34 (2,010)	2,75 (2,131)	
95 %-KI	[-4,311; 3,624]	[-1,456; 6,950]	
Veränderung zu Woche 3/4			
n/N (%)	67/127 (53)	61/111 (55)	LS MD -5,07 [-11,397; 1,261]
MW (SD)	-3,98 (22,490)	3,55 (21,967)	
LS MW (SE)	-1,20 (2,208)	3,87 (2,338)	
95 %-KI	[-5,546; 3,152]	[-0,731; 8,473]	
Veränderung zu Woche 8/9			
n/N (%)	81/126 (64)	73/108 (68)	LS MD -4,22 [-10,131; 1,697]
MW (SD)	-0,21 (25,207)	2,28 (27,543)	
LS MW (SE)	-0,83 (2,073)	3,39 (2,170)	
95 %-KI	[-4,916; 3,257]	[-0,890; 7,665]	
Veränderung zu Woche 12			
n/N (%)	49/122 (40)	45/108 (42)	LS MD -3,62 [-9,402; 2,159]
MW (SD)	3,74 (28,921)	8,15 (22,925)	
LS MW (SE)	-0,57 (2,022)	3,05 (2,122)	
95 %-KI	[-4,562; 3,417]	[-1,136; 7,233]	
Veränderung zu Woche 15/16			
n/N (%)	55/120 (46)	32/105 (30)	LS MD -3,03 [-8,812; 2,760]
MW (SD)	0,61 (29,739)	4,17 (31,679)	
LS MW (SE)	-0,32 (2,011)	2,71 (2,136)	
95 %-KI	[-4,284; 3,653]	[-1,502; 6,922]	
Veränderung zu Woche 20/21			
n/N (%)	39/117 (33)	30/101 (30)	LS MD -2,17 [-8,208; 3,859]
MW (SD)	-1,71 (24,719)	5,00 (33,088)	
LS MW (SE)	0,05 (2,065)	2,23 (2,260)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-4,022; 4,125]	[-2,226; 6,679]	
Veränderung zu Woche 24			
n/N (%)	27/112 (24)	21/96 (22)	LS MD -1,58 [-7,937; 4,780]
MW (SD)	-6,17 (24,085)	3,97 (21,019)	
LS MW (SE)	0,31 (2,149)	1,89 (2,411)	
95 %-KI	[-3,927; 4,545]	[-2,858; 6,633]	
Veränderung zu Woche 36			
n/N (%)	51/99 (52)	31/87 (36)	LS MD 0,46 [-7,709; 8,637]
MW (SD)	-1,96 (27,213)	-4,84 (27,953)	
LS MW (SE)	1,19 (2,660)	0,73 (3,202)	
95 %-KI	[-4,039; 6,419]	[-5,563; 7,016]	
Veränderung zu Woche 48			
n/N (%)	5/87 (6)	3/72 (4)	LS MD 2,51 [-8,108; 13,121]
MW (SD)	-3,33 (27,386)	-33,33 (28,868)	
LS MW (SE)	2,07 (3,385)	-0,43 (4,221)	
95 %-KI	[-4,576; 8,719]	[-8,723; 7,853]	
<b>Baseline ECOG PS: 1</b>			
Baseline			
n/N (%)	70/90 (78)	60/91 (66)	-
MW (SD)	35,71 (29,934)	29,72 (30,853)	
Absolute Werte zum Studienende			
n/N (%)	3/53 (6)	3/37 (8)	-
MW (SD)	16,67 (16,667)	22,22 (19,245)	
Effekt über Studiendauer			
n	70	60	LS MD -13,76 [-21,032; -6,497] 0,0003
LS MW (SE)	-6,67 (2,429)	7,10 (2,740)	
95 %-KI	[-11,478; -1,855]	[1,679; 12,517]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	45/86 (52)	41/87 (47)	LS MD -11,28 [-19,133; -3,421]
MW (SD)	-10,00 (28,293)	4,88 (30,787)	
LS MW (SE)	-6,75 (2,674)	4,53 (2,938)	
95 %-KI	[-12,026; -1,467]	[-1,267; 10,327]	
Veränderung zu Woche 8/9			
n/N (%)	56/84 (67)	48/78 (62)	LS MD -12,40 [-19,746; -5,051]
MW (SD)	-4,17 (25,475)	7,29 (22,256)	
LS MW (SE)	-6,71 (2,499)	5,69 (2,736)	
95 %-KI	[-11,653; -1,768]	[0,279; 11,097]	
Veränderung zu Woche 12			
n/N (%)	42/83 (51)	25/74 (34)	LS MD -13,18 [-20,410; -5,959]
MW (SD)	-9,52 (23,896)	8,67 (28,916)	
LS MW (SE)	-6,69 (2,438)	6,50 (2,703)	
95 %-KI	[-11,513; -1,858]	[1,151; 11,847]	
Veränderung zu Woche 15/16			
n/N (%)	38/79 (48)	20/72 (28)	LS MD -13,97 [-21,278; -6,661]
MW (SD)	-7,89 (22,507)	5,83 (23,116)	
LS MW (SE)	-6,66 (2,433)	7,31 (2,766)	
95 %-KI	[-11,479; -1,840]	[1,842; 12,778]	
Veränderung zu Woche 20/21			
n/N (%)	26/73 (36)	18/63 (29)	LS MD -15,09 [-22,857; -7,327]
MW (SD)	-15,38 (26,214)	2,78 (24,421)	
LS MW (SE)	-6,62 (2,524)	8,47 (3,005)	
95 %-KI	[-11,617; -1,630]	[2,539; 14,398]	
Veränderung zu Woche 24			
n/N (%)	25/72 (35)	15/58 (26)	LS MD -15,88 [-24,171; -7,584]
MW (SD)	-12,00 (25,240)	14,44 (24,289)	
LS MW (SE)	-6,60 (2,650)	9,28 (3,259)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-11,833; -1,363]	[2,857; 15,701]	
Veränderung zu Woche 36			
n/N (%)	30/61 (49)	12/46 (26)	LS MD -18,57 [-29,571; -7,571]
MW (SD)	-8,33 (24,662)	2,78 (21,122)	
LS MW (SE)	-6,51 (3,372)	12,06 (4,472)	
95 %-KI	[-13,146; 0,124]	[3,267; 20,852]	
Veränderung zu Woche 48			
n/N (%)	3/53 (6)	2/37 (5)	LS MD -21,26 [-35,726; -6,801]
MW (SD)	5,56 (9,623)	16,67 (23,570)	
LS MW (SE)	-6,42 (4,356)	14,84 (5,954)	
95 %-KI	[-14,986; 2,139]	[3,138; 26,542]	
<b>Anzahl vorheriger Therapielinien: 1</b>			
Baseline			
n/N (%)	23/31 (74)	21/29 (72)	-
MW (SD)	26,81 (27,404)	22,22 (19,954)	
Absolute Werte zum Studienende			
n/N (%)	1/22 (5)	0/14 (0)	-
MW (SD)	33,33 (NA)	NA (NA)	
Effekt über Studiendauer			
n	23	21	LS MD 1,15 [-10,232; 12,522] 0,8398  Hedges' g 0,06 [-0,531; 0,652]
LS MW (SE)	7,38 (3,842)	6,23 (4,124)	
95 %-KI	[-0,400; 15,157]	[-2,089; 14,555]	
Veränderung zu Woche 3/4			
n/N (%)	15/31 (48)	13/29 (45)	LS MD 3,78 [-8,823; 16,373]
MW (SD)	3,33 (19,107)	-2,56 (26,217)	
LS MW (SE)	8,38 (4,293)	4,60 (4,630)	
95 %-KI	[-0,213; 16,972]	[-4,638; 13,847]	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	19/31 (61)	16/26 (62)	LS MD 2,65 [-9,038; 14,346]
MW (SD)	16,67 (20,031)	11,46 (26,330)	
LS MW (SE)	7,95 (4,002)	5,30 (4,220)	
95 %-KI	[-0,108; 16,013]	[-3,188; 13,786]	
Veränderung zu Woche 12			
n/N (%)	14/31 (45)	12/24 (50)	LS MD 1,87 [-9,524; 13,262]
MW (SD)	5,95 (28,947)	8,33 (19,462)	
LS MW (SE)	7,65 (3,883)	5,78 (4,100)	
95 %-KI	[-0,195; 15,503]	[-2,488; 14,058]	
Veränderung zu Woche 15/16			
n/N (%)	15/31 (48)	11/22 (50)	LS MD 1,08 [-10,303; 12,471]
MW (SD)	6,67 (20,702)	3,03 (17,979)	
LS MW (SE)	7,36 (3,842)	6,27 (4,132)	
95 %-KI	[-0,423; 15,133]	[-2,065; 14,607]	
Veränderung zu Woche 20/21			
n/N (%)	11/30 (37)	9/22 (41)	LS MD -0,04 [-11,920; 11,846]
MW (SD)	-3,03 (22,134)	7,41 (16,897)	
LS MW (SE)	6,93 (3,924)	6,97 (4,433)	
95 %-KI	[-0,996; 14,852]	[-1,927; 15,858]	
Veränderung zu Woche 24			
n/N (%)	8/30 (27)	10/20 (50)	LS MD -0,82 [-13,381; 11,736]
MW (SD)	-10,42 (12,400)	1,67 (14,593)	
LS MW (SE)	6,63 (4,074)	7,45 (4,795)	
95 %-KI	[-1,565; 14,824]	[-2,119; 17,023]	
Veränderung zu Woche 36			
n/N (%)	14/26 (54)	4/18 (22)	LS MD -3,51 [-19,929; 12,902]
MW (SD)	10,71 (18,030)	4,17 (34,359)	
LS MW (SE)	5,61 (5,043)	9,12 (6,638)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-4,408; 15,619]	[-4,010; 22,247]	
Veränderung zu Woche 48			
n/N (%)	0/22 (0)	0/14 (0)	LS MD -6,20 [-27,835; 15,426]
MW (SD)	NA (NA)	NA (NA)	
LS MW (SE)	4,58 (6,450)	10,79 (8,945)	
95 %-KI	[-8,165; 17,326]	[-6,879; 28,449]	
<b>Anzahl vorheriger Therapielinien: 2</b>			
Baseline			
n/N (%)	73/89 (82)	65/83 (78)	-
MW (SD)	31,74 (25,785)	27,95 (27,181)	
Absolute Werte zum Studienende			
n/N (%)	4/59 (7)	2/50 (4)	-
MW (SD)	41,67 (39,675)	16,67 (23,570)	
Effekt über Studiendauer			
n	73	65	LS MD -5,50 [-12,559; 1,556] 0,1255  Hedges' g -0,26 [-0,599; 0,073]
LS MW (SE)	-2,89 (2,375)	2,61 (2,647)	
95 %-KI	[-7,590; 1,814]	[-2,619; 7,846]	
Veränderung zu Woche 3/4			
n/N (%)	49/86 (57)	44/80 (55)	LS MD -7,62 [-15,296; 0,063]
MW (SD)	-1,36 (16,610)	7,58 (24,499)	
LS MW (SE)	-3,06 (2,616)	4,56 (2,874)	
95 %-KI	[-8,219; 2,103]	[-1,109; 10,226]	
Veränderung zu Woche 8/9			
n/N (%)	59/85 (69)	52/77 (68)	LS MD -6,67 [-13,820; 0,476]
MW (SD)	-5,37 (22,412)	1,60 (25,832)	
LS MW (SE)	-2,98 (2,447)	3,69 (2,654)	
95 %-KI	[-7,819; 1,855]	[-1,553; 8,933]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	37/83 (45)	31/75 (41)	LS MD -6,01 [-13,026; 1,005]
MW (SD)	-4,50 (23,124)	11,83 (24,417)	
LS MW (SE)	-2,93 (2,386)	3,08 (2,612)	
95 %-KI	[-7,651; 1,794]	[-2,082; 8,246]	
Veränderung zu Woche 15/16			
n/N (%)	39/80 (49)	18/74 (24)	LS MD -5,35 [-12,444; 1,745]
MW (SD)	-5,13 (30,144)	5,56 (25,565)	
LS MW (SE)	-2,88 (2,378)	2,47 (2,669)	
95 %-KI	[-7,583; 1,832]	[-2,800; 7,748]	
Veränderung zu Woche 20/21			
n/N (%)	31/78 (40)	20/68 (29)	LS MD -4,40 [-11,961; 3,152]
MW (SD)	-5,38 (28,345)	6,67 (25,592)	
LS MW (SE)	-2,80 (2,458)	1,61 (2,909)	
95 %-KI	[-7,660; 2,060]	[-4,132; 7,342]	
Veränderung zu Woche 24			
n/N (%)	25/74 (34)	13/65 (20)	LS MD -3,74 [-11,837; 4,350]
MW (SD)	-6,00 (24,944)	14,10 (25,318)	
LS MW (SE)	-2,75 (2,572)	1,00 (3,167)	
95 %-KI	[-7,826; 2,333]	[-5,240; 7,235]	
Veränderung zu Woche 36			
n/N (%)	34/65 (52)	17/58 (29)	LS MD -1,48 [-12,315; 9,362]
MW (SD)	-7,35 (25,356)	-6,86 (22,094)	
LS MW (SE)	-2,56 (3,242)	-1,09 (4,401)	
95 %-KI	[-8,944; 3,816]	[-9,737; 7,562]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	1/50 (2)	LS MD 0,79 [-13,540; 15,122]
MW (SD)	8,33 (9,623)	0,00 (NA)	
LS MW (SE)	-2,38 (4,169)	-3,17 (5,902)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-10,576; 5,813]	[-14,770; 8,426]	
<b>Anzahl vorheriger Therapielinien: 3</b>			
Baseline			
n/N (%)	73/98 (74)	69/95 (73)	-
MW (SD)	31,96 (32,245)	31,88 (31,924)	
Absolute Werte zum Studienende			
n/N (%)	5/59 (8)	4/46 (9)	-
MW (SD)	10,00 (14,907)	25,00 (16,667)	
Effekt über Studiendauer			
n	73	69	LS MD -11,43 [-18,384; -4,479] 0,0014  Hedges' g -0,54 [-0,878; -0,208]
LS MW (SE)	-6,52 (2,417)	4,91 (2,555)	
95 %-KI	[-11,299; -1,738]	[-0,138; 9,964]	
Veränderung zu Woche 3/4			
n/N (%)	48/96 (50)	46/91 (51)	LS MD -12,29 [-19,814; -4,764]
MW (SD)	-14,58 (31,062)	2,54 (26,520)	
LS MW (SE)	-7,98 (2,635)	4,31 (2,760)	
95 %-KI	[-13,175; -2,776]	[-1,130; 9,758]	
Veränderung zu Woche 8/9			
n/N (%)	59/94 (63)	54/85 (64)	LS MD -11,92 [-18,996; -4,835]
MW (SD)	-4,24 (27,262)	4,94 (25,001)	
LS MW (SE)	-7,34 (2,478)	4,57 (2,591)	
95 %-KI	[-12,238; -2,444]	[-0,543; 9,692]	
Veränderung zu Woche 12			
n/N (%)	40/91 (44)	28/84 (33)	LS MD -11,65 [-18,600; -4,709]
MW (SD)	-3,33 (30,476)	4,17 (27,452)	
LS MW (SE)	-6,90 (2,424)	4,76 (2,544)	
95 %-KI	[-11,691; -2,103]	[-0,272; 9,787]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	39/88 (44)	23/82 (28)	LS MD -11,39 [-18,358; -4,427]
MW (SD)	-4,27 (26,134)	5,07 (34,973)	
LS MW (SE)	-6,45 (2,419)	4,94 (2,562)	
95 %-KI	[-11,238; -1,667]	[-0,124; 10,004]	
Veränderung zu Woche 20/21			
n/N (%)	23/82 (28)	20/75 (27)	LS MD -11,02 [-18,277; -3,762]
MW (SD)	-11,59 (24,840)	-0,83 (37,648)	
LS MW (SE)	-5,82 (2,499)	5,20 (2,695)	
95 %-KI	[-10,758; -0,879]	[-0,119; 10,521]	
Veränderung zu Woche 24			
n/N (%)	19/80 (24)	14/70 (20)	LS MD -10,76 [-18,389; -3,127]
MW (SD)	-12,28 (28,242)	7,14 (24,209)	
LS MW (SE)	-5,37 (2,611)	5,38 (2,854)	
95 %-KI	[-10,529; -0,219]	[-0,245; 11,012]	
Veränderung zu Woche 36			
n/N (%)	33/69 (48)	22/58 (38)	LS MD -9,86 [-19,561; -0,162]
MW (SD)	-7,58 (28,593)	-0,76 (28,395)	
LS MW (SE)	-3,85 (3,262)	6,01 (3,698)	
95 %-KI	[-10,269; 2,566]	[-1,263; 13,282]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	4/46 (9)	LS MD -8,96 [-21,457; 3,527]
MW (SD)	-8,33 (28,868)	-16,67 (40,825)	
LS MW (SE)	-2,33 (4,164)	6,64 (4,802)	
95 %-KI	[-10,513; 5,855]	[-2,801; 16,073]	
<b>Vorherige Verabreichung von Bevacizumab: Ja</b>			
Baseline			
n/N (%)	98/134 (73)	97/132 (73)	-
MW (SD)	30,27 (29,539)	29,73 (29,485)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	3/79 (4)	3/62 (5)	-
MW (SD)	38,89 (38,490)	22,22 (19,245)	
Effekt über Studiendauer			
n	98	97	LS MD -7,86 [-13,867; -1,858] 0,0105  Hedges' g -0,37 [-0,652; -0,086]
LS MW (SE)	-3,85 (2,099)	4,01 (2,204)	
95 %-KI	[-7,992; 0,292]	[-0,332; 8,357]	
Veränderung zu Woche 3/4			
n/N (%)	60/130 (46)	65/127 (51)	LS MD -8,34 [-14,885; -1,800]
MW (SD)	-9,17 (23,655)	4,87 (24,602)	
LS MW (SE)	-4,79 (2,310)	3,55 (2,387)	
95 %-KI	[-9,342; -0,242]	[-1,147; 8,249]	
Veränderung zu Woche 8/9			
n/N (%)	79/130 (61)	73/119 (61)	LS MD -8,12 [-14,209; -2,035]
MW (SD)	-1,90 (26,147)	3,20 (27,026)	
LS MW (SE)	-4,36 (2,160)	3,76 (2,206)	
95 %-KI	[-8,618; -0,101]	[-0,586; 8,111]	
Veränderung zu Woche 12			
n/N (%)	50/126 (40)	38/114 (33)	LS MD -7,97 [-13,943; -1,992]
MW (SD)	-2,67 (27,430)	6,58 (27,547)	
LS MW (SE)	-4,06 (2,107)	3,91 (2,176)	
95 %-KI	[-8,215; 0,101]	[-0,379; 8,202]	
Veränderung zu Woche 15/16			
n/N (%)	55/122 (45)	31/112 (28)	LS MD -7,81 [-13,860; -1,767]
MW (SD)	-4,85 (30,711)	9,68 (26,448)	
LS MW (SE)	-3,75 (2,103)	4,06 (2,230)	
95 %-KI	[-7,904; 0,396]	[-0,336; 8,455]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	37/114 (32)	28/103 (27)	LS MD -7,59 [-14,041; -1,145]
MW (SD)	-7,66 (23,437)	3,57 (30,884)	
LS MW (SE)	-3,32 (2,179)	4,27 (2,440)	
95 %-KI	[-7,619; 0,975]	[-0,531; 9,075]	
Veränderung zu Woche 24			
n/N (%)	29/109 (27)	17/95 (18)	LS MD -7,44 [-14,351; -0,526]
MW (SD)	-6,90 (26,170)	6,86 (25,725)	
LS MW (SE)	-3,02 (2,286)	4,42 (2,663)	
95 %-KI	[-7,522; 1,485]	[-0,817; 9,657]	
Veränderung zu Woche 36			
n/N (%)	44/93 (47)	20/79 (25)	LS MD -6,91 [-16,183; 2,362]
MW (SD)	-6,06 (26,190)	1,67 (20,160)	
LS MW (SE)	-1,98 (2,901)	4,93 (3,714)	
95 %-KI	[-7,681; 3,719]	[-2,365; 12,223]	
Veränderung zu Woche 48			
n/N (%)	3/79 (4)	2/62 (3)	LS MD -6,38 [-18,647; 5,884]
MW (SD)	16,67 (0,000)	-8,33 (11,785)	
LS MW (SE)	-0,94 (3,742)	5,44 (4,985)	
95 %-KI	[-8,292; 6,406]	[-4,351; 15,227]	
<b>Vorherige Verabreichung von Bevacizumab: Nein</b>			
Baseline			
n/N (%)	71/84 (85)	58/75 (77)	-
MW (SD)	32,39 (28,015)	27,59 (27,315)	
Absolute Werte zum Studienende			
n/N (%)	7/61 (11)	3/48 (6)	-
MW (SD)	19,05 (26,227)	22,22 (19,245)	
Effekt über Studiendauer			
n	71	58	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-1,90 (2,326)	4,59 (2,628)	LS MD -6,49 [-13,443; 0,461] 0,0670  Hedges' g -0,33 [-0,675; 0,023]
95 %-KI	[-6,503; 2,708]	[-0,605; 9,792]	
Veränderung zu Woche 3/4			
n/N (%)	52/83 (63)	38/73 (52)	LS MD -7,32 [-14,913; 0,266]
MW (SD)	-3,21 (26,412)	2,63 (27,544)	
LS MW (SE)	-1,86 (2,550)	5,46 (2,876)	
95 %-KI	[-6,895; 3,171]	[-0,212; 11,135]	
Veränderung zu Woche 8/9			
n/N (%)	58/80 (72)	49/69 (71)	LS MD -6,98 [-14,110; 0,153]
MW (SD)	-1,72 (24,321)	6,12 (23,247)	
LS MW (SE)	-1,88 (2,397)	5,10 (2,691)	
95 %-KI	[-6,618; 2,865]	[-0,217; 10,420]	
Veränderung zu Woche 12			
n/N (%)	41/79 (52)	33/69 (48)	LS MD -6,74 [-13,707; 0,234]
MW (SD)	-2,03 (27,688)	10,10 (21,626)	
LS MW (SE)	-1,89 (2,340)	4,85 (2,629)	
95 %-KI	[-6,518; 2,745]	[-0,351; 10,050]	
Veränderung zu Woche 15/16			
n/N (%)	38/77 (49)	21/66 (32)	LS MD -6,49 [-13,446; 0,457]
MW (SD)	-0,00 (21,224)	-2,38 (30,407)	
LS MW (SE)	-1,90 (2,326)	4,60 (2,627)	
95 %-KI	[-6,502; 2,708]	[-0,600; 9,796]	
Veränderung zu Woche 20/21			
n/N (%)	28/76 (37)	21/62 (34)	LS MD -6,15 [-13,320; 1,021]
MW (SD)	-6,55 (29,516)	3,97 (28,822)	
LS MW (SE)	-1,91 (2,383)	4,24 (2,729)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,626; 2,802]	[-1,157; 9,632]	
Veränderung zu Woche 24			
n/N (%)	23/75 (31)	20/60 (33)	LS MD -5,91 [-13,393; 1,577]
MW (SD)	-11,59 (22,716)	9,17 (19,850)	
LS MW (SE)	-1,92 (2,474)	3,99 (2,868)	
95 %-KI	[-6,811; 2,966]	[-1,675; 9,646]	
Veränderung zu Woche 36			
n/N (%)	37/67 (55)	23/55 (42)	LS MD -5,08 [-14,423; 4,264]
MW (SD)	-2,25 (26,690)	-6,52 (30,459)	
LS MW (SE)	-1,96 (3,035)	3,12 (3,651)	
95 %-KI	[-7,934; 4,018]	[-4,060; 10,303]	
Veränderung zu Woche 48			
n/N (%)	5/61 (8)	3/48 (6)	LS MD -4,25 [-16,198; 7,696]
MW (SD)	-10,00 (22,361)	-16,67 (50,000)	
LS MW (SE)	-1,99 (3,842)	2,26 (4,714)	
95 %-KI	[-9,545; 5,558]	[-7,006; 11,521]	
<b>Letztes Platin-freies Intervall: ≤ 3 Monate</b>			
Baseline			
n/N (%)	63/83 (76)	62/91 (68)	-
MW (SD)	33,07 (29,708)	34,68 (30,523)	
Absolute Werte zum Studienende			
n/N (%)	3/55 (5)	5/39 (13)	-
MW (SD)	27,78 (48,113)	20,00 (18,257)	
Effekt über Studiendauer			
n	63	62	LS MD -13,01 [-20,351; -5,664] 0,0006
LS MW (SE)	-8,53 (2,559)	4,48 (2,684)	
95 %-KI	[-13,601; -3,461]	[-0,834; 9,787]	Hedges' g -0,62 [-0,983; -0,265]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	45/82 (55)	44/86 (51)	LS MD -16,36 [-24,203; -8,526]
MW (SD)	-12,59 (26,149)	3,79 (27,811)	
LS MW (SE)	-9,73 (2,764)	6,64 (2,847)	
95 %-KI	[-15,190; -4,268]	[1,015; 12,257]	
Veränderung zu Woche 8/9			
n/N (%)	49/81 (60)	46/80 (57)	LS MD -14,86 [-22,279; -7,439]
MW (SD)	-7,48 (22,064)	5,80 (24,144)	
LS MW (SE)	-9,19 (2,609)	5,67 (2,693)	
95 %-KI	[-14,356; -4,027]	[0,341; 10,993]	
Veränderung zu Woche 12			
n/N (%)	31/78 (40)	25/78 (32)	LS MD -13,80 [-21,120; -6,490]
MW (SD)	-5,38 (28,991)	6,00 (27,588)	
LS MW (SE)	-8,82 (2,561)	4,99 (2,662)	
95 %-KI	[-13,888; -3,743]	[-0,280; 10,258]	
Veränderung zu Woche 15/16			
n/N (%)	34/76 (45)	13/75 (17)	LS MD -12,75 [-20,123; -5,378]
MW (SD)	-6,86 (32,077)	-5,13 (41,042)	
LS MW (SE)	-8,44 (2,565)	4,31 (2,699)	
95 %-KI	[-13,521; -3,358]	[-1,028; 9,651]	
Veränderung zu Woche 20/21			
n/N (%)	21/72 (29)	14/67 (21)	LS MD -11,24 [-18,971; -3,518]
MW (SD)	-13,49 (26,677)	-1,19 (37,247)	
LS MW (SE)	-7,90 (2,662)	3,34 (2,861)	
95 %-KI	[-13,168; -2,636]	[-2,310; 8,995]	
Veränderung zu Woche 24			
n/N (%)	16/72 (22)	12/62 (19)	LS MD -10,19 [-18,338; -2,043]
MW (SD)	-10,42 (28,464)	6,94 (22,983)	
LS MW (SE)	-7,53 (2,787)	2,66 (3,042)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-13,034; -2,018]	[-3,337; 8,666]	
Veränderung zu Woche 36			
n/N (%)	28/63 (44)	18/50 (36)	LS MD -6,58 [-16,962; 3,808]
MW (SD)	-5,36 (29,764)	-1,85 (31,253)	
LS MW (SE)	-6,24 (3,492)	0,34 (3,954)	
95 %-KI	[-13,111; 0,637]	[-7,439; 8,120]	
Veränderung zu Woche 48			
n/N (%)	2/55 (4)	4/39 (10)	LS MD -2,96 [-16,314; 10,388]
MW (SD)	8,33 (11,785)	-25,00 (28,868)	
LS MW (SE)	-4,95 (4,454)	-1,98 (5,122)	
95 %-KI	[-13,704; 3,809]	[-12,055; 8,086]	
<b>Letztes Platin-freies Intervall: &gt; 3 Monate</b>			
Baseline			
n/N (%)	106/135 (79)	93/116 (80)	-
MW (SD)	30,03 (28,398)	25,09 (26,764)	
Absolute Werte zum Studienende			
n/N (%)	7/85 (8)	1/71 (1)	-
MW (SD)	23,81 (23,288)	33,33 (NA)	
Effekt über Studiendauer			
n	106	93	LS MD -3,82 [-9,535; 1,902] 0,1896  Hedges' g -0,19 [-0,466; 0,092]
LS MW (SE)	0,11 (1,948)	3,93 (2,137)	
95 %-KI	[-3,734; 3,954]	[-0,287; 8,141]	
Veränderung zu Woche 3/4			
n/N (%)	67/131 (51)	59/114 (52)	LS MD -2,13 [-8,470; 4,204]
MW (SD)	-2,24 (23,552)	4,24 (24,091)	
LS MW (SE)	0,09 (2,163)	2,23 (2,376)	
95 %-KI	[-4,165; 4,351]	[-2,450; 6,901]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	88/129 (68)	76/108 (70)	LS MD -2,86 [-8,730; 3,005]
MW (SD)	1,33 (26,530)	3,51 (26,432)	
LS MW (SE)	0,10 (2,019)	2,96 (2,178)	
95 %-KI	[-3,880; 4,080]	[-1,329; 7,254]	
Veränderung zu Woche 12			
n/N (%)	60/127 (47)	46/105 (44)	LS MD -3,37 [-9,091; 2,344]
MW (SD)	-0,83 (26,650)	9,42 (23,479)	
LS MW (SE)	0,11 (1,963)	3,48 (2,123)	
95 %-KI	[-3,768; 3,978]	[-0,708; 7,665]	
Veränderung zu Woche 15/16			
n/N (%)	59/123 (48)	39/103 (38)	LS MD -3,88 [-9,613; 1,845]
MW (SD)	-0,56 (23,966)	8,12 (22,579)	
LS MW (SE)	0,11 (1,949)	3,99 (2,144)	
95 %-KI	[-3,734; 3,955]	[-0,233; 8,222]	
Veränderung zu Woche 20/21			
n/N (%)	44/118 (37)	35/98 (36)	LS MD -4,61 [-10,635; 1,407]
MW (SD)	-4,17 (25,448)	5,71 (26,489)	
LS MW (SE)	0,12 (2,000)	4,73 (2,301)	
95 %-KI	[-3,826; 4,061]	[0,200; 9,263]	
Veränderung zu Woche 24			
n/N (%)	36/112 (32)	25/93 (27)	LS MD -5,12 [-11,522; 1,273]
MW (SD)	-8,33 (23,060)	8,67 (22,628)	
LS MW (SE)	0,12 (2,083)	5,25 (2,486)	
95 %-KI	[-3,982; 4,228]	[0,357; 10,138]	
Veränderung zu Woche 36			
n/N (%)	53/97 (55)	25/84 (30)	LS MD -6,88 [-15,321; 1,570]
MW (SD)	-3,77 (24,600)	-3,33 (22,567)	
LS MW (SE)	0,14 (2,598)	7,02 (3,419)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-4,966; 5,247]	[0,301; 13,731]	
Veränderung zu Woche 48			
n/N (%)	6/85 (7)	1/71 (1)	LS MD -8,63 [-19,764; 2,510]
MW (SD)	-2,78 (24,533)	33,33 (NA)	
LS MW (SE)	0,16 (3,330)	8,78 (4,587)	
95 %-KI	[-6,381; 6,697]	[-0,221; 17,791]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Pegyliertes liposomales Doxorubicin</b>			
Baseline			
n/N (%)	59/80 (74)	54/76 (71)	-
MW (SD)	33,05 (28,949)	23,15 (26,186)	
Absolute Werte zum Studienende			
n/N (%)	3/51 (6)	3/41 (7)	-
MW (SD)	33,33 (33,333)	11,11 (19,245)	
Effekt über Studiendauer			
n	59	54	LS MD 0,56 [-6,590; 7,717] 0,8763  Hedges' g 0,03 [-0,340; 0,399]
LS MW (SE)	2,94 (2,407)	2,38 (2,651)	
95 %-KI	[-1,838; 7,716]	[-2,874; 7,626]	
Veränderung zu Woche 3/4			
n/N (%)	38/76 (50)	38/74 (51)	LS MD -0,35 [-8,407; 7,703]
MW (SD)	-6,14 (25,826)	2,19 (23,305)	
LS MW (SE)	3,54 (2,767)	3,89 (2,955)	
95 %-KI	[-1,923; 9,004]	[-1,938; 9,723]	
Veränderung zu Woche 8/9			
n/N (%)	48/76 (63)	41/66 (62)	LS MD 0,04 [-7,327; 7,414]
MW (SD)	2,78 (28,833)	9,76 (22,662)	
LS MW (SE)	3,28 (2,533)	3,24 (2,687)	
95 %-KI	[-1,734; 8,295]	[-2,080; 8,554]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	32/75 (43)	23/64 (36)	LS MD 0,32 [-6,831; 7,472]
MW (SD)	3,65 (33,530)	5,80 (19,207)	
LS MW (SE)	3,10 (2,438)	2,78 (2,620)	
95 %-KI	[-1,735; 7,932]	[-2,412; 7,968]	
Veränderung zu Woche 15/16			
n/N (%)	33/74 (45)	19/62 (31)	LS MD 0,60 [-6,571; 7,766]
MW (SD)	8,59 (32,575)	-0,88 (16,172)	
LS MW (SE)	2,92 (2,407)	2,32 (2,662)	
95 %-KI	[-1,860; 7,693]	[-2,953; 7,590]	
Veränderung zu Woche 20/21			
n/N (%)	26/72 (36)	18/59 (31)	LS MD 0,99 [-6,603; 8,590]
MW (SD)	-3,85 (31,731)	4,63 (24,790)	
LS MW (SE)	2,66 (2,479)	1,66 (2,898)	
95 %-KI	[-2,257; 7,570]	[-4,063; 7,390]	
Veränderung zu Woche 24			
n/N (%)	20/69 (29)	15/54 (28)	LS MD 1,27 [-6,875; 9,415]
MW (SD)	-12,50 (28,032)	0,00 (17,817)	
LS MW (SE)	2,47 (2,605)	1,20 (3,165)	
95 %-KI	[-2,680; 7,629]	[-5,039; 7,448]	
Veränderung zu Woche 36			
n/N (%)	30/60 (50)	13/48 (27)	LS MD 2,22 [-8,854; 13,295]
MW (SD)	-1,11 (28,679)	-2,56 (20,237)	
LS MW (SE)	1,85 (3,385)	-0,37 (4,466)	
95 %-KI	[-4,813; 8,514]	[-9,154; 8,415]	
Veränderung zu Woche 48			
n/N (%)	2/51 (4)	2/41 (5)	LS MD 3,17 [-11,679; 18,019]
MW (SD)	0,00 (0,000)	-8,33 (11,785)	
LS MW (SE)	1,23 (4,466)	-1,94 (6,054)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-7,555; 10,008]	[-13,846; 9,959]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Paclitaxel</b>			
Baseline			
n/N (%)	73/88 (83)	70/82 (85)	-
MW (SD)	32,65 (29,323)	29,52 (28,822)	
Absolute Werte zum Studienende			
n/N (%)	1/56 (2)	1/49 (2)	-
MW (SD)	83,33 (NA)	33,33 (NA)	
Effekt über Studiendauer			
n	73	70	LS MD -11,74 [-18,713; -4,776] 0,0011  Hedges' g -0,56 [-0,890; -0,221]
LS MW (SE)	-5,53 (2,430)	6,21 (2,548)	
95 %-KI	[-10,339; -0,723]	[1,178; 11,249]	
Veränderung zu Woche 3/4			
n/N (%)	53/87 (61)	49/81 (60)	LS MD -12,61 [-20,151; -5,062]
MW (SD)	-4,40 (25,975)	3,40 (28,863)	
LS MW (SE)	-6,47 (2,644)	6,13 (2,762)	
95 %-KI	[-11,691; -1,259]	[0,685; 11,578]	
Veränderung zu Woche 8/9			
n/N (%)	61/86 (71)	55/79 (70)	LS MD -12,22 [-19,300; -5,133]
MW (SD)	-5,19 (23,480)	5,45 (23,363)	
LS MW (SE)	-6,05 (2,487)	6,17 (2,579)	
95 %-KI	[-10,964; -1,132]	[1,074; 11,263]	
Veränderung zu Woche 12			
n/N (%)	40/84 (48)	37/77 (48)	LS MD -11,94 [-18,898; -4,988]
MW (SD)	-5,42 (22,452)	11,71 (29,883)	
LS MW (SE)	-5,75 (2,436)	6,19 (2,534)	
95 %-KI	[-10,567; -0,931]	[1,185; 11,203]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	44/81 (54)	26/76 (34)	LS MD -11,67 [-18,667; -4,673]
MW (SD)	-8,71 (23,430)	7,69 (36,887)	
LS MW (SE)	-5,45 (2,436)	6,22 (2,563)	
95 %-KI	[-10,268; -0,632]	[1,156; 11,285]	
Veränderung zu Woche 20/21			
n/N (%)	28/77 (36)	25/73 (34)	LS MD -11,28 [-18,623; -3,936]
MW (SD)	-7,74 (21,508)	6,67 (31,914)	
LS MW (SE)	-5,02 (2,524)	6,26 (2,725)	
95 %-KI	[-10,011; -0,035]	[0,879; 11,635]	
Veränderung zu Woche 24			
n/N (%)	21/74 (28)	19/72 (26)	LS MD -11,01 [-18,774; -3,239]
MW (SD)	-0,79 (17,059)	15,79 (25,138)	
LS MW (SE)	-4,72 (2,643)	6,28 (2,913)	
95 %-KI	[-9,941; 0,493]	[0,542; 12,023]	
Veränderung zu Woche 36			
n/N (%)	36/64 (56)	23/63 (37)	LS MD -10,07 [-20,109; -0,031]
MW (SD)	-6,02 (23,955)	-2,17 (32,296)	
LS MW (SE)	-3,70 (3,320)	6,37 (3,868)	
95 %-KI	[-10,229; 2,831]	[-1,232; 13,974]	
Veränderung zu Woche 48			
n/N (%)	1/56 (2)	1/49 (2)	LS MD -9,13 [-22,172; 3,905]
MW (SD)	16,67 (NA)	-66,67 (NA)	
LS MW (SE)	-2,67 (4,247)	6,46 (5,084)	
95 %-KI	[-11,019; 5,671]	[-3,529; 16,449]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Topotecan</b>			
Baseline			
n/N (%)	37/50 (74)	31/49 (63)	-
MW (SD)	25,23 (27,672)	37,63 (30,722)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	6/33 (18)	2/20 (10)	-
MW (SD)	11,11 (13,608)	33,33 (0,000)	
Effekt über Studiendauer			
n	37	31	LS MD -8,47 [-19,308; 2,367] 0,1234  Hedges' g -0,38 [-0,859; 0,104]
LS MW (SE)	-6,48 (3,532)	1,99 (4,130)	
95 %-KI	[-13,538; 0,585]	[-6,251; 10,239]	
Veränderung zu Woche 3/4			
n/N (%)	21/50 (42)	16/45 (36)	LS MD -6,84 [-18,198; 4,519]
MW (SD)	-11,90 (21,176)	10,42 (20,069)	
LS MW (SE)	-7,49 (3,713)	-0,65 (4,346)	
95 %-KI	[-14,884; -0,092]	[-9,297; 7,999]	
Veränderung zu Woche 8/9			
n/N (%)	28/48 (58)	26/43 (60)	LS MD -7,52 [-18,453; 3,411]
MW (SD)	-2,38 (22,090)	-6,41 (31,297)	
LS MW (SE)	-7,07 (3,579)	0,46 (4,159)	
95 %-KI	[-14,213; 0,082]	[-7,841; 8,752]	
Veränderung zu Woche 12			
n/N (%)	19/46 (41)	11/42 (26)	LS MD -8,00 [-18,808; 2,812]
MW (SD)	-6,14 (24,976)	1,52 (13,853)	
LS MW (SE)	-6,77 (3,535)	1,23 (4,110)	
95 %-KI	[-13,835; 0,296]	[-6,977; 9,434]	
Veränderung zu Woche 15/16			
n/N (%)	16/44 (36)	7/40 (18)	LS MD -8,48 [-19,314; 2,363]
MW (SD)	-10,42 (15,957)	9,52 (16,265)	
LS MW (SE)	-6,47 (3,532)	2,00 (4,131)	
95 %-KI	[-13,536; 0,588]	[-6,245; 10,247]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	11/41 (27)	6/33 (18)	LS MD -9,16 [-20,295; 1,981]
MW (SD)	-13,64 (22,134)	-11,11 (34,427)	
LS MW (SE)	-6,05 (3,602)	3,11 (4,281)	
95 %-KI	[-13,244; 1,141]	[-5,422; 11,633]	
Veränderung zu Woche 24			
n/N (%)	11/41 (27)	3/29 (10)	LS MD -9,63 [-21,153; 1,885]
MW (SD)	-18,18 (27,340)	0,00 (0,000)	
LS MW (SE)	-5,76 (3,700)	3,88 (4,462)	
95 %-KI	[-13,131; 1,620]	[-4,992; 12,749]	
Veränderung zu Woche 36			
n/N (%)	15/36 (42)	7/23 (30)	LS MD -11,27 [-24,985; 2,446]
MW (SD)	-6,67 (28,031)	-4,76 (12,599)	
LS MW (SE)	-4,74 (4,293)	6,53 (5,456)	
95 %-KI	[-13,244; 3,762]	[-4,256; 17,313]	
Veränderung zu Woche 48			
n/N (%)	5/33 (15)	2/20 (10)	LS MD -12,91 [-29,764; 3,953]
MW (SD)	-3,33 (27,386)	8,33 (35,355)	
LS MW (SE)	-3,73 (5,168)	9,18 (6,816)	
95 %-KI	[-13,929; 6,475]	[-4,268; 22,625]	
<p><i>Analysepopulation: ITT</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023</i></p> <p><i>Modell: Veränderung zu Baseline ~ Behandlung + Baseline-Wert * Zeit in Wochen + Behandlung * Zeit in Wochen + zufällige Effekte durch die Patientin</i></p> <p><i>Die Berechnung des LS-MW's erfolgt durch ein MMRM mit dem oben angegebenen Modell. Basierend hierauf werden KI und p-Wert ermittelt. Hedges' g basiert ebenfalls auf den LS-MW und ist somit auf das Modell angepasst.</i></p> <p><i>Es werden ausschließlich gemeinsame Analysezeitpunkte dargestellt.</i></p> <p><i>Ein LS MD und Hedges' g größer als Null bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

### 3.6 EORTC QLQ-OV28 hormonelle Symptome

#### EORTC QLQ-OV28 hormonelle Symptome: Subgruppenanalyse

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
<b>EORTC QLQ-OV28 hormonelle Symptome</b>			
<b>Alter: &lt; 65 Jahre</b>			
Baseline			
n/N (%)	90/115 (78)	90/119 (76)	-
MW (SD)	19,07 (23,379)	20,93 (24,678)	
Absolute Werte zum Studienende			
n/N (%)	4/73 (5)	4/64 (6)	-
MW (SD)	45,83 (36,956)	25,00 (39,675)	
Effekt über Studiendauer			
n	90	90	LS MD -1,01 [-5,966; 3,941] 0,6870
LS MW (SE)	1,01 (1,739)	2,02 (1,809)	
95 %-KI	[-2,428; 4,440]	[-1,551; 5,589]	Hedges' g -0,06 [-0,352; 0,232]
Veränderung zu Woche 3/4			
n/N (%)	54/113 (48)	58/115 (50)	LS MD 0,11 [-5,411; 5,639]
MW (SD)	-1,85 (21,148)	-1,15 (17,622)	
LS MW (SE)	0,00 (1,965)	-0,11 (2,003)	
95 %-KI	[-3,865; 3,873]	[-4,053; 3,833]	
Veränderung zu Woche 8/9			
n/N (%)	70/112 (62)	71/108 (66)	LS MD -0,38 [-5,470; 4,710]
MW (SD)	2,62 (20,781)	3,05 (22,941)	
LS MW (SE)	0,44 (1,810)	0,82 (1,839)	
95 %-KI	[-3,127; 4,013]	[-2,803; 4,448]	
Veränderung zu Woche 12			
n/N (%)	44/110 (40)	39/105 (37)	
MW (SD)	3,03 (22,811)	3,85 (17,713)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	0,75 (1,752)	1,48 (1,796)	LS MD -0,73 [-5,678; 4,228]
95 %-KI	[-2,708; 4,209]	[-2,067; 5,018]	
Veränderung zu Woche 15/16			
n/N (%)	51/107 (48)	31/102 (30)	LS MD -1,07 [-6,037; 3,896]
MW (SD)	-2,61 (19,825)	2,15 (25,727)	
LS MW (SE)	1,06 (1,741)	2,13 (1,817)	
95 %-KI	[-2,379; 4,495]	[-1,457; 5,714]	
Veränderung zu Woche 20/21			
n/N (%)	34/101 (34)	28/96 (29)	LS MD -1,56 [-6,807; 3,679]
MW (SD)	-0,00 (24,274)	3,57 (23,288)	
LS MW (SE)	1,50 (1,806)	3,06 (1,956)	
95 %-KI	[-2,067; 5,060]	[-0,792; 6,914]	
Veränderung zu Woche 24			
n/N (%)	24/99 (24)	19/91 (21)	LS MD -1,91 [-7,505; 3,686]
MW (SD)	2,08 (29,616)	3,51 (20,472)	
LS MW (SE)	1,80 (1,904)	3,71 (2,115)	
95 %-KI	[-1,949; 5,557]	[-0,450; 7,877]	
Veränderung zu Woche 36			
n/N (%)	40/86 (47)	25/79 (32)	LS MD -3,09 [-10,584; 4,396]
MW (SD)	3,75 (27,603)	0,67 (19,532)	
LS MW (SE)	2,86 (2,478)	5,95 (2,914)	
95 %-KI	[-2,014; 7,728]	[0,227; 11,676]	
Veränderung zu Woche 48			
n/N (%)	4/73 (5)	3/64 (5)	LS MD -4,28 [-14,230; 5,673]
MW (SD)	-8,33 (9,623)	11,11 (19,245)	
LS MW (SE)	3,91 (3,259)	8,19 (3,908)	
95 %-KI	[-2,489; 10,311]	[0,514; 15,865]	
<b>Alter: ≥ 65 Jahre</b>			
Baseline			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	78/103 (76)	64/88 (73)	-
MW (SD)	12,18 (21,601)	9,11 (18,528)	
Absolute Werte zum Studienende			
n/N (%)	6/67 (9)	2/46 (4)	-
MW (SD)	2,78 (6,804)	8,33 (11,785)	
Effekt über Studiendauer			
n	78	64	LS MD -1,11 [-6,364; 4,142] 0,6765  Hedges' g -0,07 [-0,401; 0,260]
LS MW (SE)	1,89 (1,758)	3,00 (1,990)	
95 %-KI	[-1,586; 5,370]	[-0,930; 6,937]	
Veränderung zu Woche 3/4			
n/N (%)	54/100 (54)	43/85 (51)	LS MD -1,77 [-7,334; 3,792]
MW (SD)	1,85 (19,336)	1,94 (12,708)	
LS MW (SE)	1,26 (1,869)	3,03 (2,107)	
95 %-KI	[-2,433; 4,946]	[-1,130; 7,185]	
Veränderung zu Woche 8/9			
n/N (%)	66/98 (67)	50/80 (62)	LS MD -1,48 [-6,799; 3,831]
MW (SD)	1,26 (20,942)	4,33 (18,384)	
LS MW (SE)	1,53 (1,790)	3,02 (2,005)	
95 %-KI	[-2,004; 5,071]	[-0,944; 6,978]	
Veränderung zu Woche 12			
n/N (%)	47/95 (49)	32/78 (41)	LS MD -1,28 [-6,527; 3,962]
MW (SD)	1,06 (25,633)	4,69 (19,043)	
LS MW (SE)	1,73 (1,762)	3,01 (1,980)	
95 %-KI	[-1,758; 5,212]	[-0,904; 6,923]	
Veränderung zu Woche 15/16			
n/N (%)	40/92 (43)	21/76 (28)	
MW (SD)	1,67 (20,603)	6,35 (18,616)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	1,92 (1,759)	3,00 (1,995)	LS MD -1,08 [-6,343; 4,180]
95 %-KI	[-1,559; 5,401]	[-0,941; 6,945]	
Veränderung zu Woche 20/21			
n/N (%)	29/89 (33)	20/69 (29)	LS MD -0,79 [-6,231; 4,643]
MW (SD)	-2,87 (24,016)	10,83 (18,157)	
LS MW (SE)	2,20 (1,798)	2,99 (2,085)	
95 %-KI	[-1,356; 5,751]	[-1,125; 7,107]	
Veränderung zu Woche 24			
n/N (%)	28/85 (33)	18/64 (28)	LS MD -0,59 [-6,251; 5,065]
MW (SD)	-2,98 (19,800)	2,78 (14,292)	
LS MW (SE)	2,39 (1,853)	2,98 (2,191)	
95 %-KI	[-1,269; 6,051]	[-1,336; 7,304]	
Veränderung zu Woche 36			
n/N (%)	39/74 (53)	19/55 (35)	LS MD 0,10 [-6,804; 6,998]
MW (SD)	2,56 (18,152)	3,51 (15,294)	
LS MW (SE)	3,06 (2,188)	2,96 (2,752)	
95 %-KI	[-1,252; 7,363]	[-2,454; 8,370]	
Veränderung zu Woche 48			
n/N (%)	4/67 (6)	2/46 (4)	LS MD 0,79 [-7,842; 9,415]
MW (SD)	4,17 (8,333)	8,33 (11,785)	
LS MW (SE)	3,72 (2,677)	2,93 (3,499)	
95 %-KI	[-1,543; 8,981]	[-3,942; 9,807]	
<b>Region: USA</b>			
Baseline			
n/N (%)	46/65 (71)	32/51 (63)	-
MW (SD)	14,86 (20,557)	18,75 (26,010)	
Absolute Werte zum Studienende			
n/N (%)	2/39 (5)	3/27 (11)	-
MW (SD)	50,00 (47,140)	33,33 (44,096)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Effekt über Studiendauer			
n	46	32	LS MD 0,63 [-5,238; 6,492] 0,8318  Hedges' g 0,05 [-0,402; 0,500]
LS MW (SE)	1,05 (1,863)	0,43 (2,273)	
95 %-KI	[-2,662; 4,770]	[-4,104; 4,957]	
Veränderung zu Woche 3/4			
n/N (%)	29/64 (45)	18/49 (37)	LS MD 3,78 [-2,950; 10,515]
MW (SD)	4,02 (18,716)	0,93 (13,373)	
LS MW (SE)	2,10 (2,149)	-1,69 (2,633)	
95 %-KI	[-2,157; 6,352]	[-6,900; 3,529]	
Veränderung zu Woche 8/9			
n/N (%)	39/62 (63)	28/46 (61)	LS MD 2,38 [-3,732; 8,491]
MW (SD)	-2,14 (14,398)	-2,38 (16,798)	
LS MW (SE)	1,63 (1,942)	-0,75 (2,377)	
95 %-KI	[-2,229; 5,496]	[-5,472; 3,980]	
Veränderung zu Woche 12			
n/N (%)	23/59 (39)	16/45 (36)	LS MD 1,40 [-4,497; 7,292]
MW (SD)	5,80 (17,122)	1,04 (18,727)	
LS MW (SE)	1,31 (1,871)	-0,09 (2,286)	
95 %-KI	[-2,421; 5,038]	[-4,644; 4,466]	
Veränderung zu Woche 15/16			
n/N (%)	18/56 (32)	11/44 (25)	LS MD 0,42 [-5,464; 6,294]
MW (SD)	-2,78 (16,420)	4,55 (16,817)	
LS MW (SE)	0,98 (1,869)	0,57 (2,279)	
95 %-KI	[-2,743; 4,710]	[-3,973; 5,110]	
Veränderung zu Woche 20/21			
n/N (%)	11/54 (20)	9/40 (22)	
MW (SD)	9,09 (21,556)	0,00 (16,667)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	0,52 (1,984)	1,51 (2,412)	LS MD -0,99 [-7,192; 5,216]
95 %-KI	[-3,425; 4,464]	[-3,286; 6,302]	
Veränderung zu Woche 24			
n/N (%)	8/53 (15)	6/38 (16)	LS MD -1,97 [-8,619; 4,678]
MW (SD)	-2,08 (20,774)	-5,56 (17,213)	
LS MW (SE)	0,19 (2,137)	2,17 (2,594)	
95 %-KI	[-4,041; 4,430]	[-2,976; 7,306]	
Veränderung zu Woche 36			
n/N (%)	20/43 (47)	10/33 (30)	LS MD -5,34 [-14,438; 3,762]
MW (SD)	0,00 (9,366)	3,33 (10,541)	
LS MW (SE)	-0,92 (2,953)	4,42 (3,578)	
95 %-KI	[-6,740; 4,902]	[-2,636; 11,474]	
Veränderung zu Woche 48			
n/N (%)	2/39 (5)	3/27 (11)	LS MD -8,71 [-20,994; 3,583]
MW (SD)	0,00 (23,570)	16,67 (16,667)	
LS MW (SE)	-2,03 (3,995)	6,67 (4,843)	
95 %-KI	[-9,902; 5,837]	[-2,867; 16,213]	
<b>Region: Rest der Welt</b>			
Baseline			
n/N (%)	122/153 (80)	122/156 (78)	-
MW (SD)	16,26 (23,615)	15,30 (22,226)	
Absolute Werte zum Studienende			
n/N (%)	8/101 (8)	3/83 (4)	-
MW (SD)	12,50 (24,801)	5,56 (9,623)	
Effekt über Studiendauer			
n	122	122	LS MD -1,45 [-5,780; 2,875] 0,5092 Hedges' g
LS MW (SE)	1,52 (1,521)	2,97 (1,585)	
95 %-KI	[-1,479; 4,515]	[-0,152; 6,092]	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
			-0,08 [-0,335; 0,167]
Veränderung zu Woche 3/4			
n/N (%)	79/149 (53)	83/151 (55)	LS MD -1,93 [-6,604; 2,737]
MW (SD)	-1,48 (20,705)	-0,00 (16,255)	
LS MW (SE)	0,18 (1,658)	2,11 (1,698)	
95 %-KI	[-3,085; 3,441]	[-1,229; 5,451]	
Veränderung zu Woche 8/9			
n/N (%)	97/148 (66)	93/142 (65)	LS MD -1,72 [-6,120; 2,672]
MW (SD)	3,61 (22,724)	5,38 (22,001)	
LS MW (SE)	0,76 (1,564)	2,48 (1,593)	
95 %-KI	[-2,320; 3,841]	[-0,651; 5,620]	
Veränderung zu Woche 12			
n/N (%)	68/146 (47)	55/138 (40)	LS MD -1,58 [-5,894; 2,739]
MW (SD)	0,74 (26,144)	5,15 (18,108)	
LS MW (SE)	1,17 (1,529)	2,75 (1,569)	
95 %-KI	[-1,845; 4,181]	[-0,345; 5,837]	
Veränderung zu Woche 15/16			
n/N (%)	73/143 (51)	41/134 (31)	LS MD -1,43 [-5,768; 2,905]
MW (SD)	-0,23 (21,062)	3,66 (24,583)	
LS MW (SE)	1,58 (1,522)	3,01 (1,591)	
95 %-KI	[-1,423; 4,574]	[-0,126; 6,140]	
Veränderung zu Woche 20/21			
n/N (%)	52/136 (38)	39/125 (31)	LS MD -1,22 [-5,756; 3,311]
MW (SD)	-3,53 (24,104)	8,12 (22,253)	
LS MW (SE)	2,16 (1,560)	3,38 (1,695)	
95 %-KI	[-0,914; 5,230]	[0,046; 6,714]	
Veränderung zu Woche 24			
n/N (%)	44/131 (34)	31/117 (26)	
MW (SD)	-0,38 (25,540)	4,84 (17,317)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	2,57 (1,618)	3,64 (1,811)	LS MD -1,08 [-5,854; 3,702]
95 %-KI	[-0,620; 5,751]	[0,080; 7,203]	
Veränderung zu Woche 36			
n/N (%)	59/117 (50)	34/101 (34)	LS MD -0,57 [-6,680; 5,531]
MW (SD)	4,24 (26,369)	1,47 (19,405)	
LS MW (SE)	3,96 (1,977)	4,54 (2,398)	
95 %-KI	[0,079; 7,847]	[-0,171; 9,245]	
Veränderung zu Woche 48			
n/N (%)	6/101 (6)	2/83 (2)	LS MD -0,07 [-7,948; 7,803]
MW (SD)	-2,78 (6,804)	0,00 (0,000)	
LS MW (SE)	5,36 (2,491)	5,43 (3,142)	
95 %-KI	[0,470; 10,251]	[-0,734; 11,600]	
<b>Stadium bei der Diagnose: I-III</b>			
Baseline			
n/N (%)	109/141 (77)	109/144 (76)	-
MW (SD)	14,83 (21,196)	16,82 (24,162)	
Absolute Werte zum Studienende			
n/N (%)	6/91 (7)	4/76 (5)	-
MW (SD)	13,89 (26,701)	25,00 (39,675)	
Effekt über Studiendauer			
n	109	109	LS MD -1,31 [-5,925; 3,315] 0,5782
LS MW (SE)	1,41 (1,625)	2,72 (1,687)	
95 %-KI	[-1,793; 4,618]	[-0,607; 6,043]	Hedges' g -0,08 [-0,341; 0,190]
Veränderung zu Woche 3/4			
n/N (%)	69/137 (50)	73/138 (53)	LS MD -0,36 [-5,371; 4,643]
MW (SD)	0,24 (20,511)	-0,23 (16,780)	
LS MW (SE)	0,78 (1,777)	1,15 (1,819)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-2,716; 4,281]	[-2,433; 4,726]	
Veränderung zu Woche 8/9			
n/N (%)	89/136 (65)	85/129 (66)	LS MD -0,77 [-5,483; 3,939]
MW (SD)	3,37 (22,216)	3,53 (22,286)	
LS MW (SE)	1,06 (1,673)	1,83 (1,707)	
95 %-KI	[-2,242; 4,353]	[-1,535; 5,190]	
Veränderung zu Woche 12			
n/N (%)	61/133 (46)	48/128 (38)	LS MD -1,06 [-5,676; 3,561]
MW (SD)	2,46 (25,610)	3,47 (20,901)	
LS MW (SE)	1,25 (1,634)	2,30 (1,678)	
95 %-KI	[-1,976; 4,469]	[-1,002; 5,610]	
Veränderung zu Woche 15/16			
n/N (%)	63/130 (48)	33/125 (26)	LS MD -1,34 [-5,970; 3,284]
MW (SD)	-1,32 (21,018)	2,53 (25,386)	
LS MW (SE)	1,44 (1,626)	2,78 (1,692)	
95 %-KI	[-1,769; 4,644]	[-0,553; 6,114]	
Veränderung zu Woche 20/21			
n/N (%)	45/123 (37)	32/116 (28)	LS MD -1,75 [-6,562; 3,060]
MW (SD)	-0,74 (26,580)	10,42 (19,743)	
LS MW (SE)	1,71 (1,668)	3,46 (1,784)	
95 %-KI	[-1,576; 4,998]	[-0,050; 6,973]	
Veränderung zu Woche 24			
n/N (%)	34/121 (28)	26/109 (24)	LS MD -2,04 [-7,087; 3,014]
MW (SD)	-0,49 (27,366)	6,41 (18,901)	
LS MW (SE)	1,90 (1,732)	3,94 (1,893)	
95 %-KI	[-1,510; 5,314]	[0,215; 7,661]	
Veränderung zu Woche 36			
n/N (%)	52/105 (50)	32/92 (35)	
MW (SD)	2,88 (26,139)	1,56 (19,101)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	2,56 (2,126)	5,57 (2,462)	LS MD -3,01 [-9,404; 3,375]
95 %-KI	[-1,621; 6,736]	[0,736; 10,408]	
Veränderung zu Woche 48			
n/N (%)	5/91 (5)	4/76 (5)	LS MD -3,99 [-12,201; 4,214]
MW (SD)	-0,00 (11,785)	12,50 (15,957)	
LS MW (SE)	3,21 (2,690)	7,21 (3,203)	
95 %-KI	[-2,068; 8,494]	[0,918; 13,494]	
<b>Stadium bei der Diagnose: IV</b>			
Baseline			
n/N (%)	55/72 (76)	43/60 (72)	-
MW (SD)	16,97 (24,531)	14,34 (20,439)	
Absolute Werte zum Studienende			
n/N (%)	4/46 (9)	2/33 (6)	-
MW (SD)	29,17 (39,382)	8,33 (11,785)	
Effekt über Studiendauer			
n	55	43	LS MD -1,07 [-6,199; 4,057] 0,6793
LS MW (SE)	1,14 (1,677)	2,21 (1,965)	
95 %-KI	[-2,193; 4,475]	[-1,689; 6,113]	Hedges' g -0,08 [-0,483; 0,315]
Veränderung zu Woche 3/4			
n/N (%)	35/71 (49)	26/59 (44)	LS MD -3,33 [-9,174; 2,518]
MW (SD)	-0,95 (17,593)	1,92 (12,760)	
LS MW (SE)	-0,10 (1,929)	3,22 (2,240)	
95 %-KI	[-3,916; 3,708]	[-1,200; 7,648]	
Veränderung zu Woche 8/9			
n/N (%)	43/69 (62)	34/56 (61)	LS MD -2,33 [-7,610; 2,944]
MW (SD)	-0,78 (14,975)	3,92 (18,376)	
LS MW (SE)	0,44 (1,754)	2,78 (2,002)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,033; 3,922]	[-1,191; 6,747]	
Veränderung zu Woche 12			
n/N (%)	26/67 (39)	22/52 (42)	LS MD -1,64 [-6,747; 3,472]
MW (SD)	2,56 (13,898)	6,06 (10,966)	
LS MW (SE)	0,83 (1,689)	2,47 (1,942)	
95 %-KI	[-2,527; 4,185]	[-1,390; 6,322]	
Veränderung zu Woche 15/16			
n/N (%)	26/64 (41)	17/50 (34)	LS MD -0,94 [-6,093; 4,211]
MW (SD)	1,92 (15,865)	4,90 (18,413)	
LS MW (SE)	1,21 (1,680)	2,15 (1,979)	
95 %-KI	[-2,126; 4,551]	[-1,775; 6,083]	
Veränderung zu Woche 20/21			
n/N (%)	16/62 (26)	15/46 (33)	LS MD 0,05 [-5,511; 5,617]
MW (SD)	-1,04 (11,335)	-2,22 (23,458)	
LS MW (SE)	1,76 (1,761)	1,71 (2,190)	
95 %-KI	[-1,733; 5,256]	[-2,625; 6,041]	
Veränderung zu Woche 24			
n/N (%)	17/59 (29)	10/44 (23)	LS MD 0,75 [-5,312; 6,811]
MW (SD)	1,96 (15,459)	-3,33 (10,541)	
LS MW (SE)	2,15 (1,878)	1,40 (2,424)	
95 %-KI	[-1,573; 5,864]	[-3,391; 6,183]	
Veränderung zu Woche 36			
n/N (%)	26/52 (50)	11/41 (27)	LS MD 3,14 [-5,445; 11,717]
MW (SD)	3,21 (17,009)	1,52 (13,853)	
LS MW (SE)	3,46 (2,535)	0,33 (3,538)	
95 %-KI	[-1,531; 8,454]	[-6,636; 7,288]	
Veränderung zu Woche 48			
n/N (%)	3/46 (7)	1/33 (3)	
MW (SD)	-5,56 (9,623)	0,00 (NA)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	4,78 (3,398)	-0,74 (4,866)	LS MD 5,52 [-6,183; 17,228]
95 %-KI	[-1,907; 11,463]	[-10,318; 8,829]	
<b>BRCA Status: Positiv</b>			
Baseline			
n/N (%)	24/27 (89)	23/35 (66)	-
MW (SD)	18,75 (25,685)	12,32 (15,257)	
Absolute Werte zum Studienende			
n/N (%)	1/19 (5)	0/15 (0)	-
MW (SD)	33,33 (NA)	NA (NA)	
Effekt über Studiendauer			
n	24	23	LS MD -1,49 [-9,748; 6,771] 0,7181
LS MW (SE)	2,54 (2,785)	4,02 (3,008)	
95 %-KI	[-3,100; 8,172]	[-2,023; 10,072]	Hedges' g -0,10 [-0,677; 0,468]
Veränderung zu Woche 3/4			
n/N (%)	16/27 (59)	17/35 (49)	LS MD 3,30 [-5,719; 12,316]
MW (SD)	-3,13 (10,918)	-2,94 (13,483)	
LS MW (SE)	0,88 (3,139)	-2,42 (3,249)	
95 %-KI	[-5,401; 7,155]	[-8,904; 4,061]	
Veränderung zu Woche 8/9			
n/N (%)	20/26 (77)	20/30 (67)	LS MD 0,97 [-7,328; 9,270]
MW (SD)	3,33 (14,907)	2,50 (15,555)	
LS MW (SE)	1,68 (2,890)	0,71 (2,944)	
95 %-KI	[-4,139; 7,506]	[-5,210; 6,634]	
Veränderung zu Woche 12			
n/N (%)	13/26 (50)	11/30 (37)	LS MD -0,66 [-8,845; 7,530]
MW (SD)	0,00 (18,002)	3,03 (14,564)	
LS MW (SE)	2,25 (2,801)	2,91 (2,940)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,415; 7,911]	[-3,016; 8,827]	
Veränderung zu Woche 15/16			
n/N (%)	12/26 (46)	7/29 (24)	LS MD -2,29 [-10,696; 6,123]
MW (SD)	1,39 (15,006)	14,29 (32,530)	
LS MW (SE)	2,81 (2,789)	5,10 (3,113)	
95 %-KI	[-2,832; 8,457]	[-1,145; 11,343]	
Veränderung zu Woche 20/21			
n/N (%)	10/25 (40)	4/25 (16)	LS MD -4,61 [-13,875; 4,648]
MW (SD)	1,67 (5,270)	8,33 (28,868)	
LS MW (SE)	3,62 (2,907)	8,23 (3,612)	
95 %-KI	[-2,240; 9,478]	[1,045; 15,420]	
Veränderung zu Woche 24			
n/N (%)	8/25 (32)	4/24 (17)	LS MD -6,24 [-16,412; 3,927]
MW (SD)	4,17 (11,785)	16,67 (30,429)	
LS MW (SE)	4,18 (3,075)	10,43 (4,085)	
95 %-KI	[-1,986; 10,353]	[2,326; 18,526]	
Veränderung zu Woche 36			
n/N (%)	9/21 (43)	5/20 (25)	LS MD -11,83 [-26,297; 2,643]
MW (SD)	12,96 (13,889)	10,00 (38,370)	
LS MW (SE)	6,12 (4,034)	17,95 (6,107)	
95 %-KI	[-1,878; 14,117]	[5,878; 30,014]	
Veränderung zu Woche 48			
n/N (%)	1/19 (5)	0/15 (0)	LS MD -17,41 [-37,051; 2,228]
MW (SD)	0,00 (NA)	NA (NA)	
LS MW (SE)	8,06 (5,319)	25,47 (8,396)	
95 %-KI	[-2,459; 18,569]	[8,877; 42,057]	
<b>BRCA Status: Negativ/Unbekannt</b>			
Baseline			
n/N (%)	144/191 (75)	131/172 (76)	-

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	15,39 (22,307)	16,67 (24,108)	
Absolute Werte zum Studienende			
n/N (%)	9/121 (7)	6/95 (6)	-
MW (SD)	18,52 (32,750)	19,44 (32,347)	
Effekt über Studiendauer			
n	144	131	LS MD -1,45 [-5,444; 2,542] 0,4750  Hedges' g -0,09 [-0,323; 0,150]
LS MW (SE)	1,12 (1,376)	2,57 (1,490)	
95 %-KI	[-1,589; 3,832]	[-0,360; 5,504]	
Veränderung zu Woche 3/4			
n/N (%)	92/186 (49)	84/165 (51)	LS MD -1,47 [-5,816; 2,868]
MW (SD)	0,54 (21,462)	0,79 (16,137)	
LS MW (SE)	0,47 (1,505)	1,95 (1,616)	
95 %-KI	[-2,485; 3,432]	[-1,229; 5,124]	
Veränderung zu Woche 8/9			
n/N (%)	116/184 (63)	101/158 (64)	LS MD -1,46 [-5,541; 2,612]
MW (SD)	1,72 (21,689)	3,80 (22,096)	
LS MW (SE)	0,75 (1,415)	2,22 (1,512)	
95 %-KI	[-2,034; 3,537]	[-0,760; 5,192]	
Veränderung zu Woche 12			
n/N (%)	78/179 (44)	60/153 (39)	LS MD -1,46 [-5,450; 2,535]
MW (SD)	2,35 (25,158)	4,44 (18,883)	
LS MW (SE)	0,95 (1,383)	2,40 (1,483)	
95 %-KI	[-1,776; 3,669]	[-0,516; 5,323]	
Veränderung zu Woche 15/16			
n/N (%)	79/173 (46)	45/149 (30)	LS MD -1,45 [-5,449; 2,548]
MW (SD)	-1,05 (20,902)	2,22 (21,201)	
LS MW (SE)	1,14 (1,377)	2,59 (1,492)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-1,570; 3,853]	[-0,346; 5,529]	
Veränderung zu Woche 20/21			
n/N (%)	53/165 (32)	44/140 (31)	LS MD -1,44 [-5,601; 2,720]
MW (SD)	-1,89 (26,079)	6,44 (21,025)	
LS MW (SE)	1,42 (1,416)	2,86 (1,570)	
95 %-KI	[-1,368; 4,207]	[-0,228; 5,948]	
Veränderung zu Woche 24			
n/N (%)	44/159 (28)	33/131 (25)	LS MD -1,43 [-5,806; 2,939]
MW (SD)	-1,52 (26,369)	1,52 (15,232)	
LS MW (SE)	1,61 (1,474)	3,05 (1,664)	
95 %-KI	[-1,286; 4,514]	[-0,224; 6,320]	
Veränderung zu Woche 36			
n/N (%)	70/139 (50)	39/114 (34)	LS MD -1,41 [-6,967; 4,148]
MW (SD)	1,90 (24,001)	0,85 (13,759)	
LS MW (SE)	2,28 (1,823)	3,69 (2,165)	
95 %-KI	[-1,297; 5,861]	[-0,559; 7,942]	
Veränderung zu Woche 48			
n/N (%)	7/121 (6)	5/95 (5)	LS MD -1,39 [-8,547; 5,776]
MW (SD)	-2,38 (11,501)	10,00 (14,907)	
LS MW (SE)	2,95 (2,315)	4,34 (2,820)	
95 %-KI	[-1,593; 7,493]	[-1,199; 9,870]	
<b>Baseline ECOG PS: 0</b>			
Baseline			
n/N (%)	98/128 (77)	93/113 (82)	-
MW (SD)	12,24 (20,102)	16,49 (23,761)	
Absolute Werte zum Studienende			
n/N (%)	7/87 (8)	3/72 (4)	-
MW (SD)	28,57 (34,311)	33,33 (44,096)	
Effekt über Studiendauer			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n	98	93	LS MD -0,30 [-5,115; 4,512] 0,9017  Hedges' g -0,02 [-0,302; 0,266]
LS MW (SE)	2,36 (1,676)	2,66 (1,767)	
95 %-KI	[-0,946; 5,669]	[-0,821; 6,147]	
Veränderung zu Woche 3/4			
n/N (%)	65/127 (51)	60/111 (54)	LS MD -0,23 [-5,466; 5,003]
MW (SD)	2,56 (19,815)	0,83 (16,360)	
LS MW (SE)	2,06 (1,829)	2,29 (1,924)	
95 %-KI	[-1,546; 5,658]	[-1,500; 6,075]	
Veränderung zu Woche 8/9			
n/N (%)	80/126 (63)	73/108 (68)	LS MD -0,26 [-5,181; 4,658]
MW (SD)	3,96 (19,168)	3,65 (24,096)	
LS MW (SE)	2,19 (1,724)	2,45 (1,797)	
95 %-KI	[-1,212; 5,586]	[-1,094; 5,992]	
Veränderung zu Woche 12			
n/N (%)	50/122 (41)	45/108 (42)	LS MD -0,28 [-5,100; 4,534]
MW (SD)	5,67 (21,980)	6,30 (20,191)	
LS MW (SE)	2,28 (1,685)	2,56 (1,760)	
95 %-KI	[-1,046; 5,603]	[-0,911; 6,034]	
Veränderung zu Woche 15/16			
n/N (%)	54/120 (45)	32/105 (30)	LS MD -0,30 [-5,122; 4,514]
MW (SD)	-0,31 (19,824)	4,17 (24,319)	
LS MW (SE)	2,37 (1,677)	2,67 (1,770)	
95 %-KI	[-0,938; 5,679]	[-0,816; 6,164]	
Veränderung zu Woche 20/21			
n/N (%)	37/117 (32)	29/101 (29)	LS MD -0,33 [-5,334; 4,666]
MW (SD)	-0,00 (23,241)	6,90 (25,400)	
LS MW (SE)	2,50 (1,719)	2,83 (1,860)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-0,890; 5,891]	[-0,831; 6,500]	
Veränderung zu Woche 24			
n/N (%)	27/112 (24)	21/96 (22)	LS MD -0,36 [-5,598; 4,888]
MW (SD)	-1,23 (24,861)	0,79 (17,059)	
LS MW (SE)	2,59 (1,785)	2,95 (1,972)	
95 %-KI	[-0,924; 6,109]	[-0,935; 6,830]	
Veränderung zu Woche 36			
n/N (%)	50/99 (51)	32/87 (37)	LS MD -0,43 [-7,047; 6,192]
MW (SD)	3,00 (22,510)	-0,52 (13,707)	
LS MW (SE)	2,91 (2,185)	3,33 (2,569)	
95 %-KI	[-1,389; 7,201]	[-1,713; 8,380]	
Veränderung zu Woche 48			
n/N (%)	5/87 (6)	3/72 (4)	LS MD -0,50 [-9,003; 8,004]
MW (SD)	-3,33 (13,944)	16,67 (16,667)	
LS MW (SE)	3,22 (2,758)	3,72 (3,351)	
95 %-KI	[-2,196; 8,637]	[-2,860; 10,299]	
<b>Baseline ECOG PS: 1</b>			
Baseline			
n/N (%)	70/90 (78)	60/91 (66)	-
MW (SD)	20,95 (25,330)	15,56 (22,099)	
Absolute Werte zum Studienende			
n/N (%)	3/53 (6)	3/37 (8)	-
MW (SD)	0,00 (0,000)	5,56 (9,623)	
Effekt über Studiendauer			
n	70	60	LS MD -2,63 [-8,228; 2,963] 0,3536
LS MW (SE)	-0,00 (1,867)	2,63 (2,116)	
95 %-KI	[-3,702; 3,696]	[-1,556; 6,815]	Hedges' g -0,16 [-0,509; 0,182]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	43/86 (50)	40/87 (46)	LS MD -1,48 [-7,551; 4,589]
MW (SD)	-3,88 (20,521)	-0,83 (15,073)	
LS MW (SE)	-1,42 (2,068)	0,06 (2,269)	
95 %-KI	[-5,497; 2,665]	[-4,413; 4,542]	
Veränderung zu Woche 8/9			
n/N (%)	56/84 (67)	47/78 (60)	LS MD -2,00 [-7,665; 3,669]
MW (SD)	-0,89 (22,790)	3,55 (15,901)	
LS MW (SE)	-0,78 (1,925)	1,22 (2,114)	
95 %-KI	[-4,591; 3,026]	[-2,964; 5,395]	
Veränderung zu Woche 12			
n/N (%)	41/83 (49)	25/74 (34)	LS MD -2,36 [-7,926; 3,207]
MW (SD)	-2,44 (26,236)	0,67 (14,011)	
LS MW (SE)	-0,34 (1,876)	2,02 (2,088)	
95 %-KI	[-4,052; 3,375]	[-2,110; 6,152]	
Veränderung zu Woche 15/16			
n/N (%)	37/79 (47)	20/72 (28)	LS MD -2,72 [-8,345; 2,903]
MW (SD)	-1,35 (20,927)	3,33 (21,357)	
LS MW (SE)	0,11 (1,870)	2,83 (2,134)	
95 %-KI	[-3,599; 3,810]	[-1,393; 7,046]	
Veränderung zu Woche 20/21			
n/N (%)	26/73 (36)	18/63 (29)	LS MD -3,24 [-9,209; 2,733]
MW (SD)	-3,21 (25,394)	6,48 (14,164)	
LS MW (SE)	0,74 (1,941)	3,98 (2,314)	
95 %-KI	[-3,100; 4,580]	[-0,589; 8,544]	
Veränderung zu Woche 24			
n/N (%)	25/72 (35)	15/58 (26)	LS MD -3,60 [-9,976; 2,777]
MW (SD)	-0,00 (25,000)	6,67 (18,687)	
LS MW (SE)	1,18 (2,041)	4,78 (2,506)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-2,847; 5,214]	[-0,156; 9,722]	
Veränderung zu Woche 36			
n/N (%)	29/61 (48)	12/46 (26)	LS MD -4,84 [-13,305; 3,626]
MW (SD)	3,45 (24,952)	8,33 (25,126)	
LS MW (SE)	2,71 (2,611)	7,54 (3,428)	
95 %-KI	[-2,433; 7,844]	[0,805; 14,285]	
Veränderung zu Woche 48			
n/N (%)	3/53 (6)	2/37 (5)	LS MD -6,08 [-17,224; 5,064]
MW (SD)	0,00 (0,000)	0,00 (0,000)	
LS MW (SE)	4,23 (3,388)	10,31 (4,558)	
95 %-KI	[-2,433; 10,888]	[1,348; 19,266]	
<b>Anzahl vorheriger Therapielinien: 1</b>			
Baseline			
n/N (%)	23/31 (74)	21/29 (72)	-
MW (SD)	22,46 (29,563)	15,08 (20,348)	
Absolute Werte zum Studienende			
n/N (%)	1/22 (5)	0/14 (0)	-
MW (SD)	0,00 (NA)	NA (NA)	
Effekt über Studiendauer			
n	23	21	LS MD -1,06 [-11,873; 9,752] 0,8438
LS MW (SE)	-0,56 (3,631)	0,50 (3,900)	
95 %-KI	[-7,910; 6,782]	[-7,375; 8,369]	Hedges' g -0,06 [-0,651; 0,533]
Veränderung zu Woche 3/4			
n/N (%)	15/31 (48)	12/29 (41)	LS MD -5,44 [-17,107; 6,230]
MW (SD)	-8,89 (25,871)	4,17 (16,088)	
LS MW (SE)	-2,46 (3,924)	2,98 (4,265)	
95 %-KI	[-10,333; 5,412]	[-5,556; 11,512]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	19/31 (61)	16/26 (62)	LS MD -3,61 [-14,673; 7,449]
MW (SD)	0,88 (30,668)	5,21 (24,884)	
LS MW (SE)	-1,67 (3,736)	1,94 (3,990)	
95 %-KI	[-9,200; 5,861]	[-6,088; 9,974]	
Veränderung zu Woche 12			
n/N (%)	14/31 (45)	12/24 (50)	LS MD -2,33 [-13,180; 8,513]
MW (SD)	-3,57 (39,320)	8,33 (27,979)	
LS MW (SE)	-1,12 (3,659)	1,22 (3,900)	
95 %-KI	[-8,509; 6,279]	[-6,651; 9,087]	
Veränderung zu Woche 15/16			
n/N (%)	15/31 (48)	11/22 (50)	LS MD -1,06 [-11,868; 9,758]
MW (SD)	3,33 (28,312)	6,06 (21,438)	
LS MW (SE)	-0,56 (3,631)	0,49 (3,900)	
95 %-KI	[-7,907; 6,785]	[-7,378; 8,366]	
Veränderung zu Woche 20/21			
n/N (%)	11/30 (37)	8/22 (36)	LS MD 0,77 [-10,308; 11,850]
MW (SD)	-9,09 (32,799)	6,25 (26,633)	
LS MW (SE)	0,23 (3,679)	-0,54 (4,057)	
95 %-KI	[-7,201; 7,661]	[-8,701; 7,618]	
Veränderung zu Woche 24			
n/N (%)	9/30 (30)	10/20 (50)	LS MD 2,05 [-9,427; 13,527]
MW (SD)	-12,96 (29,788)	-1,67 (18,342)	
LS MW (SE)	0,78 (3,772)	-1,27 (4,267)	
95 %-KI	[-6,814; 8,382]	[-9,813; 7,281]	
Veränderung zu Woche 36			
n/N (%)	14/26 (54)	5/18 (28)	LS MD 6,43 [-7,513; 20,380]
MW (SD)	-1,19 (28,841)	0,00 (11,785)	
LS MW (SE)	2,68 (4,402)	-3,75 (5,444)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,083; 11,449]	[-14,540; 7,040]	
Veränderung zu Woche 48			
n/N (%)	0/22 (0)	0/14 (0)	LS MD 10,82 [-6,739; 28,372]
MW (SD)	NA (NA)	NA (NA)	
LS MW (SE)	4,58 (5,371)	-6,23 (7,035)	
95 %-KI	[-6,045; 15,211]	[-20,132; 7,665]	
<b>Anzahl vorheriger Therapielinien: 2</b>			
Baseline			
n/N (%)	72/89 (81)	65/83 (78)	-
MW (SD)	14,81 (19,889)	17,18 (26,837)	
Absolute Werte zum Studienende			
n/N (%)	4/59 (7)	2/50 (4)	-
MW (SD)	25,00 (31,914)	8,33 (11,785)	
Effekt über Studiendauer			
n	72	65	LS MD -2,95 [-8,445; 2,551] 0,2909  Hedges' g -0,18 [-0,517; 0,155]
LS MW (SE)	-0,27 (1,861)	2,68 (2,063)	
95 %-KI	[-3,952; 3,415]	[-1,398; 6,756]	
Veränderung zu Woche 3/4			
n/N (%)	48/86 (56)	44/80 (55)	LS MD -3,10 [-9,055; 2,860]
MW (SD)	0,69 (16,828)	3,41 (17,080)	
LS MW (SE)	-0,89 (2,041)	2,21 (2,225)	
95 %-KI	[-4,912; 3,141]	[-2,175; 6,600]	
Veränderung zu Woche 8/9			
n/N (%)	59/85 (69)	52/77 (68)	LS MD -3,03 [-8,601; 2,540]
MW (SD)	-0,56 (20,754)	1,92 (24,400)	
LS MW (SE)	-0,61 (1,914)	2,42 (2,067)	
95 %-KI	[-4,393; 3,175]	[-1,662; 6,505]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	37/83 (45)	31/75 (41)	LS MD -2,98 [-8,455; 2,489]
MW (SD)	0,00 (20,787)	2,15 (15,361)	
LS MW (SE)	-0,42 (1,869)	2,57 (2,037)	
95 %-KI	[-4,114; 3,283]	[-1,460; 6,596]	
Veränderung zu Woche 15/16			
n/N (%)	38/80 (48)	18/74 (24)	LS MD -2,94 [-8,460; 2,588]
MW (SD)	-3,07 (19,703)	0,93 (29,413)	
LS MW (SE)	-0,22 (1,863)	2,71 (2,079)	
95 %-KI	[-3,909; 3,466]	[-1,394; 6,824]	
Veränderung zu Woche 20/21			
n/N (%)	30/78 (38)	20/68 (29)	LS MD -2,87 [-8,720; 2,983]
MW (SD)	-0,00 (19,078)	6,67 (17,438)	
LS MW (SE)	0,06 (1,923)	2,92 (2,253)	
95 %-KI	[-3,747; 3,858]	[-1,520; 7,368]	
Veränderung zu Woche 24			
n/N (%)	25/74 (34)	13/65 (20)	LS MD -2,82 [-9,057; 3,415]
MW (SD)	0,67 (20,683)	-2,56 (16,452)	
LS MW (SE)	0,25 (2,009)	3,07 (2,441)	
95 %-KI	[-3,719; 4,217]	[-1,738; 7,879]	
Veränderung zu Woche 36			
n/N (%)	33/65 (51)	17/58 (29)	LS MD -2,66 [-10,890; 5,571]
MW (SD)	3,03 (21,832)	-0,00 (21,246)	
LS MW (SE)	0,91 (2,515)	3,57 (3,346)	
95 %-KI	[-4,036; 5,863]	[-3,005; 10,151]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	1/50 (2)	LS MD -2,50 [-13,300; 8,305]
MW (SD)	-4,17 (8,333)	0,00 (NA)	
LS MW (SE)	1,58 (3,219)	4,08 (4,458)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-4,749; 7,904]	[-4,685; 12,836]	
<b>Anzahl vorheriger Therapielinien: 3</b>			
Baseline			
n/N (%)	73/98 (74)	68/95 (72)	-
MW (SD)	14,84 (23,001)	15,20 (19,895)	
Absolute Werte zum Studienende			
n/N (%)	5/59 (8)	4/46 (9)	-
MW (SD)	20,00 (36,132)	25,00 (39,675)	
Effekt über Studiendauer			
n	73	68	LS MD 1,15 [-3,941; 6,236] 0,6563  Hedges' g 0,07 [-0,256; 0,405]
LS MW (SE)	3,83 (1,761)	2,68 (1,878)	
95 %-KI	[0,347; 7,314]	[-1,030; 6,396]	
Veränderung zu Woche 3/4			
n/N (%)	45/96 (47)	45/91 (49)	LS MD 3,26 [-2,364; 8,885]
MW (SD)	2,22 (21,201)	-4,07 (13,369)	
LS MW (SE)	3,30 (1,971)	0,04 (2,064)	
95 %-KI	[-0,584; 7,188]	[-4,028; 4,110]	
Veränderung zu Woche 8/9			
n/N (%)	58/94 (62)	53/85 (62)	LS MD 2,35 [-2,874; 7,565]
MW (SD)	4,89 (16,522)	4,72 (16,138)	
LS MW (SE)	3,53 (1,823)	1,19 (1,914)	
95 %-KI	[-0,071; 7,133]	[-2,595; 4,966]	
Veränderung zu Woche 12			
n/N (%)	40/91 (44)	28/84 (33)	LS MD 1,70 [-3,385; 6,794]
MW (SD)	5,83 (20,167)	4,76 (16,265)	
LS MW (SE)	3,69 (1,770)	1,99 (1,871)	
95 %-KI	[0,191; 7,191]	[-1,712; 5,685]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	38/88 (43)	23/82 (28)	LS MD 1,06 [-4,033; 6,162]
MW (SD)	-0,00 (16,890)	5,07 (18,419)	
LS MW (SE)	3,85 (1,762)	2,79 (1,883)	
95 %-KI	[0,365; 7,338]	[-0,935; 6,510]	
Veränderung zu Woche 20/21			
n/N (%)	22/82 (27)	20/75 (27)	LS MD 0,15 [-5,195; 5,493]
MW (SD)	0,76 (25,447)	6,67 (23,817)	
LS MW (SE)	4,08 (1,832)	3,93 (1,993)	
95 %-KI	[0,460; 7,700]	[-0,004; 7,867]	
Veränderung zu Woche 24			
n/N (%)	18/80 (22)	14/70 (20)	LS MD -0,49 [-6,157; 5,174]
MW (SD)	3,70 (26,541)	11,90 (15,231)	
LS MW (SE)	4,24 (1,931)	4,73 (2,128)	
95 %-KI	[0,429; 8,053]	[0,537; 8,927]	
Veränderung zu Woche 36			
n/N (%)	32/69 (46)	22/58 (38)	LS MD -2,69 [-10,117; 4,742]
MW (SD)	5,21 (22,575)	3,79 (16,209)	
LS MW (SE)	4,79 (2,504)	7,48 (2,830)	
95 %-KI	[-0,136; 9,717]	[1,913; 13,043]	
Veränderung zu Woche 48			
n/N (%)	4/59 (7)	4/46 (9)	LS MD -4,88 [-14,650; 4,882]
MW (SD)	0,00 (13,608)	12,50 (15,957)	
LS MW (SE)	5,34 (3,280)	10,22 (3,735)	
95 %-KI	[-1,106; 11,786]	[2,884; 17,564]	
<b>Vorherige Verabreichung von Bevacizumab: Ja</b>			
Baseline			
n/N (%)	97/134 (72)	96/132 (73)	-
MW (SD)	12,89 (19,470)	15,28 (21,854)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	3/79 (4)	3/62 (5)	-
MW (SD)	27,78 (34,694)	33,33 (44,096)	
Effekt über Studiendauer			
n	97	96	LS MD -0,47 [-4,822; 3,875] 0,8301  Hedges' g -0,03 [-0,313; 0,251]
LS MW (SE)	2,41 (1,512)	2,88 (1,604)	
95 %-KI	[-0,575; 5,392]	[-0,282; 6,045]	
Veränderung zu Woche 3/4			
n/N (%)	57/130 (44)	63/127 (50)	LS MD 0,97 [-3,843; 5,773]
MW (SD)	2,34 (16,797)	-1,32 (14,757)	
LS MW (SE)	1,09 (1,696)	0,13 (1,759)	
95 %-KI	[-2,249; 4,431]	[-3,336; 3,587]	
Veränderung zu Woche 8/9			
n/N (%)	78/130 (60)	72/119 (61)	LS MD 0,30 [-4,123; 4,729]
MW (SD)	2,35 (19,504)	2,78 (18,765)	
LS MW (SE)	1,70 (1,566)	1,39 (1,609)	
95 %-KI	[-1,391; 4,784]	[-1,779; 4,565]	
Veränderung zu Woche 12			
n/N (%)	50/126 (40)	38/114 (33)	LS MD -0,16 [-4,488; 4,169]
MW (SD)	4,00 (18,916)	4,39 (19,252)	
LS MW (SE)	2,12 (1,520)	2,28 (1,583)	
95 %-KI	[-0,878; 5,120]	[-0,841; 5,402]	
Veränderung zu Woche 15/16			
n/N (%)	53/122 (43)	31/112 (28)	LS MD -0,62 [-5,005; 3,759]
MW (SD)	-0,63 (18,188)	8,60 (21,025)	
LS MW (SE)	2,55 (1,515)	3,17 (1,625)	
95 %-KI	[-0,444; 5,535]	[-0,036; 6,373]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	35/114 (31)	28/103 (27)	LS MD -1,28 [-5,993; 3,424]
MW (SD)	2,86 (21,574)	5,36 (20,813)	
LS MW (SE)	3,15 (1,580)	4,44 (1,795)	
95 %-KI	[0,036; 6,266]	[0,903; 7,969]	
Veränderung zu Woche 24			
n/N (%)	27/109 (25)	17/95 (18)	LS MD -1,75 [-6,834; 3,338]
MW (SD)	6,17 (20,749)	5,88 (16,605)	
LS MW (SE)	3,58 (1,671)	5,32 (1,974)	
95 %-KI	[0,285; 6,866]	[1,441; 9,205]	
Veränderung zu Woche 36			
n/N (%)	42/93 (45)	20/79 (25)	LS MD -3,34 [-10,318; 3,646]
MW (SD)	5,56 (21,039)	3,33 (13,892)	
LS MW (SE)	5,03 (2,185)	8,37 (2,809)	
95 %-KI	[0,735; 9,324]	[2,850; 13,882]	
Veränderung zu Woche 48			
n/N (%)	3/79 (4)	2/62 (3)	LS MD -4,92 [-14,275; 4,427]
MW (SD)	-0,00 (16,667)	16,67 (23,570)	
LS MW (SE)	6,48 (2,875)	11,41 (3,806)	
95 %-KI	[0,838; 12,130]	[3,935; 18,882]	
<b>Vorherige Verabreichung von Bevacizumab: Nein</b>			
Baseline			
n/N (%)	71/84 (85)	58/75 (77)	-
MW (SD)	19,95 (26,219)	17,24 (24,969)	
Absolute Werte zum Studienende			
n/N (%)	7/61 (11)	3/48 (6)	-
MW (SD)	16,67 (31,914)	5,56 (9,623)	
Effekt über Studiendauer			
n	71	58	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	0,27 (2,074)	2,51 (2,337)	LS MD -2,24 [-8,428; 3,946] 0,4748  Hedges' g -0,13 [-0,474; 0,221]
95 %-KI	[-3,838; 4,376]	[-2,114; 7,134]	
Veränderung zu Woche 3/4			
n/N (%)	51/83 (61)	38/73 (52)	LS MD -3,26 [-9,894; 3,378]
MW (SD)	-2,61 (23,422)	2,63 (17,123)	
LS MW (SE)	0,09 (2,229)	3,35 (2,511)	
95 %-KI	[-4,313; 4,491]	[-1,610; 8,304]	
Veränderung zu Woche 8/9			
n/N (%)	58/80 (72)	49/69 (71)	LS MD -2,84 [-9,154; 3,473]
MW (SD)	1,44 (22,574)	4,76 (24,296)	
LS MW (SE)	0,16 (2,123)	3,00 (2,382)	
95 %-KI	[-4,037; 4,362]	[-1,706; 7,713]	
Veränderung zu Woche 12			
n/N (%)	41/79 (52)	33/69 (48)	LS MD -2,55 [-8,748; 3,652]
MW (SD)	-0,41 (29,460)	4,04 (17,195)	
LS MW (SE)	0,21 (2,084)	2,76 (2,339)	
95 %-KI	[-3,910; 4,339]	[-1,864; 7,389]	
Veränderung zu Woche 15/16			
n/N (%)	38/77 (49)	21/66 (32)	LS MD -2,26 [-8,441; 3,930]
MW (SD)	-0,88 (22,907)	-3,17 (24,506)	
LS MW (SE)	0,27 (2,074)	2,52 (2,336)	
95 %-KI	[-3,840; 4,372]	[-2,101; 7,144]	
Veränderung zu Woche 20/21			
n/N (%)	28/76 (37)	20/62 (32)	LS MD -1,84 [-8,172; 4,497]
MW (SD)	-6,55 (26,191)	8,33 (22,621)	
LS MW (SE)	0,34 (2,114)	2,18 (2,405)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-3,842; 4,522]	[-2,576; 6,931]	
Veränderung zu Woche 24			
n/N (%)	25/75 (33)	20/60 (33)	LS MD -1,54 [-8,097; 5,008]
MW (SD)	-8,00 (26,840)	0,83 (18,317)	
LS MW (SE)	0,39 (2,177)	1,94 (2,499)	
95 %-KI	[-3,911; 4,694]	[-2,998; 6,872]	
Veränderung zu Woche 36			
n/N (%)	37/67 (55)	24/55 (44)	LS MD -0,54 [-8,420; 7,337]
MW (SD)	0,45 (25,606)	0,69 (20,548)	
LS MW (SE)	0,57 (2,576)	1,11 (3,052)	
95 %-KI	[-4,505; 5,643]	[-4,896; 7,118]	
Veränderung zu Woche 48			
n/N (%)	5/61 (8)	3/48 (6)	LS MD 0,46 [-9,339; 10,262]
MW (SD)	-3,33 (7,454)	5,56 (9,623)	
LS MW (SE)	0,75 (3,168)	0,29 (3,831)	
95 %-KI	[-5,482; 6,975]	[-7,245; 7,815]	
<b>Letztes Platin-freies Intervall: ≤ 3 Monate</b>			
Baseline			
n/N (%)	62/83 (75)	62/91 (68)	-
MW (SD)	13,44 (21,090)	15,32 (21,824)	
Absolute Werte zum Studienende			
n/N (%)	3/55 (5)	5/39 (13)	-
MW (SD)	22,22 (38,490)	23,33 (34,561)	
Effekt über Studiendauer			
n	62	62	LS MD -2,80 [-8,739; 3,141] 0,3527
LS MW (SE)	1,47 (2,078)	4,26 (2,163)	
95 %-KI	[-2,652; 5,583]	[-0,016; 8,544]	Hedges' g -0,17 [-0,519; 0,186]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	43/82 (52)	44/86 (51)	LS MD -0,40 [-6,752; 5,954]
MW (SD)	1,16 (22,828)	-3,03 (16,964)	
LS MW (SE)	0,97 (2,251)	1,37 (2,296)	
95 %-KI	[-3,479; 5,414]	[-3,168; 5,901]	
Veränderung zu Woche 8/9			
n/N (%)	49/81 (60)	45/80 (56)	LS MD -1,48 [-7,484; 4,522]
MW (SD)	0,68 (17,334)	6,67 (18,600)	
LS MW (SE)	1,19 (2,119)	2,67 (2,171)	
95 %-KI	[-3,002; 5,386]	[-1,621; 6,967]	
Veränderung zu Woche 12			
n/N (%)	30/78 (38)	25/78 (32)	LS MD -2,24 [-8,155; 3,678]
MW (SD)	2,78 (21,479)	8,00 (14,530)	
LS MW (SE)	1,35 (2,078)	3,59 (2,146)	
95 %-KI	[-2,769; 5,467]	[-0,660; 7,835]	
Veränderung zu Woche 15/16			
n/N (%)	33/76 (43)	13/75 (17)	LS MD -3,00 [-8,962; 2,970]
MW (SD)	-4,55 (18,761)	11,54 (23,945)	
LS MW (SE)	1,51 (2,084)	4,50 (2,176)	
95 %-KI	[-2,623; 5,635]	[0,197; 8,807]	
Veränderung zu Woche 20/21			
n/N (%)	20/72 (28)	14/67 (21)	LS MD -4,08 [-10,345; 2,190]
MW (SD)	-0,00 (22,295)	15,48 (20,111)	
LS MW (SE)	1,73 (2,170)	5,81 (2,308)	
95 %-KI	[-2,564; 6,024]	[1,249; 10,367]	
Veränderung zu Woche 24			
n/N (%)	14/72 (19)	12/62 (19)	LS MD -4,83 [-11,458; 1,788]
MW (SD)	-3,57 (22,813)	11,11 (16,412)	
LS MW (SE)	1,89 (2,281)	6,72 (2,454)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-2,619; 6,393]	[1,880; 11,565]	
Veränderung zu Woche 36			
n/N (%)	27/63 (43)	18/50 (36)	LS MD -7,43 [-15,932; 1,069]
MW (SD)	2,47 (23,887)	9,26 (21,559)	
LS MW (SE)	2,43 (2,890)	9,86 (3,194)	
95 %-KI	[-3,262; 8,114]	[3,573; 16,142]	
Veränderung zu Woche 48			
n/N (%)	2/55 (4)	4/39 (10)	LS MD -10,03 [-21,001; 0,945]
MW (SD)	-8,33 (11,785)	12,50 (15,957)	
LS MW (SE)	2,96 (3,711)	12,99 (4,141)	
95 %-KI	[-4,332; 10,260]	[4,851; 21,134]	
<b>Letztes Platin-freies Intervall: &gt; 3 Monate</b>			
Baseline			
n/N (%)	106/135 (79)	92/116 (79)	-
MW (SD)	17,30 (23,674)	16,49 (23,891)	
Absolute Werte zum Studienende			
n/N (%)	7/85 (8)	1/71 (1)	-
MW (SD)	19,05 (31,074)	0,00 (NA)	
Effekt über Studiendauer			
n	106	92	LS MD -0,24 [-4,758; 4,287] 0,9182  Hedges' g -0,01 [-0,294; 0,265]
LS MW (SE)	1,37 (1,537)	1,60 (1,702)	
95 %-KI	[-1,666; 4,399]	[-1,753; 4,957]	
Veränderung zu Woche 3/4			
n/N (%)	65/131 (50)	57/114 (50)	LS MD -1,15 [-6,138; 3,848]
MW (SD)	-0,77 (18,501)	2,63 (14,361)	
LS MW (SE)	0,57 (1,702)	1,72 (1,881)	
95 %-KI	[-2,777; 3,924]	[-1,984; 5,421]	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	87/129 (67)	76/108 (70)	LS MD -0,75 [-5,395; 3,886]
MW (SD)	2,68 (22,573)	1,75 (22,374)	
LS MW (SE)	0,91 (1,592)	1,67 (1,735)	
95 %-KI	[-2,224; 4,052]	[-1,751; 5,088]	
Veränderung zu Woche 12			
n/N (%)	61/127 (48)	46/105 (44)	LS MD -0,48 [-5,007; 4,044]
MW (SD)	1,64 (25,587)	2,17 (19,754)	
LS MW (SE)	1,15 (1,549)	1,63 (1,693)	
95 %-KI	[-1,903; 4,208]	[-1,705; 4,972]	
Veränderung zu Woche 15/16			
n/N (%)	58/123 (47)	39/103 (38)	LS MD -0,21 [-4,736; 4,320]
MW (SD)	1,44 (20,776)	1,28 (22,421)	
LS MW (SE)	1,39 (1,537)	1,60 (1,705)	
95 %-KI	[-1,643; 4,424]	[-1,764; 4,961]	
Veränderung zu Woche 20/21			
n/N (%)	43/118 (36)	34/98 (35)	LS MD 0,18 [-4,551; 4,917]
MW (SD)	-1,94 (24,989)	2,94 (21,110)	
LS MW (SE)	1,73 (1,575)	1,55 (1,814)	
95 %-KI	[-1,375; 4,837]	[-2,024; 5,121]	
Veränderung zu Woche 24			
n/N (%)	38/112 (34)	25/93 (27)	LS MD 0,46 [-4,550; 5,462]
MW (SD)	0,44 (25,553)	-0,67 (16,997)	
LS MW (SE)	1,97 (1,638)	1,51 (1,945)	
95 %-KI	[-1,258; 5,197]	[-2,314; 5,341]	
Veränderung zu Woche 36			
n/N (%)	52/97 (54)	26/84 (31)	LS MD 1,39 [-5,123; 7,909]
MW (SD)	3,53 (23,183)	-3,21 (12,489)	
LS MW (SE)	2,79 (2,029)	1,39 (2,624)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-1,202; 6,775]	[-3,761; 6,547]	
Veränderung zu Woche 48			
n/N (%)	6/85 (7)	1/71 (1)	LS MD 2,33 [-6,199; 10,860]
MW (SD)	0,00 (10,541)	0,00 (NA)	
LS MW (SE)	3,60 (2,589)	1,27 (3,489)	
95 %-KI	[-1,481; 8,688]	[-5,578; 8,124]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Pegyliertes liposomales Doxorubicin</b>			
Baseline			
n/N (%)	58/80 (72)	53/76 (70)	-
MW (SD)	18,68 (24,795)	13,84 (21,368)	
Absolute Werte zum Studienende			
n/N (%)	3/51 (6)	3/41 (7)	-
MW (SD)	11,11 (19,245)	11,11 (9,623)	
Effekt über Studiendauer			
n	58	53	LS MD 0,05 [-6,258; 6,354] 0,9880  Hedges' g 0,00 [-0,370; 0,375]
LS MW (SE)	1,09 (2,151)	1,04 (2,338)	
95 %-KI	[-3,182; 5,353]	[-3,594; 5,669]	
Veränderung zu Woche 3/4			
n/N (%)	37/76 (49)	37/74 (50)	LS MD -1,14 [-7,976; 5,705]
MW (SD)	-3,60 (25,195)	2,25 (17,639)	
LS MW (SE)	0,00 (2,364)	1,14 (2,520)	
95 %-KI	[-4,669; 4,675]	[-3,839; 6,117]	
Veränderung zu Woche 8/9			
n/N (%)	47/76 (62)	41/66 (62)	LS MD -0,63 [-7,061; 5,808]
MW (SD)	1,77 (23,113)	4,07 (23,799)	
LS MW (SE)	0,47 (2,223)	1,10 (2,362)	
95 %-KI	[-3,934; 4,872]	[-3,582; 5,772]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	32/75 (43)	23/64 (36)	LS MD -0,27 [-6,575; 6,036]
MW (SD)	-3,13 (27,251)	5,80 (22,813)	
LS MW (SE)	0,79 (2,168)	1,06 (2,322)	
95 %-KI	[-3,503; 5,093]	[-3,536; 5,665]	
Veränderung zu Woche 15/16			
n/N (%)	32/74 (43)	18/62 (29)	LS MD 0,09 [-6,227; 6,401]
MW (SD)	0,52 (20,947)	0,93 (22,486)	
LS MW (SE)	1,12 (2,152)	1,03 (2,343)	
95 %-KI	[-3,147; 5,389]	[-3,608; 5,676]	
Veränderung zu Woche 20/21			
n/N (%)	25/72 (35)	17/59 (29)	LS MD 0,60 [-5,963; 7,155]
MW (SD)	-3,33 (28,054)	5,88 (24,254)	
LS MW (SE)	1,59 (2,197)	0,99 (2,476)	
95 %-KI	[-2,769; 5,942]	[-3,907; 5,887]	
Veränderung zu Woche 24			
n/N (%)	20/69 (29)	15/54 (28)	LS MD 0,95 [-5,929; 7,835]
MW (SD)	-1,67 (31,016)	-1,11 (16,019)	
LS MW (SE)	1,91 (2,276)	0,96 (2,632)	
95 %-KI	[-2,592; 6,417]	[-4,238; 6,157]	
Veränderung zu Woche 36			
n/N (%)	29/60 (48)	14/48 (29)	LS MD 2,18 [-6,530; 10,881]
MW (SD)	1,72 (28,293)	-1,19 (15,281)	
LS MW (SE)	3,03 (2,773)	0,85 (3,443)	
95 %-KI	[-2,434; 8,494]	[-5,920; 7,629]	
Veränderung zu Woche 48			
n/N (%)	2/51 (4)	2/41 (5)	LS MD 3,40 [-7,796; 14,593]
MW (SD)	0,00 (0,000)	8,33 (11,785)	
LS MW (SE)	4,15 (3,498)	0,75 (4,490)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-2,732; 11,027]	[-8,079; 9,577]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Paclitaxel</b>			
Baseline			
n/N (%)	73/88 (83)	70/82 (85)	-
MW (SD)	13,93 (19,447)	14,76 (23,147)	
Absolute Werte zum Studienende			
n/N (%)	1/56 (2)	1/49 (2)	-
MW (SD)	66,67 (NA)	0,00 (NA)	
Effekt über Studiendauer			
n	73	70	LS MD -1,11 [-6,407; 4,184] 0,6787  Hedges' g -0,07 [-0,397; 0,259]
LS MW (SE)	3,87 (1,840)	4,98 (1,946)	
95 %-KI	[0,229; 7,509]	[1,134; 8,826]	
Veränderung zu Woche 3/4			
n/N (%)	50/87 (57)	48/81 (59)	LS MD -0,57 [-6,437; 5,296]
MW (SD)	4,00 (14,892)	-1,39 (15,311)	
LS MW (SE)	2,46 (2,053)	3,03 (2,155)	
95 %-KI	[-1,591; 6,507]	[-1,218; 7,275]	
Veränderung zu Woche 8/9			
n/N (%)	61/86 (71)	54/79 (68)	LS MD -0,81 [-6,235; 4,607]
MW (SD)	4,64 (20,890)	7,41 (19,063)	
LS MW (SE)	3,09 (1,900)	3,91 (1,981)	
95 %-KI	[-0,661; 6,847]	[-0,006; 7,820]	
Veränderung zu Woche 12			
n/N (%)	40/84 (48)	37/77 (48)	LS MD -0,98 [-6,274; 4,305]
MW (SD)	9,17 (22,630)	4,05 (15,911)	
LS MW (SE)	3,54 (1,847)	4,52 (1,936)	
95 %-KI	[-0,116; 7,191]	[0,696; 8,348]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	43/81 (53)	27/76 (36)	LS MD -1,15 [-6,472; 4,163]
MW (SD)	1,55 (19,181)	6,17 (26,209)	
LS MW (SE)	3,98 (1,844)	5,14 (1,958)	
95 %-KI	[0,334; 7,631]	[1,268; 9,006]	
Veränderung zu Woche 20/21			
n/N (%)	27/77 (35)	25/73 (34)	LS MD -1,40 [-7,027; 4,230]
MW (SD)	0,62 (21,917)	11,33 (15,000)	
LS MW (SE)	4,62 (1,926)	6,02 (2,102)	
95 %-KI	[0,812; 8,423]	[1,869; 10,163]	
Veränderung zu Woche 24			
n/N (%)	21/74 (28)	19/72 (26)	LS MD -1,57 [-7,583; 4,445]
MW (SD)	3,97 (20,348)	7,02 (19,497)	
LS MW (SE)	5,06 (2,038)	6,63 (2,269)	
95 %-KI	[1,041; 9,083]	[2,160; 11,102]	
Veränderung zu Woche 36			
n/N (%)	35/64 (55)	23/63 (37)	LS MD -2,15 [-10,205; 5,899]
MW (SD)	7,14 (21,875)	4,35 (20,851)	
LS MW (SE)	6,59 (2,663)	8,74 (3,110)	
95 %-KI	[1,350; 11,823]	[2,627; 14,852]	
Veränderung zu Woche 48			
n/N (%)	1/56 (2)	1/49 (2)	LS MD -2,74 [-13,422; 7,947]
MW (SD)	-16,67 (NA)	0,00 (NA)	
LS MW (SE)	8,11 (3,497)	10,85 (4,162)	
95 %-KI	[1,240; 14,982]	[2,672; 19,025]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Topotecan</b>			
Baseline			
n/N (%)	37/50 (74)	31/49 (63)	-
MW (SD)	15,32 (25,573)	22,58 (24,925)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	6/33 (18)	2/20 (10)	-
MW (SD)	16,67 (33,333)	41,67 (58,926)	
Effekt über Studiendauer			
n	37	31	LS MD -0,15 [-7,766; 7,475] 0,9697  Hedges' g -0,01 [-0,486; 0,468]
LS MW (SE)	-2,64 (2,508)	-2,50 (2,870)	
95 %-KI	[-7,656; 2,372]	[-8,223; 3,231]	
Veränderung zu Woche 3/4			
n/N (%)	21/50 (42)	16/45 (36)	LS MD 2,96 [-5,052; 10,974]
MW (SD)	-3,17 (20,829)	-0,00 (12,172)	
LS MW (SE)	-1,66 (2,648)	-4,62 (3,034)	
95 %-KI	[-6,930; 3,616]	[-10,653; 1,417]	
Veränderung zu Woche 8/9			
n/N (%)	28/48 (58)	26/43 (60)	LS MD 1,66 [-6,026; 9,352]
MW (SD)	-3,57 (15,287)	-5,13 (18,720)	
LS MW (SE)	-2,07 (2,546)	-3,73 (2,890)	
95 %-KI	[-7,152; 3,015]	[-9,496; 2,033]	
Veränderung zu Woche 12			
n/N (%)	19/46 (41)	11/42 (26)	LS MD 0,75 [-6,843; 8,352]
MW (SD)	-4,39 (18,293)	1,52 (15,731)	
LS MW (SE)	-2,36 (2,511)	-3,11 (2,853)	
95 %-KI	[-7,376; 2,663]	[-8,806; 2,584]	
Veränderung zu Woche 15/16			
n/N (%)	16/44 (36)	7/40 (18)	LS MD -0,15 [-7,776; 7,467]
MW (SD)	-9,38 (20,156)	2,38 (6,299)	
LS MW (SE)	-2,64 (2,508)	-2,49 (2,870)	
95 %-KI	[-7,659; 2,370]	[-8,218; 3,238]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	11/41 (27)	6/33 (18)	LS MD -1,45 [-9,305; 6,400]
MW (SD)	-1,52 (20,350)	-11,11 (29,187)	
LS MW (SE)	-3,06 (2,558)	-1,60 (2,988)	
95 %-KI	[-8,164; 2,052]	[-7,553; 4,345]	
Veränderung zu Woche 24			
n/N (%)	11/41 (27)	3/29 (10)	LS MD -2,36 [-10,505; 5,783]
MW (SD)	-7,58 (18,803)	0,00 (0,000)	
LS MW (SE)	-3,34 (2,630)	-0,98 (3,129)	
95 %-KI	[-8,587; 1,899]	[-7,200; 5,234]	
Veränderung zu Woche 36			
n/N (%)	15/36 (42)	7/23 (30)	LS MD -5,48 [-15,285; 4,333]
MW (SD)	-3,33 (12,910)	-0,00 (9,623)	
LS MW (SE)	-4,33 (3,068)	1,14 (3,891)	
95 %-KI	[-10,408; 1,745]	[-6,543; 8,832]	
Veränderung zu Woche 48			
n/N (%)	5/33 (15)	2/20 (10)	LS MD -8,59 [-20,755; 3,572]
MW (SD)	0,00 (11,785)	16,67 (23,570)	
LS MW (SE)	-5,32 (3,714)	3,27 (4,917)	
95 %-KI	[-12,650; 2,012]	[-6,427; 12,971]	
<p><i>Analysepopulation: ITT</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023</i></p> <p><i>Modell: Veränderung zu Baseline ~ Behandlung + Baseline-Wert * Zeit in Wochen + Behandlung * Zeit in Wochen + zufällige Effekte durch die Patientin</i></p> <p><i>Die Berechnung des LS-MW's erfolgt durch ein MMRM mit dem oben angegebenen Modell. Basierend hierauf werden KI und p-Wert ermittelt. Hedges' g basiert ebenfalls auf den LS-MW und ist somit auf das Modell angepasst.</i></p> <p><i>Es werden ausschließlich gemeinsame Analysezeitpunkte dargestellt.</i></p> <p><i>Ein LS MD und Hedges' g kleiner als Null bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

### 3.7 EORTC QLQ-OV28 Nebenwirkungen der Chemotherapie

#### EORTC QLQ-OV28 Nebenwirkungen der Chemotherapie: Subgruppenanalyse

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
<b>EORTC QLQ-OV28 Nebenwirkungen der Chemotherapie</b>			
<b>Alter: &lt; 65 Jahre</b>			
Baseline			
n/N (%)	25/115 (22)	35/119 (29)	-
MW (SD)	20,38 (16,013)	24,08 (19,202)	
Absolute Werte zum Studienende			
n/N (%)	3/73 (4)	4/64 (6)	-
MW (SD)	30,56 (27,743)	17,71 (19,946)	
Effekt über Studiendauer			
n	25	35	LS MD -2,19 [-9,685; 5,305] 0,5593  Hedges' g -0,15 [-0,666; 0,362]
LS MW (SE)	1,55 (2,841)	3,74 (2,404)	
95 %-KI	[-4,166; 7,261]	[-1,103; 8,579]	
Veränderung zu Woche 3/4			
n/N (%)	7/113 (6)	20/115 (17)	LS MD -0,22 [-8,451; 8,007]
MW (SD)	2,38 (18,767)	-0,18 (15,273)	
LS MW (SE)	0,54 (3,254)	0,77 (2,516)	
95 %-KI	[-5,944; 7,033]	[-4,275; 5,809]	
Veränderung zu Woche 8/9			
n/N (%)	13/112 (12)	21/108 (19)	LS MD -1,06 [-8,794; 6,679]
MW (SD)	3,21 (19,629)	1,79 (16,903)	
LS MW (SE)	0,97 (3,003)	2,03 (2,410)	
95 %-KI	[-5,044; 6,986]	[-2,821; 6,879]	
Veränderung zu Woche 12			
n/N (%)	6/110 (5)	12/105 (11)	
MW (SD)	4,17 (18,447)	4,51 (12,368)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	1,27 (2,892)	2,91 (2,386)	LS MD -1,64 [-9,191; 5,905]
95 %-KI	[-4,538; 7,076]	[-1,897; 7,720]	
Veränderung zu Woche 15/16			
n/N (%)	6/107 (6)	10/102 (10)	LS MD -2,23 [-9,724; 5,268]
MW (SD)	4,86 (16,545)	-1,25 (11,956)	
LS MW (SE)	1,57 (2,840)	3,79 (2,406)	
95 %-KI	[-4,144; 7,278]	[-1,051; 8,641]	
Veränderung zu Woche 20/21			
n/N (%)	5/101 (5)	6/96 (6)	LS MD -3,06 [-10,726; 4,599]
MW (SD)	9,17 (15,975)	1,39 (6,804)	
LS MW (SE)	1,99 (2,875)	5,06 (2,507)	
95 %-KI	[-3,782; 7,768]	[0,025; 10,088]	
Veränderung zu Woche 24			
n/N (%)	6/99 (6)	5/91 (5)	LS MD -3,65 [-11,589; 4,292]
MW (SD)	-0,79 (19,640)	2,50 (3,727)	
LS MW (SE)	2,29 (2,975)	5,94 (2,624)	
95 %-KI	[-3,667; 8,250]	[0,691; 11,189]	
Veränderung zu Woche 36			
n/N (%)	7/86 (8)	9/79 (11)	LS MD -5,65 [-15,389; 4,080]
MW (SD)	5,36 (11,715)	2,78 (13,010)	
LS MW (SE)	3,31 (3,686)	8,97 (3,243)	
95 %-KI	[-4,003; 10,630]	[2,534; 15,401]	
Veränderung zu Woche 48			
n/N (%)	1/73 (1)	2/64 (3)	LS MD -7,66 [-20,033; 4,713]
MW (SD)	25,00 (NA)	4,17 (5,893)	
LS MW (SE)	4,34 (4,752)	12,00 (4,074)	
95 %-KI	[-5,068; 13,740]	[3,935; 20,057]	
<b>Alter: ≥ 65 Jahre</b>			
Baseline			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n/N (%)	28/103 (27)	22/88 (25)	-
MW (SD)	19,78 (14,893)	22,35 (15,148)	
Absolute Werte zum Studienende			
n/N (%)	0/67 (0)	1/46 (2)	-
MW (SD)	NA (NA)	14,29 (NA)	
Effekt über Studiendauer			
n	28	22	LS MD -7,12 [-15,766; 1,534] 0,1036  Hedges' g -0,46 [-1,029; 0,103]
LS MW (SE)	-4,51 (3,059)	2,60 (2,910)	
95 %-KI	[-10,725; 1,695]	[-3,340; 8,543]	
Veränderung zu Woche 3/4			
n/N (%)	6/100 (6)	10/85 (12)	LS MD -8,92 [-18,717; 0,884]
MW (SD)	-9,72 (16,387)	5,00 (12,699)	
LS MW (SE)	-5,99 (3,707)	2,92 (3,154)	
95 %-KI	[-13,425; 1,435]	[-3,445; 9,288]	
Veränderung zu Woche 8/9			
n/N (%)	8/98 (8)	13/80 (16)	LS MD -8,16 [-17,198; 0,881]
MW (SD)	-1,34 (18,562)	3,11 (14,532)	
LS MW (SE)	-5,37 (3,322)	2,79 (2,956)	
95 %-KI	[-12,069; 1,326]	[-3,228; 8,801]	
Veränderung zu Woche 12			
n/N (%)	2/95 (2)	8/78 (10)	LS MD -7,63 [-16,369; 1,114]
MW (SD)	2,08 (8,839)	7,07 (22,033)	
LS MW (SE)	-4,94 (3,144)	2,69 (2,898)	
95 %-KI	[-11,302; 1,431]	[-3,225; 8,609]	
Veränderung zu Woche 15/16			
n/N (%)	3/92 (3)	6/76 (8)	
MW (SD)	-10,12 (18,757)	10,42 (17,430)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-4,50 (3,057)	2,60 (2,912)	LS MD -7,10 [-15,747; 1,554]
95 %-KI	[-10,707; 1,709]	[-3,347; 8,543]	
Veränderung zu Woche 20/21			
n/N (%)	4/89 (4)	6/69 (9)	LS MD -6,34 [-15,226; 2,548]
MW (SD)	-2,23 (9,869)	12,50 (24,580)	
LS MW (SE)	-3,88 (3,107)	2,46 (3,055)	
95 %-KI	[-10,171; 2,419]	[-3,735; 8,661]	
Veränderung zu Woche 24			
n/N (%)	2/85 (2)	6/64 (9)	LS MD -5,81 [-15,109; 3,493]
MW (SD)	-18,06 (9,821)	12,20 (20,522)	
LS MW (SE)	-3,44 (3,257)	2,37 (3,232)	
95 %-KI	[-10,012; 3,133]	[-4,149; 8,886]	
Veränderung zu Woche 36			
n/N (%)	6/74 (8)	5/55 (9)	LS MD -3,99 [-15,952; 7,975]
MW (SD)	-2,88 (12,282)	6,19 (25,842)	
LS MW (SE)	-1,94 (4,310)	2,04 (4,178)	
95 %-KI	[-10,538; 6,651]	[-6,280; 10,370]	
Veränderung zu Woche 48			
n/N (%)	0/67 (0)	1/46 (2)	LS MD -2,17 [-17,938; 13,601]
MW (SD)	NA (NA)	-28,57 (NA)	
LS MW (SE)	-0,45 (5,811)	1,72 (5,425)	
95 %-KI	[-12,013; 11,117]	[-9,077; 12,518]	
<b>Region: USA</b>			
Baseline			
n/N (%)	13/65 (20)	13/51 (25)	-
MW (SD)	26,01 (18,035)	37,59 (19,934)	
Absolute Werte zum Studienende			
n/N (%)	0/39 (0)	2/27 (7)	-
MW (SD)	NA (NA)	30,06 (22,308)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Effekt über Studiendauer			
n	13	13	LS MD -4,63 [-17,279; 8,013] 0,4486  Hedges' g -0,30 [-1,073; 0,474]
LS MW (SE)	-3,95 (4,878)	0,69 (3,278)	
95 %-KI	[-14,210; 6,318]	[-6,311; 7,686]	
Veränderung zu Woche 3/4			
n/N (%)	4/64 (6)	5/49 (10)	LS MD -6,02 [-21,300; 9,261]
MW (SD)	2,08 (21,651)	0,00 (14,731)	
LS MW (SE)	-6,66 (6,167)	-0,64 (3,760)	
95 %-KI	[-19,403; 6,087]	[-8,407; 7,131]	
Veränderung zu Woche 8/9			
n/N (%)	4/62 (6)	9/46 (20)	LS MD -5,50 [-19,183; 8,189]
MW (SD)	-3,12 (7,116)	0,33 (18,052)	
LS MW (SE)	-5,64 (5,362)	-0,14 (3,458)	
95 %-KI	[-16,857; 5,587]	[-7,401; 7,124]	
Veränderung zu Woche 12			
n/N (%)	0/59 (0)	5/45 (11)	LS MD -5,13 [-18,113; 7,851]
MW (SD)	NA (NA)	2,98 (13,851)	
LS MW (SE)	-4,92 (5,007)	0,21 (3,328)	
95 %-KI	[-15,471; 5,633]	[-6,853; 7,277]	
Veränderung zu Woche 15/16			
n/N (%)	1/56 (2)	3/44 (7)	LS MD -4,76 [-17,427; 7,897]
MW (SD)	-12,50 (NA)	8,33 (11,024)	
LS MW (SE)	-4,20 (4,870)	0,56 (3,277)	
95 %-KI	[-14,469; 6,063]	[-6,432; 7,556]	
Veränderung zu Woche 20/21			
n/N (%)	2/54 (4)	4/40 (10)	
MW (SD)	-6,25 (8,839)	6,25 (17,180)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-3,18 (5,081)	1,06 (3,344)	LS MD -4,24 [-17,158; 8,673]
95 %-KI	[-13,764; 7,403]	[-6,043; 8,166]	
Veränderung zu Woche 24			
n/N (%)	2/53 (4)	2/38 (5)	LS MD -3,88 [-17,471; 9,718]
MW (SD)	-8,63 (5,472)	16,67 (23,570)	
LS MW (SE)	-2,46 (5,488)	1,41 (3,485)	
95 %-KI	[-13,772; 8,843]	[-5,919; 8,742]	
Veränderung zu Woche 36			
n/N (%)	1/43 (2)	6/33 (18)	LS MD -2,62 [-20,994; 15,750]
MW (SD)	16,67 (NA)	0,30 (20,905)	
LS MW (SE)	-0,01 (7,905)	2,61 (4,419)	
95 %-KI	[-16,004; 15,984]	[-6,385; 11,609]	
Veränderung zu Woche 48			
n/N (%)	0/39 (0)	2/27 (7)	LS MD -1,37 [-26,512; 23,778]
MW (SD)	NA (NA)	-14,29 (20,203)	
LS MW (SE)	2,44 (11,055)	3,81 (5,763)	
95 %-KI	[-19,852; 24,741]	[-7,812; 15,435]	
<b>Region: Rest der Welt</b>			
Baseline			
n/N (%)	40/153 (26)	44/156 (28)	-
MW (SD)	18,13 (13,993)	19,22 (14,660)	
Absolute Werte zum Studienende			
n/N (%)	3/101 (3)	3/83 (4)	-
MW (SD)	30,56 (27,743)	8,33 (8,333)	
Effekt über Studiendauer			
n	40	44	LS MD -4,63 [-11,181; 1,931] 0,1636 Hedges' g
LS MW (SE)	-0,20 (2,383)	4,43 (2,271)	
95 %-KI	[-4,955; 4,559]	[-0,110; 8,964]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
			-0,30 [-0,735; 0,127]
Veränderung zu Woche 3/4			
n/N (%)	9/149 (6)	25/151 (17)	LS MD -2,53 [-9,744; 4,693]
MW (SD)	-5,56 (17,180)	1,86 (14,691)	
LS MW (SE)	-0,85 (2,754)	1,68 (2,346)	
95 %-KI	[-6,313; 4,616]	[-2,996; 6,352]	
Veränderung zu Woche 8/9			
n/N (%)	17/148 (11)	25/142 (18)	LS MD -3,45 [-10,166; 3,272]
MW (SD)	2,56 (20,738)	3,00 (15,287)	
LS MW (SE)	-0,56 (2,531)	2,88 (2,238)	
95 %-KI	[-5,599; 4,474]	[-1,589; 7,358]	
Veränderung zu Woche 12			
n/N (%)	8/146 (5)	15/138 (11)	LS MD -4,09 [-10,652; 2,468]
MW (SD)	3,65 (15,973)	6,39 (17,527)	
LS MW (SE)	-0,36 (2,428)	3,73 (2,232)	
95 %-KI	[-5,206; 4,480]	[-0,735; 8,193]	
Veränderung zu Woche 15/16			
n/N (%)	8/143 (6)	13/134 (10)	LS MD -4,74 [-11,306; 1,833]
MW (SD)	1,41 (18,319)	1,92 (15,739)	
LS MW (SE)	-0,16 (2,378)	4,57 (2,284)	
95 %-KI	[-4,912; 4,585]	[0,012; 9,135]	
Veränderung zu Woche 20/21			
n/N (%)	7/136 (5)	8/125 (6)	LS MD -5,66 [-12,530; 1,213]
MW (SD)	7,06 (14,423)	7,29 (19,764)	
LS MW (SE)	0,12 (2,402)	5,78 (2,452)	
95 %-KI	[-4,671; 4,915]	[0,903; 10,658]	
Veränderung zu Woche 24			
n/N (%)	6/131 (5)	9/117 (8)	
MW (SD)	-3,94 (21,950)	5,82 (14,448)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	0,32 (2,485)	6,63 (2,624)	LS MD -6,30 [-13,572; 0,965]
95 %-KI	[-4,626; 5,270]	[1,418; 11,832]	
Veränderung zu Woche 36			
n/N (%)	12/117 (10)	8/101 (8)	LS MD -8,51 [-17,991; 0,962]
MW (SD)	0,30 (11,868)	6,77 (15,739)	
LS MW (SE)	1,01 (3,092)	9,52 (3,448)	
95 %-KI	[-5,112; 7,125]	[2,711; 16,332]	
Veränderung zu Woche 48			
n/N (%)	1/101 (1)	1/83 (1)	LS MD -10,73 [-23,155; 1,704]
MW (SD)	25,00 (NA)	8,33 (NA)	
LS MW (SE)	1,69 (4,008)	12,42 (4,471)	
95 %-KI	[-6,223; 9,606]	[3,589; 21,245]	
<b>Stadium bei der Diagnose: I-III</b>			
Baseline			
n/N (%)	41/141 (29)	41/144 (28)	-
MW (SD)	19,39 (16,070)	22,52 (18,618)	
Absolute Werte zum Studienende			
n/N (%)	1/91 (1)	3/76 (4)	-
MW (SD)	37,50 (NA)	22,82 (20,153)	
Effekt über Studiendauer			
n	41	41	LS MD -1,15 [-7,420; 5,122] 0,7152  Hedges' g -0,08 [-0,513; 0,353]
LS MW (SE)	0,50 (2,311)	1,65 (2,108)	
95 %-KI	[-4,116; 5,117]	[-2,572; 5,871]	
Veränderung zu Woche 3/4			
n/N (%)	11/137 (8)	23/138 (17)	LS MD -0,21 [-7,092; 6,663]
MW (SD)	-5,68 (15,621)	-1,06 (12,713)	
LS MW (SE)	-0,26 (2,648)	-0,04 (2,213)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-5,514; 5,001]	[-4,455; 4,371]	
Veränderung zu Woche 8/9			
n/N (%)	16/136 (12)	27/129 (21)	LS MD -0,60 [-7,076; 5,884]
MW (SD)	5,84 (17,590)	0,57 (14,860)	
LS MW (SE)	0,05 (2,446)	0,65 (2,125)	
95 %-KI	[-4,819; 4,924]	[-3,602; 4,899]	
Veränderung zu Woche 12			
n/N (%)	7/133 (5)	15/128 (12)	LS MD -0,86 [-7,185; 5,459]
MW (SD)	5,95 (15,749)	4,33 (18,318)	
LS MW (SE)	0,27 (2,355)	1,13 (2,100)	
95 %-KI	[-4,431; 4,968]	[-3,073; 5,337]	
Veränderung zu Woche 15/16			
n/N (%)	7/130 (5)	12/125 (10)	LS MD -1,13 [-7,401; 5,140]
MW (SD)	2,98 (19,202)	1,74 (16,898)	
LS MW (SE)	0,48 (2,312)	1,61 (2,107)	
95 %-KI	[-4,134; 5,103]	[-2,603; 5,833]	
Veränderung zu Woche 20/21			
n/N (%)	6/123 (5)	9/116 (8)	LS MD -1,51 [-7,895; 4,872]
MW (SD)	9,03 (12,752)	8,80 (19,922)	
LS MW (SE)	0,79 (2,339)	2,31 (2,170)	
95 %-KI	[-3,874; 5,461]	[-2,031; 6,642]	
Veränderung zu Woche 24			
n/N (%)	5/121 (4)	9/109 (8)	LS MD -1,78 [-8,368; 4,811]
MW (SD)	1,11 (20,280)	11,11 (14,878)	
LS MW (SE)	1,01 (2,417)	2,79 (2,250)	
95 %-KI	[-3,805; 5,825]	[-1,697; 7,274]	
Veränderung zu Woche 36			
n/N (%)	11/105 (10)	13/92 (14)	
MW (SD)	2,22 (13,254)	3,66 (18,354)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	1,75 (2,984)	4,45 (2,699)	LS MD -2,69 [-10,651; 5,263]
95 %-KI	[-4,155; 7,657]	[-0,898; 9,789]	
Veränderung zu Woche 48			
n/N (%)	1/91 (1)	3/76 (4)	LS MD -3,61 [-13,618; 6,399]
MW (SD)	25,00 (NA)	-6,75 (19,355)	
LS MW (SE)	2,49 (3,839)	6,10 (3,328)	
95 %-KI	[-5,088; 10,073]	[-0,470; 12,674]	
<b>Stadium bei der Diagnose: IV</b>			
Baseline			
n/N (%)	11/72 (15)	16/60 (27)	-
MW (SD)	23,27 (12,762)	25,71 (15,085)	
Absolute Werte zum Studienende			
n/N (%)	2/46 (4)	2/33 (6)	-
MW (SD)	27,08 (38,302)	8,33 (11,785)	
Effekt über Studiendauer			
n	11	16	LS MD -13,36 [-26,370; -0,349] 0,0448  Hedges' g -0,82 [-1,625; -0,019]
LS MW (SE)	-7,08 (4,764)	6,28 (3,934)	
95 %-KI	[-17,096; 2,930]	[-1,989; 14,542]	
Veränderung zu Woche 3/4			
n/N (%)	2/71 (3)	7/59 (12)	LS MD -8,81 [-26,301; 8,680]
MW (SD)	10,42 (32,409)	10,12 (17,490)	
LS MW (SE)	-7,31 (6,642)	1,50 (4,862)	
95 %-KI	[-20,862; 6,238]	[-8,440; 11,437]	
Veränderung zu Woche 8/9			
n/N (%)	5/69 (7)	7/56 (12)	LS MD -11,05 [-25,493; 3,402]
MW (SD)	-12,50 (17,430)	8,93 (18,854)	
LS MW (SE)	-7,20 (5,490)	3,85 (4,049)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-18,544; 4,145]	[-4,620; 12,312]	
Veränderung zu Woche 12			
n/N (%)	1/67 (1)	5/52 (10)	LS MD -12,61 [-25,861; 0,641]
MW (SD)	-12,50 (NA)	9,17 (9,033)	
LS MW (SE)	-7,12 (4,932)	5,49 (3,878)	
95 %-KI	[-17,438; 3,196]	[-2,687; 13,665]	
Veränderung zu Woche 15/16			
n/N (%)	2/64 (3)	4/50 (8)	LS MD -14,17 [-27,186; -1,163]
MW (SD)	-11,01 (2,104)	7,29 (5,243)	
LS MW (SE)	-7,04 (4,667)	7,13 (4,092)	
95 %-KI	[-16,876; 2,791]	[-1,398; 15,663]	
Veränderung zu Woche 20/21			
n/N (%)	3/62 (5)	3/46 (7)	LS MD -16,41 [-30,823; -1,996]
MW (SD)	-5,75 (13,261)	1,39 (12,729)	
LS MW (SE)	-6,93 (4,879)	9,48 (4,949)	
95 %-KI	[-17,110; 3,251]	[-0,613; 19,573]	
Veränderung zu Woche 24			
n/N (%)	3/59 (5)	2/44 (5)	LS MD -17,97 [-34,422; -1,526]
MW (SD)	-15,48 (12,472)	-7,14 (10,102)	
LS MW (SE)	-6,85 (5,403)	11,12 (5,799)	
95 %-KI	[-17,981; 4,279]	[-0,621; 22,867]	
Veränderung zu Woche 36			
n/N (%)	2/52 (4)	1/41 (2)	LS MD -23,34 [-50,095; 3,419]
MW (SD)	-2,08 (2,946)	8,33 (NA)	
LS MW (SE)	-6,58 (8,513)	16,76 (9,391)	
95 %-KI	[-23,800; 10,638]	[-2,220; 35,735]	
Veränderung zu Woche 48			
n/N (%)	0/46 (0)	0/33 (0)	
MW (SD)	NA (NA)	NA (NA)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-6,31 (12,417)	22,39 (13,369)	LS MD -28,70 [-67,595; 10,190]
95 %-KI	[-31,388; 18,765]	[-4,675; 49,457]	
<b>BRCA Status: Positiv</b>			
Baseline			
n/N (%)	8/27 (30)	9/35 (26)	-
MW (SD)	20,68 (19,483)	20,37 (15,790)	
Absolute Werte zum Studienende			
n/N (%)	1/19 (5)	0/15 (0)	-
MW (SD)	54,17 (NA)	NA (NA)	
Effekt über Studiendauer			
n	8	9	LS MD -9,83 [-31,571; 11,917] 0,3372  Hedges' g -0,47 [-1,436; 0,502]
LS MW (SE)	0,57 (7,922)	10,39 (5,854)	
95 %-KI	[-16,973; 18,105]	[-2,840; 23,626]	
Veränderung zu Woche 3/4			
n/N (%)	0/27 (0)	6/35 (17)	LS MD -2,45 [-31,590; 26,699]
MW (SD)	NA (NA)	7,64 (20,141)	
LS MW (SE)	2,81 (12,468)	5,25 (5,983)	
95 %-KI	[-23,516; 29,134]	[-8,087; 18,597]	
Veränderung zu Woche 8/9			
n/N (%)	2/26 (8)	7/30 (23)	LS MD -5,83 [-30,618; 18,965]
MW (SD)	4,17 (11,785)	4,76 (18,854)	
LS MW (SE)	1,78 (9,946)	7,61 (5,838)	
95 %-KI	[-19,578; 23,142]	[-5,601; 20,818]	
Veränderung zu Woche 12			
n/N (%)	1/26 (4)	5/30 (17)	LS MD -8,19 [-30,853; 14,466]
MW (SD)	-4,17 (NA)	18,33 (23,680)	
LS MW (SE)	1,06 (8,574)	9,26 (5,823)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-17,683; 19,808]	[-3,946; 22,458]	
Veränderung zu Woche 15/16			
n/N (%)	2/26 (8)	3/29 (10)	LS MD -10,56 [-32,055; 10,935]
MW (SD)	-8,93 (0,842)	18,06 (20,554)	
LS MW (SE)	0,34 (7,729)	10,90 (5,879)	
95 %-KI	[-16,841; 17,528]	[-2,354; 24,161]	
Veränderung zu Woche 20/21			
n/N (%)	2/25 (8)	2/25 (8)	LS MD -13,94 [-35,647; 7,765]
MW (SD)	-7,14 (10,102)	27,08 (38,302)	
LS MW (SE)	-0,68 (7,763)	13,26 (6,079)	
95 %-KI	[-17,877; 16,509]	[-0,212; 26,726]	
Veränderung zu Woche 24			
n/N (%)	0/25 (0)	3/24 (12)	LS MD -16,31 [-39,473; 6,857]
MW (SD)	NA (NA)	15,28 (19,691)	
LS MW (SE)	-1,40 (8,648)	14,90 (6,296)	
95 %-KI	[-20,189; 17,382]	[1,170; 28,638]	
Veränderung zu Woche 36			
n/N (%)	1/21 (5)	3/20 (15)	LS MD -24,42 [-58,454; 9,610]
MW (SD)	-4,76 (NA)	16,67 (22,048)	
LS MW (SE)	-3,87 (14,595)	20,55 (7,431)	
95 %-KI	[-34,359; 26,621]	[5,056; 36,050]	
Veränderung zu Woche 48			
n/N (%)	0/19 (0)	0/15 (0)	LS MD -32,54 [-81,521; 16,448]
MW (SD)	NA (NA)	NA (NA)	
LS MW (SE)	-6,33 (22,095)	26,20 (8,980)	
95 %-KI	[-52,111; 39,441]	[7,817; 44,586]	
<b>BRCA Status: Negativ/Unbekannt</b>			
Baseline			
n/N (%)	45/191 (24)	48/172 (28)	-

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
MW (SD)	19,96 (14,683)	23,98 (18,044)	
Absolute Werte zum Studienende			
n/N (%)	2/121 (2)	5/95 (5)	-
MW (SD)	18,75 (26,517)	17,02 (17,342)	
Effekt über Studiendauer			
n	45	48	LS MD -2,82 [-8,558; 2,913] 0,3297  Hedges' g -0,20 [-0,611; 0,205]
LS MW (SE)	-1,04 (2,116)	1,78 (1,931)	
95 %-KI	[-5,257; 3,180]	[-2,071; 5,639]	
Veränderung zu Woche 3/4			
n/N (%)	13/186 (7)	24/165 (15)	LS MD -2,84 [-9,257; 3,580]
MW (SD)	-3,21 (18,095)	0,02 (12,778)	
LS MW (SE)	-2,51 (2,476)	0,33 (2,065)	
95 %-KI	[-7,414; 2,399]	[-3,773; 4,436]	
Veränderung zu Woche 8/9			
n/N (%)	19/184 (10)	27/158 (17)	LS MD -2,83 [-8,794; 3,130]
MW (SD)	1,19 (19,696)	1,65 (15,287)	
LS MW (SE)	-1,89 (2,258)	0,94 (1,949)	
95 %-KI	[-6,384; 2,594]	[-2,950; 4,824]	
Veränderung zu Woche 12			
n/N (%)	7/179 (4)	15/153 (10)	LS MD -2,83 [-8,612; 2,958]
MW (SD)	4,76 (16,913)	1,27 (11,267)	
LS MW (SE)	-1,47 (2,161)	1,36 (1,918)	
95 %-KI	[-5,770; 2,837]	[-2,470; 5,191]	
Veränderung zu Woche 15/16			
n/N (%)	7/173 (4)	13/149 (9)	LS MD -2,82 [-8,558; 2,914]
MW (SD)	2,38 (19,670)	-0,32 (11,719)	
LS MW (SE)	-1,04 (2,116)	1,78 (1,931)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-5,256; 3,181]	[-2,070; 5,640]	
Veränderung zu Woche 20/21			
n/N (%)	7/165 (4)	10/140 (7)	LS MD -2,82 [-8,709; 3,077]
MW (SD)	7,31 (13,992)	2,92 (11,461)	
LS MW (SE)	-0,43 (2,150)	2,39 (2,023)	
95 %-KI	[-4,707; 3,856]	[-1,638; 6,419]	
Veränderung zu Woche 24			
n/N (%)	8/159 (5)	8/131 (6)	LS MD -2,81 [-8,964; 3,343]
MW (SD)	-5,11 (18,792)	4,99 (14,200)	
LS MW (SE)	0,00 (2,239)	2,81 (2,134)	
95 %-KI	[-4,447; 4,454]	[-1,425; 7,053]	
Veränderung zu Woche 36			
n/N (%)	12/139 (9)	11/114 (10)	LS MD -2,79 [-10,578; 4,988]
MW (SD)	2,08 (12,626)	0,54 (15,741)	
LS MW (SE)	1,47 (2,859)	4,27 (2,723)	
95 %-KI	[-4,177; 7,123]	[-1,112; 9,648]	
Veränderung zu Woche 48			
n/N (%)	1/121 (1)	3/95 (3)	LS MD -2,78 [-12,880; 7,323]
MW (SD)	25,00 (NA)	-6,75 (19,355)	
LS MW (SE)	2,94 (3,762)	5,72 (3,503)	
95 %-KI	[-4,481; 10,367]	[-1,191; 12,634]	
<b>Baseline ECOG PS: 0</b>			
Baseline			
n/N (%)	28/128 (22)	37/113 (33)	-
MW (SD)	16,28 (13,205)	24,47 (16,502)	
Absolute Werte zum Studienende			
n/N (%)	2/87 (2)	3/72 (4)	-
MW (SD)	45,83 (11,785)	20,04 (23,452)	
Effekt über Studiendauer			

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
n	28	37	LS MD -3,38 [-10,877; 4,108] 0,3677  Hedges' g -0,23 [-0,725; 0,261]
LS MW (SE)	-0,24 (2,849)	3,14 (2,284)	
95 %-KI	[-5,978; 5,494]	[-1,465; 7,749]	
Veränderung zu Woche 3/4			
n/N (%)	6/127 (5)	18/111 (16)	LS MD -1,55 [-9,891; 6,789]
MW (SD)	2,08 (9,410)	2,58 (13,649)	
LS MW (SE)	0,78 (3,338)	2,33 (2,446)	
95 %-KI	[-5,879; 7,434]	[-2,571; 7,228]	
Veränderung zu Woche 8/9			
n/N (%)	11/126 (9)	19/108 (18)	LS MD -2,30 [-10,076; 5,474]
MW (SD)	8,71 (17,820)	1,91 (14,508)	
LS MW (SE)	0,36 (3,057)	2,66 (2,304)	
95 %-KI	[-5,764; 6,484]	[-1,979; 7,302]	
Veränderung zu Woche 12			
n/N (%)	3/122 (2)	12/108 (11)	LS MD -2,83 [-10,382; 4,729]
MW (SD)	16,67 (18,162)	1,59 (12,689)	
LS MW (SE)	0,07 (2,924)	2,89 (2,266)	
95 %-KI	[-5,807; 5,943]	[-1,679; 7,468]	
Veränderung zu Woche 15/16			
n/N (%)	6/120 (5)	8/105 (8)	LS MD -3,35 [-10,843; 4,140]
MW (SD)	-0,00 (21,731)	-1,04 (15,228)	
LS MW (SE)	-0,22 (2,851)	3,13 (2,281)	
95 %-KI	[-5,964; 5,517]	[-1,475; 7,729]	
Veränderung zu Woche 20/21			
n/N (%)	6/117 (5)	7/101 (7)	LS MD -4,10 [-11,776; 3,573]
MW (SD)	7,64 (14,771)	3,57 (13,909)	
LS MW (SE)	-0,64 (2,862)	3,46 (2,393)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-6,398; 5,116]	[-1,347; 8,268]	
Veränderung zu Woche 24			
n/N (%)	5/112 (4)	6/96 (6)	LS MD -4,63 [-12,614; 3,361]
MW (SD)	3,61 (16,713)	6,65 (16,403)	
LS MW (SE)	-0,93 (2,948)	3,69 (2,528)	
95 %-KI	[-6,849; 4,982]	[-1,365; 8,751]	
Veränderung zu Woche 36			
n/N (%)	7/99 (7)	9/87 (10)	LS MD -6,43 [-16,423; 3,571]
MW (SD)	2,89 (10,750)	-0,73 (17,282)	
LS MW (SE)	-1,93 (3,645)	4,49 (3,243)	
95 %-KI	[-9,175; 5,307]	[-1,940; 10,924]	
Veränderung zu Woche 48			
n/N (%)	1/87 (1)	2/72 (3)	LS MD -8,23 [-21,137; 4,684]
MW (SD)	25,00 (NA)	-14,29 (20,203)	
LS MW (SE)	-2,94 (4,726)	5,29 (4,185)	
95 %-KI	[-12,294; 6,423]	[-2,995; 13,577]	
<b>Baseline ECOG PS: 1</b>			
Baseline			
n/N (%)	25/90 (28)	20/91 (22)	-
MW (SD)	24,31 (16,567)	21,46 (19,835)	
Absolute Werte zum Studienende			
n/N (%)	1/53 (2)	2/37 (5)	-
MW (SD)	0,00 (NA)	12,50 (5,893)	
Effekt über Studiendauer			
n	25	20	LS MD -6,74 [-15,587; 2,103] 0,1309
LS MW (SE)	-2,56 (3,170)	4,18 (3,045)	
95 %-KI	[-8,991; 3,865]	[-2,006; 10,364]	Hedges' g -0,44 [-1,040; 0,151]



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	7/86 (8)	12/87 (14)	LS MD -4,75 [-14,345; 4,836]
MW (SD)	-7,74 (23,002)	0,00 (16,088)	
LS MW (SE)	-4,85 (3,621)	-0,09 (3,146)	
95 %-KI	[-12,108; 2,413]	[-6,450; 6,264]	
Veränderung zu Woche 8/9			
n/N (%)	10/84 (12)	15/78 (19)	LS MD -5,64 [-14,636; 3,365]
MW (SD)	-6,49 (17,486)	2,78 (17,864)	
LS MW (SE)	-3,83 (3,313)	1,80 (3,031)	
95 %-KI	[-10,523; 2,853]	[-4,355; 7,957]	
Veränderung zu Woche 12			
n/N (%)	5/83 (6)	8/74 (11)	LS MD -6,25 [-15,083; 2,579]
MW (SD)	-4,17 (8,839)	11,46 (20,260)	
LS MW (SE)	-3,13 (3,197)	3,13 (3,017)	
95 %-KI	[-9,602; 3,350]	[-3,007; 9,260]	
Veränderung zu Woche 15/16			
n/N (%)	3/79 (4)	8/72 (11)	LS MD -6,87 [-15,740; 2,002]
MW (SD)	-0,40 (8,935)	7,29 (14,217)	
LS MW (SE)	-2,42 (3,173)	4,45 (3,058)	
95 %-KI	[-8,850; 4,016]	[-1,756; 10,660]	
Veränderung zu Woche 20/21			
n/N (%)	3/73 (4)	5/63 (8)	LS MD -7,75 [-17,034; 1,534]
MW (SD)	-2,98 (11,949)	11,67 (23,827)	
LS MW (SE)	-1,40 (3,302)	6,35 (3,208)	
95 %-KI	[-8,070; 5,262]	[-0,132; 12,825]	
Veränderung zu Woche 24			
n/N (%)	3/72 (4)	5/58 (9)	LS MD -8,37 [-18,174; 1,441]
MW (SD)	-19,64 (13,055)	9,17 (16,245)	
LS MW (SE)	-0,69 (3,496)	7,67 (3,370)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-7,720; 6,330]	[0,896; 14,448]	
Veränderung zu Woche 36			
n/N (%)	6/61 (10)	5/46 (11)	LS MD -10,48 [-23,189; 2,226]
MW (SD)	-0,00 (14,672)	12,50 (16,667)	
LS MW (SE)	1,74 (4,620)	12,22 (4,193)	
95 %-KI	[-7,455; 10,927]	[3,871; 20,563]	
Veränderung zu Woche 48			
n/N (%)	0/53 (0)	1/37 (3)	LS MD -12,60 [-29,199; 4,007]
MW (SD)	NA (NA)	8,33 (NA)	
LS MW (SE)	4,17 (6,131)	16,76 (5,269)	
95 %-KI	[-8,014; 16,348]	[6,294; 27,231]	
<b>Anzahl vorheriger Therapielinien: 1</b>			
Baseline			
n/N (%)	5/31 (16)	9/29 (31)	-
MW (SD)	17,26 (18,653)	19,31 (16,225)	
Absolute Werte zum Studienende			
n/N (%)	0/22 (0)	0/14 (0)	-
MW (SD)	NA (NA)	NA (NA)	
Effekt über Studiendauer			
n	5	9	LS MD 3,81 [-7,892; 15,512] 0,4757  Hedges' g 0,41 [-0,696; 1,519]
LS MW (SE)	4,73 (4,155)	0,92 (2,777)	
95 %-KI	[-4,532; 13,992]	[-5,892; 7,732]	
Veränderung zu Woche 3/4			
n/N (%)	1/31 (3)	4/29 (14)	LS MD 5,82 [-8,786; 20,425]
MW (SD)	8,33 (NA)	-5,21 (17,800)	
LS MW (SE)	3,87 (5,883)	-1,95 (3,259)	
95 %-KI	[-8,672; 16,411]	[-8,979; 5,079]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	2/31 (6)	4/26 (15)	LS MD 5,08 [-7,883; 18,038]
MW (SD)	9,23 (7,155)	2,08 (12,955)	
LS MW (SE)	4,19 (5,049)	-0,89 (2,860)	
95 %-KI	[-6,753; 15,127]	[-7,453; 5,672]	
Veränderung zu Woche 12			
n/N (%)	0/31 (0)	4/24 (17)	LS MD 4,56 [-7,645; 16,761]
MW (SD)	NA (NA)	5,21 (10,958)	
LS MW (SE)	4,41 (4,582)	-0,15 (2,724)	
95 %-KI	[-5,658; 14,477]	[-6,714; 6,417]	
Veränderung zu Woche 15/16			
n/N (%)	1/31 (3)	3/22 (14)	LS MD 4,04 [-7,747; 15,824]
MW (SD)	0,00 (NA)	0,00 (0,000)	
LS MW (SE)	4,63 (4,250)	0,59 (2,730)	
95 %-KI	[-4,815; 14,079]	[-6,130; 7,317]	
Veränderung zu Woche 20/21			
n/N (%)	1/30 (3)	3/22 (14)	LS MD 3,30 [-8,438; 15,031]
MW (SD)	16,67 (NA)	1,39 (2,406)	
LS MW (SE)	4,95 (4,071)	1,65 (2,976)	
95 %-KI	[-4,106; 14,005]	[-5,408; 8,715]	
Veränderung zu Woche 24			
n/N (%)	0/30 (0)	4/20 (20)	LS MD 2,78 [-9,336; 14,891]
MW (SD)	NA (NA)	0,60 (12,655)	
LS MW (SE)	5,17 (4,175)	2,39 (3,285)	
95 %-KI	[-3,991; 14,336]	[-5,063; 9,853]	
Veränderung zu Woche 36			
n/N (%)	3/26 (12)	2/18 (11)	LS MD 1,00 [-15,080; 17,073]
MW (SD)	6,94 (8,674)	-2,08 (8,839)	
LS MW (SE)	5,94 (5,675)	4,94 (4,835)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-5,950; 17,820]	[-5,183; 15,060]	
Veränderung zu Woche 48			
n/N (%)	0/22 (0)	0/14 (0)	LS MD -0,78 [-23,146; 21,578]
MW (SD)	NA (NA)	NA (NA)	
LS MW (SE)	6,70 (8,082)	7,48 (6,722)	
95 %-KI	[-10,021; 23,417]	[-6,373; 21,337]	
<b>Anzahl vorheriger Therapielinien: 2</b>			
Baseline			
n/N (%)	23/89 (26)	20/83 (24)	-
MW (SD)	18,03 (12,788)	20,00 (17,863)	
Absolute Werte zum Studienende			
n/N (%)	2/59 (3)	1/50 (2)	-
MW (SD)	45,83 (11,785)	16,67 (NA)	
Effekt über Studiendauer			
n	23	20	LS MD -8,85 [-18,141; 0,446] 0,0613  Hedges' g -0,59 [-1,198; 0,028]
LS MW (SE)	-2,55 (2,981)	6,30 (3,453)	
95 %-KI	[-8,618; 3,522]	[-0,740; 13,338]	
Veränderung zu Woche 3/4			
n/N (%)	8/86 (9)	9/80 (11)	LS MD -9,34 [-19,577; 0,892]
MW (SD)	-2,60 (17,098)	10,19 (13,837)	
LS MW (SE)	-4,16 (3,522)	5,18 (3,646)	
95 %-KI	[-11,232; 2,912]	[-2,181; 12,546]	
Veränderung zu Woche 8/9			
n/N (%)	9/85 (11)	12/77 (16)	LS MD -9,12 [-18,619; 0,377]
MW (SD)	-0,00 (21,550)	2,78 (17,707)	
LS MW (SE)	-3,44 (3,191)	5,68 (3,413)	
95 %-KI	[-9,892; 3,011]	[-1,276; 12,638]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	4/83 (5)	6/75 (8)	LS MD -8,97 [-18,249; 0,316]
MW (SD)	0,00 (19,837)	11,11 (24,674)	
LS MW (SE)	-2,94 (3,042)	6,03 (3,389)	
95 %-KI	[-9,116; 3,243]	[-0,894; 12,953]	
Veränderung zu Woche 15/16			
n/N (%)	4/80 (5)	4/74 (5)	LS MD -8,81 [-18,138; 0,514]
MW (SD)	-2,38 (15,575)	13,54 (20,799)	
LS MW (SE)	-2,43 (2,973)	6,38 (3,485)	
95 %-KI	[-8,488; 3,622]	[-0,718; 13,475]	
Veränderung zu Woche 20/21			
n/N (%)	6/78 (8)	4/68 (6)	LS MD -8,59 [-18,419; 1,238]
MW (SD)	1,98 (15,988)	14,58 (27,743)	
LS MW (SE)	-1,71 (3,025)	6,88 (3,809)	
95 %-KI	[-7,858; 4,430]	[-0,807; 14,560]	
Veränderung zu Woche 24			
n/N (%)	7/74 (9)	3/65 (5)	LS MD -8,44 [-18,904; 2,032]
MW (SD)	-8,22 (17,936)	13,89 (20,554)	
LS MW (SE)	-1,21 (3,161)	7,23 (4,142)	
95 %-KI	[-7,600; 5,180]	[-1,081; 15,532]	
Veränderung zu Woche 36			
n/N (%)	4/65 (6)	4/58 (7)	LS MD -7,90 [-21,883; 6,073]
MW (SD)	5,06 (13,904)	5,21 (29,142)	
LS MW (SE)	0,52 (4,101)	8,42 (5,696)	
95 %-KI	[-7,664; 8,697]	[-2,917; 19,759]	
Veränderung zu Woche 48			
n/N (%)	1/59 (2)	0/50 (0)	LS MD -7,37 [-25,977; 11,228]
MW (SD)	25,00 (NA)	NA (NA)	
LS MW (SE)	2,24 (5,452)	9,62 (7,573)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-8,610; 13,096]	[-5,470; 24,704]	
<b>Anzahl vorheriger Therapielinien: 3</b>			
Baseline			
n/N (%)	25/98 (26)	28/95 (29)	-
MW (SD)	22,50 (16,925)	27,17 (17,688)	
Absolute Werte zum Studienende			
n/N (%)	1/59 (2)	4/46 (9)	-
MW (SD)	0,00 (NA)	17,11 (20,023)	
Effekt über Studiendauer			
n	25	28	LS MD -2,95 [-11,985; 6,086] 0,5120  Hedges' g -0,18 [-0,724; 0,357]
LS MW (SE)	-1,01 (3,574)	1,94 (2,612)	
95 %-KI	[-8,247; 6,233]	[-3,367; 7,253]	
Veränderung zu Woche 3/4			
n/N (%)	4/96 (4)	17/91 (19)	LS MD -0,90 [-10,785; 8,982]
MW (SD)	-7,29 (23,662)	-1,44 (12,685)	
LS MW (SE)	-0,97 (4,039)	-0,07 (2,764)	
95 %-KI	[-9,064; 7,127]	[-5,643; 5,509]	
Veränderung zu Woche 8/9			
n/N (%)	10/94 (11)	18/85 (21)	LS MD -1,77 [-11,076; 7,535]
MW (SD)	1,25 (18,947)	2,02 (15,915)	
LS MW (SE)	-0,98 (3,737)	0,79 (2,643)	
95 %-KI	[-8,520; 6,550]	[-4,577; 6,148]	
Veränderung zu Woche 12			
n/N (%)	4/91 (4)	10/84 (12)	LS MD -2,38 [-11,469; 6,710]
MW (SD)	7,29 (12,899)	2,32 (12,550)	
LS MW (SE)	-1,00 (3,614)	1,38 (2,607)	
95 %-KI	[-8,308; 6,316]	[-3,918; 6,684]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	4/88 (5)	9/82 (11)	LS MD -2,99 [-12,024; 6,049]
MW (SD)	2,08 (24,176)	-0,46 (13,412)	
LS MW (SE)	-1,01 (3,574)	1,98 (2,613)	
95 %-KI	[-8,248; 6,232]	[-3,333; 7,293]	
Veränderung zu Woche 20/21			
n/N (%)	2/82 (2)	5/75 (7)	LS MD -3,86 [-13,103; 5,390]
MW (SD)	4,17 (11,785)	4,17 (15,309)	
LS MW (SE)	-1,02 (3,663)	2,83 (2,694)	
95 %-KI	[-8,426; 6,378]	[-2,624; 8,289]	
Veränderung zu Woche 24			
n/N (%)	1/80 (1)	4/70 (6)	LS MD -4,47 [-14,052; 5,122]
MW (SD)	16,67 (NA)	10,42 (15,775)	
LS MW (SE)	-1,04 (3,823)	3,43 (2,797)	
95 %-KI	[-8,730; 6,659]	[-2,214; 9,072]	
Veränderung zu Woche 36			
n/N (%)	6/69 (9)	8/58 (14)	LS MD -6,55 [-18,315; 5,214]
MW (SD)	-3,47 (12,477)	4,91 (13,890)	
LS MW (SE)	-1,07 (4,832)	5,48 (3,381)	
95 %-KI	[-10,692; 8,543]	[-1,264; 12,217]	
Veränderung zu Woche 48			
n/N (%)	0/59 (0)	3/46 (7)	LS MD -8,64 [-23,606; 6,332]
MW (SD)	NA (NA)	-6,75 (19,355)	
LS MW (SE)	-1,11 (6,267)	7,52 (4,198)	
95 %-KI	[-13,551; 11,323]	[-0,811; 15,857]	
<b>Vorherige Verabreichung von Bevacizumab: Ja</b>			
Baseline			
n/N (%)	31/134 (23)	35/132 (27)	-
MW (SD)	16,95 (13,388)	25,27 (18,016)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	1/79 (1)	2/62 (3)	-
MW (SD)	37,50 (NA)	31,25 (20,624)	
Effekt über Studiendauer			
n	31	35	LS MD -2,50 [-10,169; 5,169] 0,5151  Hedges' g -0,16 [-0,647; 0,322]
LS MW (SE)	1,71 (2,849)	4,21 (2,465)	
95 %-KI	[-4,020; 7,444]	[-0,744; 9,168]	
Veränderung zu Woche 3/4			
n/N (%)	8/130 (6)	17/127 (13)	LS MD -0,59 [-9,037; 7,853]
MW (SD)	-0,00 (21,478)	2,49 (15,529)	
LS MW (SE)	1,04 (3,278)	1,63 (2,604)	
95 %-KI	[-5,497; 7,573]	[-3,578; 6,838]	
Veränderung zu Woche 8/9			
n/N (%)	11/130 (8)	20/119 (17)	LS MD -1,40 [-9,308; 6,505]
MW (SD)	6,98 (19,270)	2,71 (16,461)	
LS MW (SE)	1,32 (3,031)	2,73 (2,447)	
95 %-KI	[-4,745; 7,393]	[-2,195; 7,647]	
Veränderung zu Woche 12			
n/N (%)	5/126 (4)	9/114 (8)	LS MD -1,97 [-9,679; 5,741]
MW (SD)	10,83 (15,756)	5,09 (9,722)	
LS MW (SE)	1,52 (2,913)	3,49 (2,422)	
95 %-KI	[-4,325; 7,374]	[-1,383; 8,371]	
Veränderung zu Woche 15/16			
n/N (%)	6/122 (5)	7/112 (6)	LS MD -2,54 [-10,207; 5,135]
MW (SD)	4,66 (17,551)	4,17 (9,001)	
LS MW (SE)	1,73 (2,847)	4,26 (2,470)	
95 %-KI	[-4,002; 7,452]	[-0,704; 9,227]	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	8/114 (7)	5/103 (5)	LS MD -3,35 [-11,239; 4,547]
MW (SD)	2,53 (14,264)	2,50 (16,298)	
LS MW (SE)	2,01 (2,848)	5,36 (2,655)	
95 %-KI	[-3,717; 7,740]	[0,048; 10,668]	
Veränderung zu Woche 24			
n/N (%)	4/109 (4)	4/95 (4)	LS MD -3,91 [-12,146; 4,320]
MW (SD)	6,10 (17,633)	11,46 (14,975)	
LS MW (SE)	2,21 (2,916)	6,13 (2,853)	
95 %-KI	[-3,641; 8,065]	[0,439; 11,811]	
Veränderung zu Woche 36			
n/N (%)	9/93 (10)	7/79 (9)	LS MD -5,86 [-16,182; 4,466]
MW (SD)	3,17 (14,289)	2,98 (17,794)	
LS MW (SE)	2,90 (3,504)	8,76 (3,819)	
95 %-KI	[-4,065; 9,864]	[1,190; 16,323]	
Veränderung zu Woche 48			
n/N (%)	1/79 (1)	1/62 (2)	LS MD -7,80 [-21,108; 5,504]
MW (SD)	25,00 (NA)	0,00 (NA)	
LS MW (SE)	3,59 (4,450)	11,39 (5,019)	
95 %-KI	[-5,229; 12,401]	[1,444; 21,332]	
<b>Vorherige Verabreichung von Bevacizumab: Nein</b>			
Baseline			
n/N (%)	22/84 (26)	22/75 (29)	-
MW (SD)	24,45 (16,970)	20,45 (16,968)	
Absolute Werte zum Studienende			
n/N (%)	2/61 (3)	3/48 (6)	-
MW (SD)	27,08 (38,302)	7,54 (7,176)	
Effekt über Studiendauer			
n	22	22	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
LS MW (SE)	-4,63 (3,035)	1,29 (2,715)	LS MD -5,92 [-14,155; 2,319] 0,1532  Hedges' g -0,43 [-1,029; 0,168]
95 %-KI	[-10,792; 1,528]	[-4,268; 6,840]	
Veränderung zu Woche 3/4			
n/N (%)	5/83 (6)	13/73 (18)	LS MD -8,71 [-18,306; 0,880]
MW (SD)	-8,33 (11,024)	0,32 (13,444)	
LS MW (SE)	-7,75 (3,815)	0,97 (2,884)	
95 %-KI	[-15,393; -0,102]	[-4,877; 6,808]	
Veränderung zu Woche 8/9			
n/N (%)	10/80 (12)	14/69 (20)	LS MD -7,53 [-16,234; 1,165]
MW (SD)	-4,58 (17,397)	1,70 (15,457)	
LS MW (SE)	-6,43 (3,330)	1,10 (2,752)	
95 %-KI	[-13,152; 0,284]	[-4,511; 6,713]	
Veränderung zu Woche 12			
n/N (%)	3/79 (4)	11/69 (16)	LS MD -6,71 [-15,053; 1,635]
MW (SD)	-8,33 (7,217)	5,90 (20,863)	
LS MW (SE)	-5,51 (3,117)	1,20 (2,711)	
95 %-KI	[-11,830; 0,802]	[-4,349; 6,740]	
Veränderung zu Woche 15/16			
n/N (%)	3/77 (4)	9/66 (14)	LS MD -5,88 [-14,122; 2,353]
MW (SD)	-9,72 (16,839)	2,31 (18,763)	
LS MW (SE)	-4,59 (3,035)	1,29 (2,716)	
95 %-KI	[-10,753; 1,564]	[-4,266; 6,846]	
Veränderung zu Woche 20/21			
n/N (%)	1/76 (1)	7/62 (11)	LS MD -4,71 [-13,236; 3,825]
MW (SD)	16,67 (NA)	10,12 (19,962)	
LS MW (SE)	-3,28 (3,160)	1,43 (2,801)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-9,667; 3,106]	[-4,280; 7,131]	
Veränderung zu Woche 24			
n/N (%)	4/75 (5)	7/60 (12)	LS MD -3,88 [-12,909; 5,148]
MW (SD)	-16,32 (13,340)	5,70 (16,638)	
LS MW (SE)	-2,36 (3,402)	1,52 (2,912)	
95 %-KI	[-9,203; 4,482]	[-4,382; 7,422]	
Veränderung zu Woche 36			
n/N (%)	4/67 (6)	7/55 (13)	LS MD -1,05 [-13,141; 11,037]
MW (SD)	-2,08 (5,379)	5,02 (18,923)	
LS MW (SE)	0,79 (4,858)	1,84 (3,539)	
95 %-KI	[-8,877; 10,463]	[-5,226; 8,915]	
Veränderung zu Woche 48			
n/N (%)	0/61 (0)	2/48 (4)	LS MD 1,78 [-14,501; 18,055]
MW (SD)	NA (NA)	-10,12 (26,096)	
LS MW (SE)	3,95 (6,766)	2,17 (4,416)	
95 %-KI	[-9,495; 17,387]	[-6,606; 10,944]	
<b>Letztes Platin-freies Intervall: ≤ 3 Monate</b>			
Baseline			
n/N (%)	20/83 (24)	27/91 (30)	-
MW (SD)	22,53 (14,671)	26,48 (14,839)	
Absolute Werte zum Studienende			
n/N (%)	2/55 (4)	4/39 (10)	-
MW (SD)	18,75 (26,517)	19,20 (19,223)	
Effekt über Studiendauer			
n	20	27	LS MD -8,50 [-18,087; 1,078] 0,0801
LS MW (SE)	-2,48 (3,616)	6,02 (2,971)	
95 %-KI	[-9,840; 4,881]	[-0,008; 12,058]	Hedges' g -0,53 [-1,120; 0,058]

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 3/4			
n/N (%)	7/82 (9)	13/86 (15)	LS MD -8,21 [-18,562; 2,135]
MW (SD)	-8,33 (18,634)	4,85 (15,007)	
LS MW (SE)	-3,90 (4,027)	4,32 (3,170)	
95 %-KI	[-12,001; 4,207]	[-2,069; 10,701]	
Veränderung zu Woche 8/9			
n/N (%)	10/81 (12)	17/80 (21)	LS MD -8,34 [-18,148; 1,475]
MW (SD)	4,17 (20,318)	5,81 (18,580)	
LS MW (SE)	-3,30 (3,776)	5,04 (2,994)	
95 %-KI	[-10,946; 4,349]	[-1,032; 11,108]	
Veränderung zu Woche 12			
n/N (%)	7/78 (9)	9/78 (12)	LS MD -8,42 [-18,042; 1,197]
MW (SD)	2,98 (17,131)	11,38 (20,235)	
LS MW (SE)	-2,88 (3,666)	5,54 (2,950)	
95 %-KI	[-10,330; 4,570]	[-0,451; 11,536]	
Veränderung zu Woche 15/16			
n/N (%)	5/76 (7)	5/75 (7)	LS MD -8,51 [-18,093; 1,076]
MW (SD)	1,67 (13,372)	15,00 (16,822)	
LS MW (SE)	-2,46 (3,615)	6,05 (2,974)	
95 %-KI	[-9,819; 4,898]	[0,010; 12,086]	
Veränderung zu Woche 20/21			
n/N (%)	5/72 (7)	3/67 (4)	LS MD -8,63 [-18,439; 1,177]
MW (SD)	5,00 (16,245)	23,61 (33,679)	
LS MW (SE)	-1,86 (3,649)	6,77 (3,123)	
95 %-KI	[-9,278; 5,554]	[0,461; 13,077]	
Veränderung zu Woche 24			
n/N (%)	3/72 (4)	3/62 (5)	LS MD -8,72 [-18,868; 1,433]
MW (SD)	9,72 (19,691)	26,39 (15,775)	
LS MW (SE)	-1,44 (3,746)	7,27 (3,299)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-9,030; 6,144]	[0,643; 13,906]	
Veränderung zu Woche 36			
n/N (%)	7/63 (11)	7/50 (14)	LS MD -9,01 [-21,329; 3,304]
MW (SD)	-0,09 (15,803)	10,37 (20,235)	
LS MW (SE)	-0,01 (4,463)	9,01 (4,224)	
95 %-KI	[-8,921; 8,907]	[0,605; 17,407]	
Veränderung zu Woche 48			
n/N (%)	1/55 (2)	2/39 (5)	LS MD -9,31 [-24,826; 6,211]
MW (SD)	25,00 (NA)	-14,29 (20,203)	
LS MW (SE)	1,43 (5,574)	10,74 (5,439)	
95 %-KI	[-9,642; 12,501]	[-0,056; 21,530]	
<b>Letztes Platin-freies Intervall: &gt; 3 Monate</b>			
Baseline			
n/N (%)	33/135 (24)	30/116 (26)	-
MW (SD)	18,57 (15,675)	20,65 (19,642)	
Absolute Werte zum Studienende			
n/N (%)	1/85 (1)	1/71 (1)	-
MW (SD)	54,17 (NA)	8,33 (NA)	
Effekt über Studiendauer			
n	33	30	LS MD -0,84 [-7,194; 5,524] 0,7926  Hedges' g -0,07 [-0,560; 0,429]
LS MW (SE)	-0,07 (2,308)	0,77 (2,161)	
95 %-KI	[-4,702; 4,568]	[-3,601; 5,137]	
Veränderung zu Woche 3/4			
n/N (%)	6/131 (5)	17/114 (15)	LS MD 0,17 [-7,329; 7,677]
MW (SD)	2,78 (17,010)	-0,98 (13,939)	
LS MW (SE)	-0,92 (2,967)	-1,09 (2,305)	
95 %-KI	[-6,824; 4,983]	[-5,718; 3,529]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 8/9			
n/N (%)	11/129 (9)	17/108 (16)	LS MD -0,25 [-7,021; 6,513]
MW (SD)	-0,97 (18,122)	-1,23 (12,037)	
LS MW (SE)	-0,56 (2,577)	-0,30 (2,179)	
95 %-KI	[-5,707; 4,590]	[-4,701; 4,092]	
Veränderung zu Woche 12			
n/N (%)	1/127 (1)	11/105 (10)	LS MD -0,55 [-7,017; 5,909]
MW (SD)	8,33 (NA)	0,76 (11,307)	
LS MW (SE)	-0,31 (2,394)	0,25 (2,147)	
95 %-KI	[-5,103; 4,492]	[-4,092; 4,590]	
Veränderung zu Woche 15/16			
n/N (%)	4/123 (3)	11/103 (11)	LS MD -0,85 [-7,212; 5,505]
MW (SD)	-2,38 (24,286)	-2,27 (10,763)	
LS MW (SE)	-0,05 (2,306)	0,80 (2,163)	
95 %-KI	[-4,682; 4,579]	[-3,572; 5,175]	
Veränderung zu Woche 20/21			
n/N (%)	4/118 (3)	9/98 (9)	LS MD -1,28 [-8,849; 5,286]
MW (SD)	2,98 (13,381)	1,39 (5,512)	
LS MW (SE)	0,31 (2,365)	1,59 (2,270)	
95 %-KI	[-4,430; 5,050]	[-2,975; 6,159]	
Veränderung zu Woche 24			
n/N (%)	5/112 (4)	8/93 (9)	LS MD -1,58 [-8,531; 5,369]
MW (SD)	-14,01 (12,656)	0,82 (8,400)	
LS MW (SE)	0,56 (2,527)	2,14 (2,396)	
95 %-KI	[-4,486; 5,614]	[-2,655; 6,945]	
Veränderung zu Woche 36			
n/N (%)	6/97 (6)	7/84 (8)	LS MD -2,61 [-11,952; 6,735]
MW (SD)	3,47 (7,177)	-2,38 (13,145)	
LS MW (SE)	1,43 (3,591)	4,04 (3,059)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-5,691; 8,556]	[-2,030; 10,112]	
Veränderung zu Woche 48			
n/N (%)	0/85 (0)	1/71 (1)	LS MD -3,64 [-16,268; 8,996]
MW (SD)	NA (NA)	8,33 (NA)	
LS MW (SE)	2,30 (5,025)	5,94 (3,933)	
95 %-KI	[-7,655; 12,258]	[-1,856; 13,730]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Pegyliertes liposomales Doxorubicin</b>			
Baseline			
n/N (%)	15/80 (19)	20/76 (26)	-
MW (SD)	25,11 (17,870)	24,23 (20,041)	
Absolute Werte zum Studienende			
n/N (%)	1/51 (2)	2/41 (5)	-
MW (SD)	54,17 (NA)	15,48 (1,684)	
Effekt über Studiendauer			
n	15	20	LS MD 0,45 [-8,822; 9,716] 0,9214  Hedges' g 0,03 [-0,637; 0,702]
LS MW (SE)	-3,83 (3,337)	-4,28 (3,019)	
95 %-KI	[-10,731; 3,073]	[-10,513; 1,960]	
Veränderung zu Woche 3/4			
n/N (%)	4/76 (5)	9/74 (12)	LS MD -4,51 [-15,111; 6,081]
MW (SD)	-16,67 (20,694)	-1,32 (14,006)	
LS MW (SE)	-6,94 (4,137)	-2,43 (3,220)	
95 %-KI	[-15,332; 1,443]	[-8,992; 4,133]	
Veränderung zu Woche 8/9			
n/N (%)	7/76 (9)	9/66 (14)	LS MD -2,39 [-12,081; 7,299]
MW (SD)	-2,13 (21,445)	1,72 (15,569)	
LS MW (SE)	-5,61 (3,665)	-3,22 (2,987)	
95 %-KI	[-13,112; 1,890]	[-9,381; 2,941]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 12			
n/N (%)	1/75 (1)	4/64 (6)	LS MD -0,90 [-10,256; 8,446]
MW (SD)	-12,50 (NA)	0,60 (14,765)	
LS MW (SE)	-4,68 (3,443)	-3,77 (2,953)	
95 %-KI	[-11,773; 2,417]	[-9,887; 2,341]	
Veränderung zu Woche 15/16			
n/N (%)	4/74 (5)	2/62 (3)	LS MD 0,58 [-8,691; 9,854]
MW (SD)	-3,13 (24,621)	2,08 (2,946)	
LS MW (SE)	-3,74 (3,331)	-4,33 (3,031)	
95 %-KI	[-10,637; 3,147]	[-10,583; 1,930]	
Veränderung zu Woche 20/21			
n/N (%)	3/72 (4)	3/59 (5)	LS MD 2,71 [-6,910; 12,321]
MW (SD)	-0,00 (15,023)	2,78 (2,406)	
LS MW (SE)	-2,41 (3,384)	-5,12 (3,318)	
95 %-KI	[-9,386; 4,562]	[-11,891; 1,657]	
Veränderung zu Woche 24			
n/N (%)	2/69 (3)	3/54 (6)	LS MD 4,19 [-5,971; 14,355]
MW (SD)	-11,81 (0,982)	-4,76 (8,248)	
LS MW (SE)	-1,48 (3,564)	-5,67 (3,618)	
95 %-KI	[-8,770; 5,813]	[-13,003; 1,662]	
Veränderung zu Woche 36			
n/N (%)	4/60 (7)	4/48 (8)	LS MD 9,29 [-4,239; 22,816]
MW (SD)	-1,04 (17,472)	-12,05 (14,518)	
LS MW (SE)	1,72 (4,823)	-7,57 (5,029)	
95 %-KI	[-7,973; 11,415]	[-17,654; 2,519]	
Veränderung zu Woche 48			
n/N (%)	0/51 (0)	1/41 (2)	LS MD 14,39 [-3,779; 32,550]
MW (SD)	NA (NA)	-28,57 (NA)	
LS MW (SE)	4,92 (6,596)	-9,46 (6,733)	



MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
95 %-KI	[-8,304; 18,146]	[-22,969; 4,040]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Paclitaxel</b>			
Baseline			
n/N (%)	25/88 (28)	19/82 (23)	-
MW (SD)	19,10 (12,761)	25,66 (16,449)	
Absolute Werte zum Studienende			
n/N (%)	1/56 (2)	1/49 (2)	-
MW (SD)	37,50 (NA)	0,00 (NA)	
Effekt über Studiendauer			
n	25	19	LS MD -8,14 [-17,672; 1,385] 0,0914  Hedges' g -0,51 [-1,117; 0,097]
LS MW (SE)	2,41 (3,339)	10,55 (3,263)	
95 %-KI	[-4,372; 9,191]	[3,905; 17,200]	
Veränderung zu Woche 3/4			
n/N (%)	7/87 (8)	13/81 (16)	LS MD -5,42 [-15,751; 4,917]
MW (SD)	5,36 (14,773)	5,13 (17,690)	
LS MW (SE)	1,23 (3,761)	6,65 (3,471)	
95 %-KI	[-6,316; 8,785]	[-0,354; 13,658]	
Veränderung zu Woche 8/9			
n/N (%)	10/86 (12)	13/79 (16)	LS MD -6,59 [-16,340; 3,151]
MW (SD)	5,83 (20,990)	8,33 (18,162)	
LS MW (SE)	1,74 (3,500)	8,34 (3,271)	
95 %-KI	[-5,328; 8,812]	[1,682; 14,990]	
Veränderung zu Woche 12			
n/N (%)	5/84 (6)	11/77 (14)	LS MD -7,42 [-16,967; 2,131]
MW (SD)	10,83 (15,756)	11,74 (17,660)	
LS MW (SE)	2,10 (3,386)	9,51 (3,229)	
95 %-KI	[-4,769; 8,962]	[2,929; 16,100]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 15/16			
n/N (%)	4/81 (5)	8/76 (11)	LS MD -8,24 [-17,779; 1,295]
MW (SD)	2,83 (14,510)	10,94 (15,095)	
LS MW (SE)	2,45 (3,336)	10,69 (3,273)	
95 %-KI	[-4,325; 9,229]	[4,029; 17,358]	
Veränderung zu Woche 20/21			
n/N (%)	6/77 (8)	6/73 (8)	LS MD -9,42 [-19,257; 0,419]
MW (SD)	6,15 (14,661)	12,50 (25,413)	
LS MW (SE)	2,96 (3,381)	12,38 (3,476)	
95 %-KI	[-3,897; 9,815]	[5,350; 19,405]	
Veränderung zu Woche 24			
n/N (%)	4/74 (5)	5/72 (7)	LS MD -10,24 [-20,507; 0,021]
MW (SD)	1,93 (24,229)	20,00 (14,849)	
LS MW (SE)	3,31 (3,490)	13,56 (3,704)	
95 %-KI	[-3,739; 10,367]	[6,113; 21,001]	
Veränderung zu Woche 36			
n/N (%)	7/64 (11)	6/63 (10)	LS MD -13,07 [-25,887; -0,249]
MW (SD)	5,36 (10,125)	11,11 (19,484)	
LS MW (SE)	4,53 (4,263)	17,60 (4,851)	
95 %-KI	[-3,970; 13,032]	[7,957; 27,240]	
Veränderung zu Woche 48			
n/N (%)	1/56 (2)	0/49 (0)	LS MD -15,89 [-32,341; 0,556]
MW (SD)	25,00 (NA)	NA (NA)	
LS MW (SE)	5,75 (5,425)	21,64 (6,315)	
95 %-KI	[-5,021; 16,517]	[9,111; 34,170]	
<b>IC-Chemotherapie vor der Randomisierung zugewiesen: Topotecan</b>			
Baseline			
n/N (%)	13/50 (26)	18/49 (37)	-
MW (SD)	16,12 (16,231)	20,14 (16,435)	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Absolute Werte zum Studienende			
n/N (%)	1/33 (3)	2/20 (10)	-
MW (SD)	0,00 (NA)	27,08 (26,517)	
Effekt über Studiendauer			
n	13	18	LS MD -6,54 [-13,718; 0,631] 0,0715  Hedges' g -0,69 [-1,430; 0,044]
LS MW (SE)	-5,87 (2,653)	0,68 (2,104)	
95 %-KI	[-11,382; -0,351]	[-3,771; 5,125]	
Veränderung zu Woche 3/4			
n/N (%)	2/50 (4)	8/45 (18)	LS MD -0,67 [-9,543; 8,204]
MW (SD)	-6,25 (8,839)	-1,04 (7,953)	
LS MW (SE)	-2,42 (3,662)	-1,75 (2,211)	
95 %-KI	[-9,904; 5,058]	[-6,358; 2,849]	
Veränderung zu Woche 8/9			
n/N (%)	4/48 (8)	12/43 (28)	LS MD -3,04 [-10,901; 4,821]
MW (SD)	-3,12 (3,989)	-3,82 (11,440)	
LS MW (SE)	-3,81 (3,082)	-0,77 (2,129)	
95 %-KI	[-10,160; 2,534]	[-5,251; 3,705]	
Veränderung zu Woche 12			
n/N (%)	2/46 (4)	5/42 (12)	LS MD -4,70 [-12,100; 2,701]
MW (SD)	-6,25 (8,839)	-4,17 (9,317)	
LS MW (SE)	-4,79 (2,800)	-0,09 (2,102)	
95 %-KI	[-10,587; 1,016]	[-4,527; 4,355]	
Veränderung zu Woche 15/16			
n/N (%)	1/44 (2)	6/40 (15)	LS MD -6,36 [-13,542; 0,824]
MW (SD)	0,00 (NA)	-6,94 (11,076)	
LS MW (SE)	-5,76 (2,659)	0,60 (2,103)	
95 %-KI	[-11,285; -0,231]	[-3,844; 5,046]	

MIRASOL	Behandlungsarm		Effektmaß [95 %-KI] p-Wert
	MIRV	Chemotherapie	
Veränderung zu Woche 20/21			
n/N (%)	0/41 (0)	3/33 (9)	LS MD -8,73 [-16,056; -1,403]
MW (SD)	NA (NA)	0,00 (0,000)	
LS MW (SE)	-7,15 (2,740)	1,58 (2,149)	
95 %-KI	[-12,818; -1,477]	[-2,938; 6,102]	
Veränderung zu Woche 24			
n/N (%)	2/41 (5)	3/29 (10)	LS MD -10,39 [-18,127; -2,652]
MW (SD)	-12,50 (17,678)	0,00 (0,000)	
LS MW (SE)	-8,12 (2,982)	2,27 (2,212)	
95 %-KI	[-14,249; -1,991]	[-2,353; 6,891]	
Veränderung zu Woche 36			
n/N (%)	2/36 (6)	4/23 (17)	LS MD -16,08 [-26,657; -5,501]
MW (SD)	-6,55 (2,525)	9,38 (5,243)	
LS MW (SE)	-11,45 (4,515)	4,62 (2,589)	
95 %-KI	[-20,598; -2,311]	[-0,652; 9,901]	
Veränderung zu Woche 48			
n/N (%)	0/33 (0)	2/20 (10)	LS MD -21,77 [-36,332; -7,205]
MW (SD)	NA (NA)	4,17 (5,893)	
LS MW (SE)	-14,79 (6,505)	6,98 (3,137)	
95 %-KI	[-27,915; -1,663]	[0,661; 13,298]	
<p><i>Analysepopulation: ITT</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023</i></p> <p><i>Modell: Veränderung zu Baseline ~ Behandlung + Baseline-Wert * Zeit in Wochen + Behandlung * Zeit in Wochen + zufällige Effekte durch die Patientin</i></p> <p><i>Die Berechnung des LS-MW's erfolgt durch ein MMRM mit dem oben angegebenen Modell. Basierend hierauf werden KI und p-Wert ermittelt. Hedges' g basiert ebenfalls auf den LS-MW und ist somit auf das Modell angepasst.</i></p> <p><i>Es werden ausschließlich gemeinsame Analysezeitpunkte dargestellt.</i></p> <p><i>Ein LS MD und Hedges' g kleiner als Null bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

## 4.1 Zeit bis zum ersten UE

### 4.1.1 Zeit bis zum ersten UE: Subgruppenanalyse Alter

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UE</b>			
<b>Alter</b>			
< 65 Jahre	N	155	140
	Ereignisse, n (%)	148 (95 %)	131 (94 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	0,43 [0,286; 1,143]	1,00 [0,571; 1,143]
	HR [95 %-KI] p-Wert	1,01 [0,798; 1,284] 0,9201	
≥ 65 Jahre	N	142	99
	Ereignisse, n (%)	141 (99 %)	95 (96 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	0,43 [0,286; 0,571]	0,86 [0,571; 1,143]
	HR [95 %-KI] p-Wert	1,09 [0,828; 1,423] 0,5525	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.1.2 Zeit bis zum ersten UE: Subgruppenanalyse Region

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UE</b>			
<b>Region</b>			
USA	N	86	56
	Ereignisse, n (%)	85 (99 %)	53 (95 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	0,43 [0,286; 0,714]	0,86 [0,571; 1,143]
	HR [95 %-KI] p-Wert	1,20 [0,839; 1,705] 0,3192	
Rest der Welt	N	211	183
	Ereignisse, n (%)	204 (97 %)	173 (95 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	0,43 [0,286; 0,714]	0,86 [0,571; 1,143]
	HR [95 %-KI] p-Wert	0,99 [0,809; 1,221] 0,9516	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

### 4.1.3 Zeit bis zum ersten UE: Subgruppenanalyse Stadium bei der Diagnose

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UE</b>			
<b>Stadium bei der Diagnose</b>			
I-III	N	194	168
	Ereignisse, n (%)	189 (97 %)	159 (95 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	0,43 [0,286; 0,571]	1,00 [0,857; 1,143]
	HR [95 %-KI] p-Wert	1,11 [0,897; 1,377] 0,3342	
IV	N	97	68
	Ereignisse, n (%)	94 (97 %)	64 (94 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	0,43 [0,286; 1,143]	0,57 [0,286; 1,143]
	HR [95 %-KI] p-Wert	0,89 [0,641; 1,229] 0,4733	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.1.4 Zeit bis zum ersten UE: Subgruppenanalyse BRCA Status

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UE</b>			
<b>BRCA Status</b>			
Positiv	N	38	37
	Ereignisse, n (%)	38 (100 %)	35 (95 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	0,43 [0,286; 1,143]	0,86 [0,286; 1,429]
	HR [95 %-KI] p-Wert	1,05 [0,645; 1,711] 0,8426	
Negativ/Unbekannt	N	259	202
	Ereignisse, n (%)	251 (97 %)	191 (95 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	0,43 [0,286; 0,571]	0,86 [0,714; 1,143]
	HR [95 %-KI] p-Wert	1,04 [0,862; 1,262] 0,6664	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			



#### 4.1.5 Zeit bis zum ersten UE: Subgruppenanalyse Baseline ECOG PS

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UE</b>			
<b>Baseline ECOG PS</b>			
0	N	174	133
	Ereignisse, n (%)	169 (97 %)	125 (94 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	0,64 [0,429; 1,143]	1,00 [0,857; 1,429]
	HR [95 %-KI] p-Wert	1,10 [0,868; 1,386] 0,4364	
1	N	123	103
	Ereignisse, n (%)	120 (98 %)	98 (95 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	0,29 [0,286; 0,429]	0,86 [0,429; 1,143]
	HR [95 %-KI] p-Wert	1,03 [0,776; 1,358] 0,8551	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.1.6 Zeit bis zum ersten UE: Subgruppenanalyse Anzahl vorheriger Therapielinien

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UE</b>			
<b>Anzahl vorheriger Therapielinien</b>			
1 oder 2	N	171	131
	Ereignisse, n (%)	168 (98 %)	124 (95 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	0,43 [0,286; 0,571]	0,71 [0,429; 1,000]
	HR [95 %-KI] p-Wert	1,01 [0,795; 1,275] 0,9571	
3	N	126	108
	Ereignisse, n (%)	121 (96 %)	102 (94 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	0,43 [0,286; 1,143]	1,14 [0,857; 1,857]
	HR [95 %-KI] p-Wert	1,06 [0,807; 1,384] 0,6888	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.1.7 Zeit bis zum ersten UE: Subgruppenanalyse Vorherige Verabreichung von Bevacizumab

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UE</b>			
<b>Vorherige Verabreichung von Bevacizumab</b>			
Ja	N	173	149
	Ereignisse, n (%)	168 (97 %)	142 (95 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	0,43 [0,286; 0,571]	1,14 [0,571; 1,286]
	HR [95 %-KI] p-Wert	1,13 [0,898; 1,418] 0,2996	
Nein	N	124	90
	Ereignisse, n (%)	121 (98 %)	84 (93 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	0,50 [0,286; 0,857]	0,86 [0,429; 1,000]
	HR [95 %-KI] p-Wert	0,95 [0,712; 1,254] 0,6963	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.1.8 Zeit bis zum ersten UE: Subgruppenanalyse Letztes Platin-freies Intervall

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UE</b>			
<b>Letztes Platin-freies Intervall</b>			
≤ 3 Monate	N	112	105
	Ereignisse, n (%)	107 (96 %)	100 (95 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	0,57 [0,429; 1,143]	0,86 [0,429; 1,143]
	HR [95 %-KI] p-Wert	0,92 [0,694; 1,219] 0,5597	
> 3 Monate	N	185	134
	Ereignisse, n (%)	182 (98 %)	126 (94 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	0,43 [0,286; 0,571]	1,00 [0,571; 1,143]
	HR [95 %-KI] p-Wert	1,12 [0,893; 1,417] 0,3158	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.1.9 Zeit bis zum ersten UE: Subgruppenanalyse IC-Chemotherapie vor der Randomisierung zugewiesen

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UE</b>			
<b>IC-Chemotherapie vor der Randomisierung zugewiesen</b>			
Pegyliertes liposomales Doxorubicin	N	120	90
	Ereignisse, n (%)	117 (98 %)	83 (92 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	0,64 [0,429; 1,143]	0,86 [0,571; 2,000]
	HR [95 %-KI] p-Wert	1,04 [0,785; 1,390] 0,7641	
Paclitaxel	N	116	95
	Ereignisse, n (%)	112 (97 %)	91 (96 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	0,43 [0,286; 0,571]	0,86 [0,286; 1,000]
	HR [95 %-KI] p-Wert	0,99 [0,749; 1,315] 0,9583	
Topotecan	N	61	54
	Ereignisse, n (%)	60 (98 %)	52 (96 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	0,43 [0,286; 0,714]	1,14 [0,571; 1,429]
	HR [95 %-KI] p-Wert	1,16 [0,792; 1,709] 0,4401	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.1.10 Zeit bis zum ersten UE: Subgruppenanalyse Daten aus Studie

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UE</b>			
<b>Daten aus Studie</b>			
MIRASOL	N	218	207
	Ereignisse, n (%)	210 (96 %)	194 (94 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	0,57 [0,286; 0,857]	1,00 [0,857; 1,143]
	HR [95 %-KI] p-Wert	1,03 [0,851; 1,259] 0,7309	
FORWARD 1	N	79	32
	Ereignisse, n (%)	79 (100 %)	32 (100 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	0,43 [0,286; 0,571]	0,50 [0,286; 1,000]
	HR [95 %-KI] p-Wert	1,08 [0,717; 1,635] 0,7040	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

## 4.2 Zeit bis zum ersten schweren UE

### 4.2.1 Zeit bis zum ersten schweren UE: Subgruppenanalyse Alter

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten schweren UE</b>			
<b>Alter</b>			
< 65 Jahre	N	155	140
	Ereignisse, n (%)	60 (39 %)	74 (53 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	34,71 [22,857; NA]	14,29 [9,143; 19,143]
	HR [95 %-KI] p-Wert	0,50 [0,355; 0,716] 0,0001	
≥ 65 Jahre	N	142	99
	Ereignisse, n (%)	70 (49 %)	58 (59 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	30,14 [18,143; 41,000]	9,71 [7,143; 14,143]
	HR [95 %-KI] p-Wert	0,52 [0,359; 0,751] 0,0006	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.2.2 Zeit bis zum ersten schweren UE: Subgruppenanalyse Region

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten schweren UE</b>			
<b>Region</b>			
USA	N	86	56
	Ereignisse, n (%)	40 (47 %)	35 (62 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	22,86 [18,143; 44,714]	11,14 [4,286; 15,000]
	HR [95 %-KI] p-Wert	0,48 [0,298; 0,777] 0,0031	
Rest der Welt	N	211	183
	Ereignisse, n (%)	90 (43 %)	97 (53 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	36,29 [27,429; 55,000]	13,29 [9,286; 18,143]
	HR [95 %-KI] p-Wert	0,53 [0,392; 0,710] < 0,0001	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			



### 4.2.3 Zeit bis zum ersten schweren UE: Subgruppenanalyse Stadium bei der Diagnose

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
Zeit bis zum ersten schweren UE			
Stadium bei der Diagnose			
I-III	N	194	168
	Ereignisse, n (%)	86 (44 %)	91 (54 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	34,71 [22,857; 47,714]	14,14 [9,714; 17,714]
	HR [95 %-KI] p-Wert	0,53 [0,387; 0,719] < 0,0001	
IV	N	97	68
	Ereignisse, n (%)	44 (45 %)	40 (59 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	25,14 [16,143; NA]	8,29 [4,286; 19,143]
	HR [95 %-KI] p-Wert	0,48 [0,307; 0,757] 0,0017	
<p>Analysepopulation: Safety/relevante Biomarker-Population</p> <p>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</p> <p>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</p> <p>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</p> <p>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</p> <p>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</p>			

#### 4.2.4 Zeit bis zum ersten schweren UE: Subgruppenanalyse BRCA Status

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten schweren UE</b>			
<b>BRCA Status</b>			
Positiv	N	38	37
	Ereignisse, n (%)	13 (34 %)	20 (54 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [21,000; NA]	11,29 [4,000; NA]
	HR [95 %-KI] p-Wert	0,42 [0,192; 0,899] 0,0214	
Negativ/Unbekannt	N	259	202
	Ereignisse, n (%)	117 (45 %)	112 (55 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	30,14 [21,714; 41,000]	12,43 [9,143; 17,143]
	HR [95 %-KI] p-Wert	0,54 [0,416; 0,710] < 0,0001	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.2.5 Zeit bis zum ersten schweren UE: Subgruppenanalyse Baseline ECOG PS

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten schweren UE</b>			
<b>Baseline ECOG PS</b>			
0	N	174	133
	Ereignisse, n (%)	67 (39 %)	64 (48 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	44,71 [28,286; NA]	15,57 [10,429; 26,000]
	HR [95 %-KI] p-Wert	0,48 [0,333; 0,686] 0,0001	
1	N	123	103
	Ereignisse, n (%)	63 (51 %)	65 (63 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	19,43 [12,857; 31,571]	8,29 [5,143; 13,286]
	HR [95 %-KI] p-Wert	0,60 [0,419; 0,856] 0,0050	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.2.6 Zeit bis zum ersten schweren UE: Subgruppenanalyse Anzahl vorheriger Therapielinien

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten schweren UE</b>			
<b>Anzahl vorheriger Therapielinien</b>			
1 oder 2	N	171	131
	Ereignisse, n (%)	74 (43 %)	67 (51 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	31,86 [23,429; 106,000]	14,14 [9,143; 24,143]
	HR [95 %-KI] p-Wert	0,56 [0,397; 0,785] 0,0009	
3	N	126	108
	Ereignisse, n (%)	56 (44 %)	65 (60 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	27,43 [18,143; 44,714]	10,86 [8,000; 14,286]
	HR [95 %-KI] p-Wert	0,47 [0,320; 0,690] 0,0001	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

**4.2.7 Zeit bis zum ersten schweren UE: Subgruppenanalyse  
Vorherige Verabreichung von Bevacizumab**

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten schweren UE</b>			
<b>Vorherige Verabreichung von Bevacizumab</b>			
Ja	N	173	149
	Ereignisse, n (%)	82 (47 %)	85 (57 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	23,43 [18,000; 31,857]	11,29 [8,000; 15,000]
	HR [95 %-KI] p-Wert	0,58 [0,427; 0,797] 0,0007	
Nein	N	124	90
	Ereignisse, n (%)	48 (39 %)	47 (52 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	52,86 [31,571; NA]	14,14 [9,286; 26,143]
	HR [95 %-KI] p-Wert	0,44 [0,285; 0,672] 0,0002	
<i>Analysepopulation: Safety/relevante Biomarker-Population</i>			
<i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i>			
<i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i>			
<i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i>			
<i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i>			
<i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i>			

#### 4.2.8 Zeit bis zum ersten schweren UE: Subgruppenanalyse Letztes Platin-freies Intervall

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten schweren UE</b>			
<b>Letztes Platin-freies Intervall</b>			
≤ 3 Monate	N	112	105
	Ereignisse, n (%)	49 (44 %)	65 (62 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	29,14 [12,857; NA]	8,29 [5,143; 11,286]
	HR [95 %-KI] p-Wert	0,50 [0,344; 0,739] 0,0004	
> 3 Monate	N	185	134
	Ereignisse, n (%)	81 (44 %)	67 (50 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	36,29 [25,143; 47,714]	17,14 [12,429; 23,429]
	HR [95 %-KI] p-Wert	0,55 [0,391; 0,771] 0,0006	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.2.9 Zeit bis zum ersten schweren UE: Subgruppenanalyse IC-Chemotherapie vor der Randomisierung zugewiesen

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten schweren UE</b>			
<b>IC-Chemotherapie vor der Randomisierung zugewiesen</b>			
Pegyliertes liposomales Doxorubicin	N	120	90
	Ereignisse, n (%)	52 (43 %)	40 (44 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	40,86 [25,143; NA]	17,14 [9,286; 36,857]
	HR [95 %-KI] p-Wert	0,56 [0,364; 0,861] 0,0091	
Paclitaxel	N	116	95
	Ereignisse, n (%)	54 (47 %)	60 (63 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	22,86 [18,000; 40,000]	11,57 [8,000; 15,571]
	HR [95 %-KI] p-Wert	0,52 [0,355; 0,771] 0,0010	
Topotecan	N	61	54
	Ereignisse, n (%)	24 (39 %)	32 (59 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	47,29 [10,286; NA]	5,86 [3,286; 18,143]
	HR [95 %-KI] p-Wert	0,45 [0,263; 0,780] 0,0039	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.2.10 Zeit bis zum ersten schweren UE: Subgruppenanalyse Daten aus Studie

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten schweren UE</b>			
<b>Daten aus Studie</b>			
MIRASOL	N	218	207
	Ereignisse, n (%)	93 (43 %)	112 (54 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	31,86 [21,143; 47,714]	14,14 [9,714; 17,714]
	HR [95 %-KI] p-Wert	0,53 [0,402; 0,704] < 0,0001	
FORWARD 1	N	79	32
	Ereignisse, n (%)	37 (47 %)	20 (62 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	31,86 [19,000; NA]	9,00 [3,143; 10,429]
	HR [95 %-KI] p-Wert	0,48 [0,272; 0,835] 0,0126	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			



## 4.3 Zeit bis zum ersten SUE

### 4.3.1 Zeit bis zum ersten SUE: Subgruppenanalyse Alter

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten SUE</b>			
<b>Alter</b>			
< 65 Jahre	N	155	140
	Ereignisse, n (%)	38 (25 %)	44 (31 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	97,29 [97,286; NA]	33,71 [30,714; 45,714]
	HR [95 %-KI] p-Wert	0,56 [0,355; 0,869] 0,0099	
≥ 65 Jahre	N	142	99
	Ereignisse, n (%)	39 (27 %)	37 (37 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [59,857; NA]	76,29 [12,857; NA]
	HR [95 %-KI] p-Wert	0,53 [0,331; 0,841] 0,0077	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

### 4.3.2 Zeit bis zum ersten SUE: Subgruppenanalyse Region

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten SUE</b>			
<b>Region</b>			
USA	N	86	56
	Ereignisse, n (%)	23 (27 %)	23 (41 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [25,143; NA]	28,57 [15,000; NA]
	HR [95 %-KI] p-Wert	0,48 [0,262; 0,866] 0,0158	
Rest der Welt	N	211	183
	Ereignisse, n (%)	54 (26 %)	58 (32 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	97,29 [97,286; NA]	37,14 [30,714; NA]
	HR [95 %-KI] p-Wert	0,58 [0,392; 0,846] 0,0049	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

### 4.3.3 Zeit bis zum ersten SUE: Subgruppenanalyse Stadium bei der Diagnose

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten SUE</b>			
<b>Stadium bei der Diagnose</b>			
I-III	N	194	168
	Ereignisse, n (%)	47 (24 %)	54 (32 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	97,29 [97,286; NA]	33,71 [30,714; NA]
	HR [95 %-KI] p-Wert	0,55 [0,370; 0,831] 0,0042	
IV	N	97	68
	Ereignisse, n (%)	29 (30 %)	26 (38 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [30,143; NA]	26,00 [8,286; NA]
	HR [95 %-KI] p-Wert	0,50 [0,288; 0,871] 0,0154	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.3.4 Zeit bis zum ersten SUE: Subgruppenanalyse BRCA Status

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten SUE</b>			
<b>BRCA Status</b>			
Positiv	N	38	37
	Ereignisse, n (%)	4 (11 %)	13 (35 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [NA; NA]	NA [6,429; NA]
	HR [95 %-KI] p-Wert	0,28 [0,090; 0,892] 0,0189	
Negativ/Unbekannt	N	259	202
	Ereignisse, n (%)	73 (28 %)	68 (34 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	97,29 [59,857; NA]	33,71 [28,571; 76,286]
	HR [95 %-KI] p-Wert	0,61 [0,436; 0,859] 0,0047	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

### 4.3.5 Zeit bis zum ersten SUE: Subgruppenanalyse Baseline ECOG PS

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten SUE</b>			
<b>Baseline ECOG PS</b>			
0	N	174	133
	Ereignisse, n (%)	31 (18 %)	35 (26 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [NA; NA]	36,86 [30,714; NA]
	HR [95 %-KI] p-Wert	0,47 [0,287; 0,779] 0,0033	
1	N	123	103
	Ereignisse, n (%)	46 (37 %)	45 (44 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	47,29 [23,571; NA]	15,00 [9,429; NA]
	HR [95 %-KI] p-Wert	0,61 [0,396; 0,929] 0,0221	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

### 4.3.6 Zeit bis zum ersten SUE: Subgruppenanalyse Anzahl vorheriger Therapielinien

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
Zeit bis zum ersten SUE			
Anzahl vorheriger Therapielinien			
1 oder 2	N	171	131
	Ereignisse, n (%)	46 (27 %)	41 (31 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	97,29 [97,286; NA]	36,86 [28,571; NA]
	HR [95 %-KI] p-Wert	0,63 [0,407; 0,971] 0,0375	
3	N	126	108
	Ereignisse, n (%)	31 (25 %)	40 (37 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [59,857; NA]	30,71 [15,000; NA]
	HR [95 %-KI] p-Wert	0,45 [0,275; 0,729] 0,0012	
<p>Analysepopulation: Safety/relevante Biomarker-Population</p> <p>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</p> <p>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</p> <p>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</p> <p>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</p> <p>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</p>			

### 4.3.7 Zeit bis zum ersten SUE: Subgruppenanalyse Vorherige Verabreichung von Bevacizumab

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten SUE</b>			
<b>Vorherige Verabreichung von Bevacizumab</b>			
Ja	N	173	149
	Ereignisse, n (%)	51 (29 %)	50 (34 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	97,29 [50,857; NA]	30,71 [22,143; NA]
	HR [95 %-KI] p-Wert	0,64 [0,428; 0,960] 0,0314	
Nein	N	124	90
	Ereignisse, n (%)	26 (21 %)	31 (34 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [NA; NA]	36,86 [30,714; NA]
	HR [95 %-KI] p-Wert	0,43 [0,255; 0,739] 0,0021	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.3.8 Zeit bis zum ersten SUE: Subgruppenanalyse Letztes Platin-freies Intervall

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten SUE</b>			
<b>Letztes Platin-freies Intervall</b>			
≤ 3 Monate	N	112	105
	Ereignisse, n (%)	28 (25 %)	40 (38 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [NA; NA]	30,71 [12,714; 76,286]
	HR [95 %-KI] p-Wert	0,46 [0,280; 0,752] 0,0018	
> 3 Monate	N	185	134
	Ereignisse, n (%)	49 (26 %)	41 (31 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	97,29 [59,857; NA]	36,86 [28,571; NA]
	HR [95 %-KI] p-Wert	0,64 [0,412; 0,978] 0,0407	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			



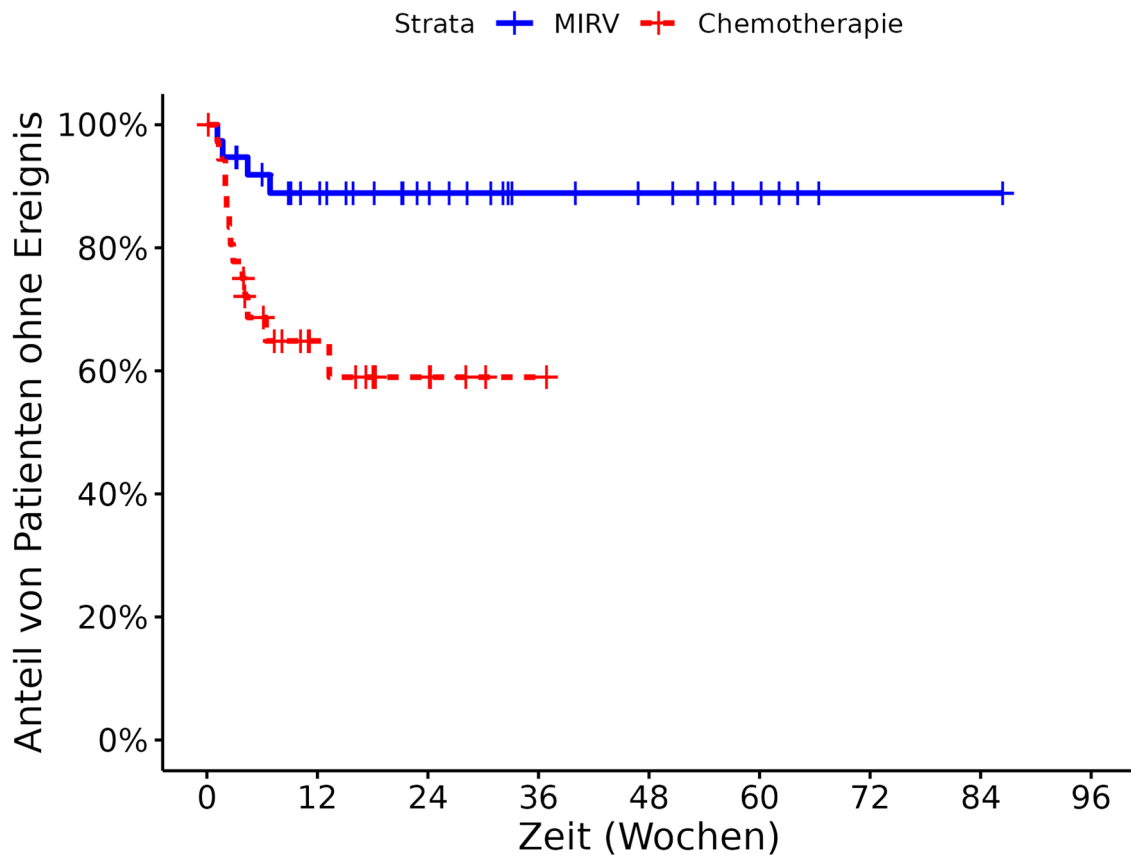
### 4.3.9 Zeit bis zum ersten SUE: Subgruppenanalyse IC-Chemotherapie vor der Randomisierung zugewiesen

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten SUE</b>			
<b>IC-Chemotherapie vor der Randomisierung zugewiesen</b>			
Pegyliertes liposomales Doxorubicin	N	120	90
	Ereignisse, n (%)	27 (22 %)	31 (34 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [97,286; NA]	36,86 [23,429; 76,286]
	HR [95 %-KI] p-Wert	0,41 [0,242; 0,709] 0,0013	
Paclitaxel	N	116	95
	Ereignisse, n (%)	34 (29 %)	31 (33 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [50,857; NA]	32,14 [30,714; NA]
	HR [95 %-KI] p-Wert	0,66 [0,394; 1,103] 0,1134	
Topotecan	N	61	54
	Ereignisse, n (%)	16 (26 %)	19 (35 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [47,286; NA]	NA [8,286; NA]
	HR [95 %-KI] p-Wert	0,59 [0,301; 1,151] 0,1207	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

### 4.3.10 Zeit bis zum ersten SUE: Subgruppenanalyse Daten aus Studie

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten SUE</b>			
<b>Daten aus Studie</b>			
MIRASOL	N	218	207
	Ereignisse, n (%)	55 (25 %)	68 (33 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [59,857; NA]	33,71 [28,571; NA]
	HR [95 %-KI] p-Wert	0,55 [0,385; 0,796] 0,0013	
FORWARD 1	N	79	32
	Ereignisse, n (%)	22 (28 %)	13 (41 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	97,29 [97,286; NA]	30,71 [7,571; NA]
	HR [95 %-KI] p-Wert	0,52 [0,260; 1,042] 0,0743	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

4.3.10.1 Zeit bis zum ersten SUE Kaplan-Meier-Plot in Subgruppe BRCA Status\_Positiv  
Kaplan Meier Plot 233.1.3.S.05.03 04000 A07

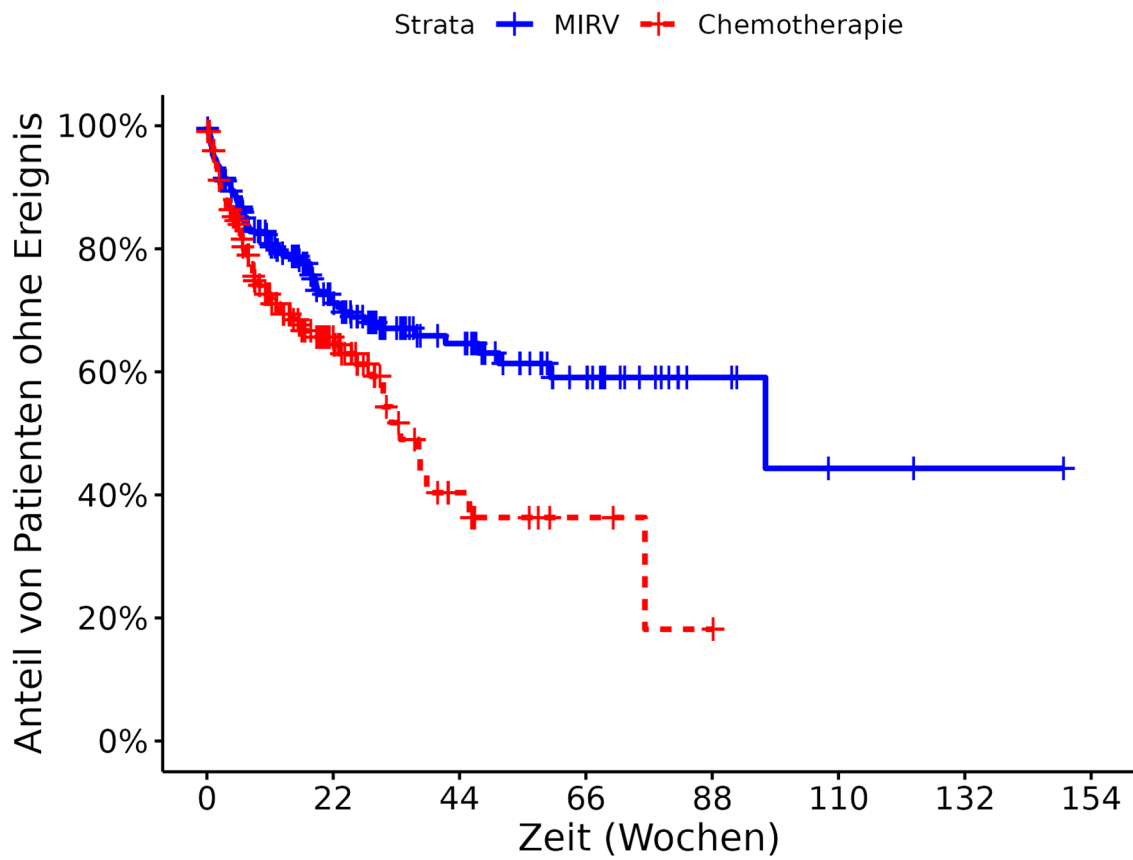


**Patienten unter Risiko**

MIRV	38	26	18	11	9	5	1	1	0
Chemotherapie	37	11	5	1	0	0	0	0	0

4.3.10.2 Zeit bis zum ersten SUE Kaplan-Meier-Plot in Subgruppe  
 pe BRCA Status\_Negativ/Unbekannt

Kaplan Meier Plot 233.1.3.S.05.03 04000 A08



**Patienten unter Risiko**

MIRV	259	102	51	21	6	2	1	0
Chemotherapie	202	54	10	3	1	0	0	0

## 4.4 UESI "Augenerkrankungen"

### 4.4.1 Zeit bis zum ersten UESI "Augenerkrankungen"

#### 4.4.1.1 Zeit bis zum ersten UESI "Augenerkrankungen": Subgruppenanalyse Alter

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Augenerkrankungen"</b>			
<b>Alter</b>			
< 65 Jahre	N	155	140
	Ereignisse, n (%)	91 (59 %)	12 (9 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	9,00 [5,857; 14,143]	NA [33,143; NA]
	HR [95 %-KI] p-Wert	8,63 [4,705; 15,842] < 0,0001	
≥ 65 Jahre	N	142	99
	Ereignisse, n (%)	84 (59 %)	12 (12 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	10,57 [7,429; 13,286]	NA [26,143; NA]
	HR [95 %-KI] p-Wert	5,08 [2,761; 9,353] < 0,0001	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.4.1.2 Zeit bis zum ersten UESI "Augenerkrankungen": Subgruppenanalyse Region

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Augenerkrankungen"</b>			
<b>Region</b>			
USA	N	86	56
	Ereignisse, n (%)	53 (62 %)	9 (16 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	5,29 [4,714; 11,143]	NA [26,143; NA]
	HR [95 %-KI] p-Wert	5,03 [2,451; 10,311] < 0,0001	
Rest der Welt	N	211	183
	Ereignisse, n (%)	122 (58 %)	15 (8 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	11,00 [9,000; 15,286]	NA [NA; NA]
	HR [95 %-KI] p-Wert	7,64 [4,456; 13,105] < 0,0001	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.4.1.3 Zeit bis zum ersten UESI "Augenerkrankungen": Subgruppenanalyse Stadium bei der Diagnose

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
Zeit bis zum ersten UESI "Augenerkrankungen"			
Stadium bei der Diagnose			
I-III	N	194	168
	Ereignisse, n (%)	119 (61 %)	18 (11 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	9,00 [6,286; 12,143]	NA [NA; NA]
	HR [95 %-KI] p-Wert	6,56 [3,983; 10,800] < 0,0001	
IV	N	97	68
	Ereignisse, n (%)	52 (54 %)	6 (9 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	11,86 [7,857; 16,286]	NA [26,143; NA]
	HR [95 %-KI] p-Wert	7,11 [3,007; 16,786] < 0,0001	
<p>Analysepopulation: Safety/relevante Biomarker-Population</p> <p>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</p> <p>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</p> <p>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</p> <p>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</p> <p>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</p>			

#### 4.4.1.4 Zeit bis zum ersten UESI "Augenerkrankungen": Subgruppenanalyse BRCA Status

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Augenerkrankungen"</b>			
<b>BRCA Status</b>			
Positiv	N	38	37
	Ereignisse, n (%)	21 (55 %)	2 (5 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	10,57 [5,000; 44,714]	NA [16,286; NA]
	HR [95 %-KI] p-Wert	8,28 [1,882; 36,421] 0,0004	
Negativ/Unbekannt	N	259	202
	Ereignisse, n (%)	154 (59 %)	22 (11 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	9,14 [8,143; 12,000]	NA [NA; NA]
	HR [95 %-KI] p-Wert	6,65 [4,244; 10,430] < 0,0001	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			



#### 4.4.1.5 Zeit bis zum ersten UESI "Augenerkrankungen": Subgruppen-analyse Baseline ECOG PS

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Augenerkrankungen"</b>			
<b>Baseline ECOG PS</b>			
0	N	174	133
	Ereignisse, n (%)	109 (63 %)	17 (13 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	8,57 [6,000; 11,143]	NA [33,143; NA]
	HR [95 %-KI] p-Wert	6,47 [3,865; 10,842] < 0,0001	
1	N	123	103
	Ereignisse, n (%)	66 (54 %)	7 (7 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	12,14 [8,286; 21,714]	NA [NA; NA]
	HR [95 %-KI] p-Wert	7,46 [3,403; 16,350] < 0,0001	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

**4.4.1.6 Zeit bis zum ersten UESI "Augenerkrankungen": Subgruppenanalyse  
Anzahl vorheriger Therapielinien**

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Augenerkrankungen"</b>			
<b>Anzahl vorheriger Therapielinien</b>			
1 oder 2	N	171	131
	Ereignisse, n (%)	103 (60 %)	16 (12 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	9,86 [7,286; 14,143]	NA [32,429; NA]
	HR [95 %-KI] p-Wert	5,53 [3,250; 9,411] < 0,0001	
3	N	126	108
	Ereignisse, n (%)	72 (57 %)	8 (7 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	9,14 [6,714; 12,143]	NA [NA; NA]
	HR [95 %-KI] p-Wert	9,29 [4,460; 19,350] < 0,0001	
<i>Analysepopulation: Safety/relevante Biomarker-Population</i>			
<i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i>			
<i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i>			
<i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i>			
<i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i>			
<i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i>			

#### 4.4.1.7 Zeit bis zum ersten UESI "Augenerkrankungen": Subgruppenanalyse Vorherige Verabreichung von Bevacizumab

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Augenerkrankungen"</b>			
<b>Vorherige Verabreichung von Bevacizumab</b>			
Ja	N	173	149
	Ereignisse, n (%)	104 (60 %)	13 (9 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	8,71 [6,286; 11,143]	NA [33,143; NA]
	HR [95 %-KI] p-Wert	9,39 [5,137; 17,177] < 0,0001	
Nein	N	124	90
	Ereignisse, n (%)	71 (57 %)	11 (12 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	15,86 [7,286; 27,857]	NA [32,429; NA]
	HR [95 %-KI] p-Wert	4,80 [2,519; 9,132] < 0,0001	
<i>Analysepopulation: Safety/relevante Biomarker-Population</i>			
<i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i>			
<i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i>			
<i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i>			
<i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i>			
<i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i>			

**4.4.1.8 Zeit bis zum ersten UESI "Augenerkrankungen": Subgruppenanalyse  
Letztes Platin-freies Intervall**

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Augenerkrankungen"</b>			
<b>Letztes Platin-freies Intervall</b>			
≤ 3 Monate	N	112	105
	Ereignisse, n (%)	62 (55 %)	10 (10 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	8,71 [5,857; 15,143]	NA [33,143; NA]
	HR [95 %-KI] p-Wert	6,14 [3,133; 12,034] < 0,0001	
> 3 Monate	N	185	134
	Ereignisse, n (%)	113 (61 %)	14 (10 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	9,86 [7,857; 14,143]	NA [NA; NA]
	HR [95 %-KI] p-Wert	7,06 [4,031; 12,348] < 0,0001	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.4.1.9 Zeit bis zum ersten UESI "Augenerkrankungen": Subgruppenanalyse IC-Chemotherapie vor der Randomisierung zugewiesen

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Augenerkrankungen"</b>			
<b>IC-Chemotherapie vor der Randomisierung zugewiesen</b>			
Pegyliertes liposomales Doxorubicin	N	120	90
	Ereignisse, n (%)	74 (62 %)	11 (12 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	9,14 [7,714; 14,143]	NA [33,143; NA]
	HR [95 %-KI] p-Wert	4,81 [2,542; 9,094] < 0,0001	
Paclitaxel	N	116	95
	Ereignisse, n (%)	67 (58 %)	12 (13 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	9,14 [5,857; 14,143]	NA [32,429; NA]
	HR [95 %-KI] p-Wert	6,34 [3,393; 11,848] < 0,0001	
Topotecan	N	61	54
	Ereignisse, n (%)	34 (56 %)	1 (2 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	10,14 [5,286; 18,429]	NA [26,143; NA]
	HR [95 %-KI] p-Wert	35,21 [4,797; 258,514] < 0,0001	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

**4.4.1.10 Zeit bis zum ersten UESI "Augenerkrankungen": Subgruppenanalyse  
Daten aus Studie**

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Augenerkrankungen"</b>			
<b>Daten aus Studie</b>			
MIRASOL	N	218	207
	Ereignisse, n (%)	124 (57 %)	18 (9 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	10,14 [8,143; 13,714]	NA [NA; NA]
	HR [95 %-KI] p-Wert	7,56 [4,607; 12,415] < 0,0001	
FORWARD 1	N	79	32
	Ereignisse, n (%)	51 (65 %)	6 (19 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	8,14 [5,143; 15,857]	NA [23,571; NA]
	HR [95 %-KI] p-Wert	4,59 [1,965; 10,735] < 0,0001	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

## 4.4.2 Zeit bis zum ersten schweren UESI "Augenerkrankungen"

### 4.4.2.1 Zeit bis zum ersten schweren UESI "Augenerkrankungen": Subgruppenanalyse Alter

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten schweren UESI "Augenerkrankungen"</b>			
<b>Alter</b>			
< 65 Jahre	N	155	140
	Ereignisse, n (%)	21 (14 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	106,00 [106,000; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
≥ 65 Jahre	N	142	99
	Ereignisse, n (%)	21 (15 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [55,000; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.4.2.2 Zeit bis zum ersten schweren UESI "Augenerkrankungen": Subgruppenanalyse Region

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
Zeit bis zum ersten schweren UESI "Augenerkrankungen"			
Region			
USA	N	86	56
	Ereignisse, n (%)	13 (15 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	106,00 [44,714; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
Rest der Welt	N	211	183
	Ereignisse, n (%)	29 (14 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [78,571; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
<p>Analysepopulation: Safety/relevante Biomarker-Population</p> <p>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</p> <p>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</p> <p>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</p> <p>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</p> <p>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</p>			



**4.4.2.3 Zeit bis zum ersten schweren UESI "Augenerkrankungen":  
Subgruppenanalyse Stadium bei der Diagnose**

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
Zeit bis zum ersten schweren UESI "Augenerkrankungen"			
Stadium bei der Diagnose			
I-III	N	194	168
	Ereignisse, n (%)	33 (17 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	106,00 [78,571; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
IV	N	97	68
	Ereignisse, n (%)	9 (9 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [NA; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

**4.4.2.4 Zeit bis zum ersten schweren UESI "Augenerkrankungen":  
Subgruppenanalyse BRCA Status**

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten schweren UESI "Augenerkrankungen"</b>			
<b>BRCA Status</b>			
Positiv	N	38	37
	Ereignisse, n (%)	7 (18 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [44,714; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
Negativ/Unbekannt	N	259	202
	Ereignisse, n (%)	35 (14 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [78,571; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

**4.4.2.5 Zeit bis zum ersten schweren UESI "Augenerkrankungen":  
Subgruppenanalyse Baseline ECOG PS**

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten schweren UESI "Augenerkrankungen"</b>			
<b>Baseline ECOG PS</b>			
0	N	174	133
	Ereignisse, n (%)	29 (17 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	106,00 [78,571; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
1	N	123	103
	Ereignisse, n (%)	13 (11 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [NA; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

**4.4.2.6 Zeit bis zum ersten schweren UESI "Augenerkrankungen":  
Subgruppenanalyse Anzahl vorheriger Therapielinien**

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten schweren UESI "Augenerkrankungen"</b>			
<b>Anzahl vorheriger Therapielinien</b>			
1 oder 2	N	171	131
	Ereignisse, n (%)	22 (13 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [78,571; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
3	N	126	108
	Ereignisse, n (%)	20 (16 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [44,714; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
<i>Analysepopulation: Safety/relevante Biomarker-Population</i>			
<i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i>			
<i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i>			
<i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i>			
<i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i>			
<i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i>			

**4.4.2.7 Zeit bis zum ersten schweren UESI "Augenerkrankungen":  
Subgruppenanalyse Vorherige Verabreichung von Bevacizumab**

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten schweren UESI "Augenerkrankungen"</b>			
<b>Vorherige Verabreichung von Bevacizumab</b>			
Ja	N	173	149
	Ereignisse, n (%)	29 (17 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [55,000; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
Nein	N	124	90
	Ereignisse, n (%)	13 (10 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [106,000; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
<i>Analysepopulation: Safety/relevante Biomarker-Population</i>			
<i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i>			
<i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i>			
<i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i>			
<i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i>			
<i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i>			

**4.4.2.8 Zeit bis zum ersten schweren UESI "Augenerkrankungen":  
Subgruppenanalyse Letztes Platin-freies Intervall**

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten schweren UESI "Augenerkrankungen"</b>			
<b>Letztes Platin-freies Intervall</b>			
≤ 3 Monate	N	112	105
	Ereignisse, n (%)	16 (14 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [NA; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
> 3 Monate	N	185	134
	Ereignisse, n (%)	26 (14 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [78,571; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

**4.4.2.9 Zeit bis zum ersten schweren UESI "Augenerkrankungen":  
Subgruppenanalyse IC-Chemotherapie vor der Randomisierung zugewiesen**

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten schweren UESI "Augenerkrankungen"</b>			
<b>IC-Chemotherapie vor der Randomisierung zugewiesen</b>			
Pegyliertes liposomales Doxorubicin	N	120	90
	Ereignisse, n (%)	19 (16 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [78,571; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
Paclitaxel	N	116	95
	Ereignisse, n (%)	17 (15 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [41,000; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
Topotecan	N	61	54
	Ereignisse, n (%)	6 (10 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [NA; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

**4.4.2.10 Zeit bis zum ersten schweren UESI "Augenerkrankungen":  
Subgruppenanalyse Daten aus Studie**

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten schweren UESI "Augenerkrankungen"</b>			
<b>Daten aus Studie</b>			
MIRASOL	N	218	207
	Ereignisse, n (%)	31 (14 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [NA; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
FORWARD 1	N	79	32
	Ereignisse, n (%)	11 (14 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	106,00 [44,714; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			



## 4.5 UESI "Periphere Neuropathie"

### 4.5.1 Zeit bis zum ersten UESI "Periphere Neuropathie"

#### 4.5.1.1 Zeit bis zum ersten UESI "Periphere Neuropathie": Subgruppenanalyse Alter

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Periphere Neuropathie"</b>			
<b>Alter</b>			
< 65 Jahre	N	155	140
	Ereignisse, n (%)	63 (41 %)	34 (24 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	60,14 [12,286; NA]	NA [19,143; NA]
	HR [95 %-KI] p-Wert	1,43 [0,940; 2,186] 0,0901	
≥ 65 Jahre	N	142	99
	Ereignisse, n (%)	54 (38 %)	22 (22 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	36,00 [17,143; NA]	NA [14,571; NA]
	HR [95 %-KI] p-Wert	1,42 [0,858; 2,364] 0,1634	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.5.1.2 Zeit bis zum ersten UESI "Periphere Neuropathie": Subgruppenanalyse Region

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Periphere Neuropathie"</b>			
<b>Region</b>			
USA	N	86	56
	Ereignisse, n (%)	32 (37 %)	8 (14 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	60,14 [8,714; NA]	NA [28,429; NA]
	HR [95 %-KI] p-Wert	2,46 [1,121; 5,420] 0,0158	
Rest der Welt	N	211	183
	Ereignisse, n (%)	85 (40 %)	48 (26 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	52,14 [19,143; NA]	NA [16,571; NA]
	HR [95 %-KI] p-Wert	1,24 [0,866; 1,780] 0,2357	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

### 4.5.1.3 Zeit bis zum ersten UESI "Periphere Neuropathie": Subgruppenanalyse Stadium bei der Diagnose

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
Zeit bis zum ersten UESI "Periphere Neuropathie"			
Stadium bei der Diagnose			
I-III	N	194	168
	Ereignisse, n (%)	81 (42 %)	40 (24 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	36,00 [12,143; NA]	NA [24,286; NA]
	HR [95 %-KI] p-Wert	1,54 [1,048; 2,264] 0,0251	
IV	N	97	68
	Ereignisse, n (%)	33 (34 %)	15 (22 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [21,000; NA]	NA [15,286; NA]
	HR [95 %-KI] p-Wert	1,19 [0,639; 2,210] 0,5821	
<p>Analysepopulation: Safety/relevante Biomarker-Population</p> <p>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</p> <p>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</p> <p>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</p> <p>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</p> <p>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</p>			

#### 4.5.1.4 Zeit bis zum ersten UESI "Periphere Neuropathie": Subgruppenanalyse BRCA Status

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Periphere Neuropathie"</b>			
<b>BRCA Status</b>			
Positiv	N	38	37
	Ereignisse, n (%)	16 (42 %)	9 (24 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	52,14 [6,143; NA]	NA [9,571; NA]
	HR [95 %-KI] p-Wert	1,45 [0,616; 3,431] 0,3882	
Negativ/Unbekannt	N	259	202
	Ereignisse, n (%)	101 (39 %)	47 (23 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	36,14 [17,143; NA]	NA [28,429; NA]
	HR [95 %-KI] p-Wert	1,45 [1,023; 2,061] 0,0332	
<i>Analysepopulation: Safety/relevante Biomarker-Population</i>			
<i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i>			
<i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i>			
<i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i>			
<i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i>			
<i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i>			

#### 4.5.1.5 Zeit bis zum ersten UESI "Periphere Neuropathie": Subgruppenanalyse Baseline ECOG PS

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Periphere Neuropathie"</b>			
<b>Baseline ECOG PS</b>			
0	N	174	133
	Ereignisse, n (%)	76 (44 %)	28 (21 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	36,14 [10,143; NA]	NA [28,429; NA]
	HR [95 %-KI] p-Wert	1,96 [1,266; 3,044] 0,0017	
1	N	123	103
	Ereignisse, n (%)	41 (33 %)	27 (26 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [16,143; NA]	19,14 [14,286; NA]
	HR [95 %-KI] p-Wert	0,89 [0,538; 1,466] 0,6430	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.5.1.6 Zeit bis zum ersten UESI "Periphere Neuropathie": Subgruppenanalyse Anzahl vorheriger Therapielinien

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Periphere Neuropathie"</b>			
<b>Anzahl vorheriger Therapielinien</b>			
1 oder 2	N	171	131
	Ereignisse, n (%)	76 (44 %)	30 (23 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	27,86 [11,857; NA]	NA [28,429; NA]
	HR [95 %-KI] p-Wert	1,62 [1,050; 2,488] 0,0249	
3	N	126	108
	Ereignisse, n (%)	41 (33 %)	26 (24 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [17,143; NA]	NA [14,286; NA]
	HR [95 %-KI] p-Wert	1,17 [0,711; 1,918] 0,5383	
<i>Analysepopulation: Safety/relevante Biomarker-Population</i>			
<i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i>			
<i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i>			
<i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i>			
<i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i>			
<i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i>			

#### 4.5.1.7 Zeit bis zum ersten UESI "Periphere Neuropathie": Subgruppenanalyse Vorherige Verabreichung von Bevacizumab

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Periphere Neuropathie"</b>			
<b>Vorherige Verabreichung von Bevacizumab</b>			
Ja	N	173	149
	Ereignisse, n (%)	71 (41 %)	28 (19 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	27,29 [12,143; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	1,99 [1,276; 3,093] 0,0016	
Nein	N	124	90
	Ereignisse, n (%)	46 (37 %)	28 (31 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	60,14 [36,000; NA]	24,29 [14,571; NA]
	HR [95 %-KI] p-Wert	0,92 [0,571; 1,494] 0,7463	
<i>Analysepopulation: Safety/relevante Biomarker-Population</i>			
<i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i>			
<i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i>			
<i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i>			
<i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i>			
<i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i>			

#### 4.5.1.8 Zeit bis zum ersten UESI "Periphere Neuropathie": Subgruppenanalyse Letztes Platin-freies Intervall

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Periphere Neuropathie"</b>			
<b>Letztes Platin-freies Intervall</b>			
≤ 3 Monate	N	112	105
	Ereignisse, n (%)	40 (36 %)	23 (22 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [10,143; NA]	NA [14,571; NA]
	HR [95 %-KI] p-Wert	1,48 [0,882; 2,485] 0,1322	
> 3 Monate	N	185	134
	Ereignisse, n (%)	77 (42 %)	33 (25 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	36,00 [15,286; NA]	NA [24,286; NA]
	HR [95 %-KI] p-Wert	1,37 [0,904; 2,079] 0,1312	
<i>Analysepopulation: Safety/relevante Biomarker-Population</i>			
<i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i>			
<i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i>			
<i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i>			
<i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i>			
<i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i>			



#### 4.5.1.9 Zeit bis zum ersten UESI "Periphere Neuropathie": Subgruppenanalyse IC-Chemotherapie vor der Randomisierung zugewiesen

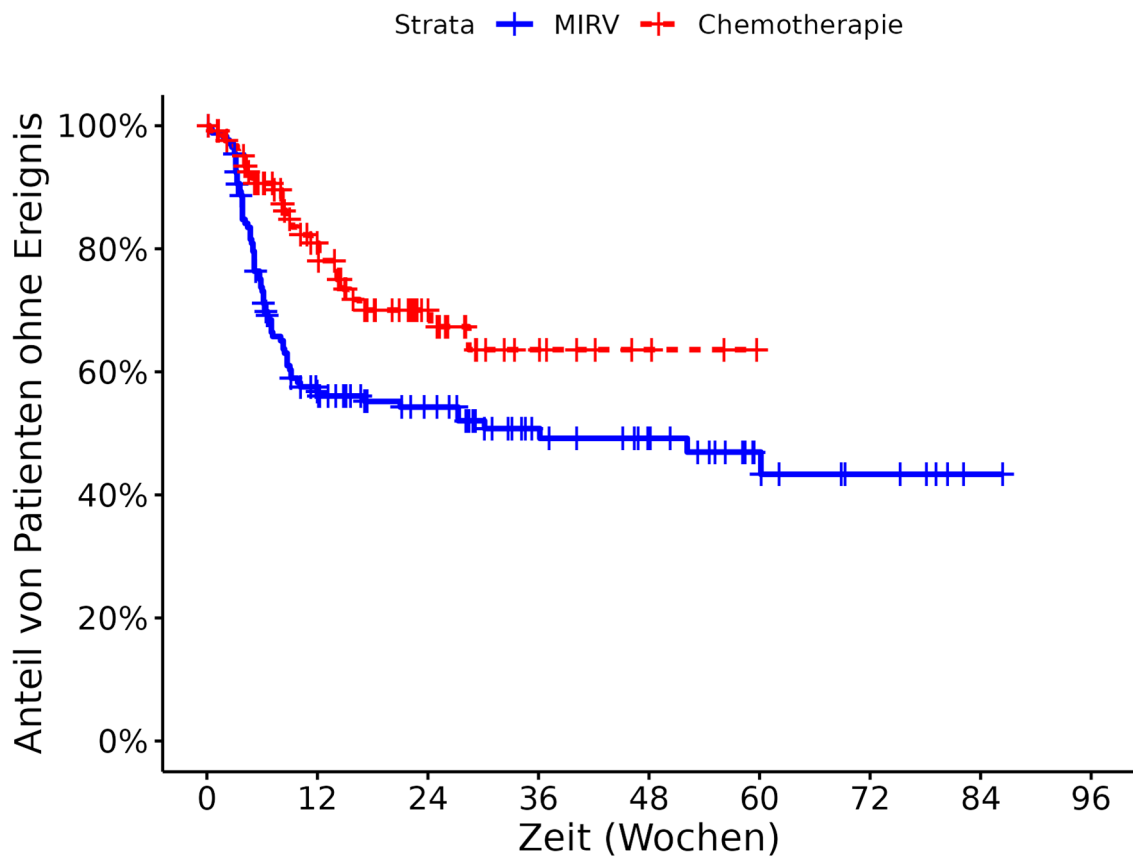
MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Periphere Neuropathie"</b>			
<b>IC-Chemotherapie vor der Randomisierung zugewiesen</b>			
Pegyliertes liposomales Doxorubicin	N	120	90
	Ereignisse, n (%)	41 (34 %)	11 (12 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [27,286; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	2,15 [1,095; 4,230] 0,0180	
Paclitaxel	N	116	95
	Ereignisse, n (%)	54 (47 %)	44 (46 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	27,86 [8,714; NA]	13,14 [9,286; 16,571]
	HR [95 %-KI] p-Wert	0,81 [0,533; 1,218] 0,3072	
Topotecan	N	61	54
	Ereignisse, n (%)	22 (36 %)	1 (2 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [8,857; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	19,04 [2,562; 141,464] < 0,0001	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.4.1.10 Zeit bis zum ersten UESI "Periphere Neuropathie": Subgruppenanalyse Daten aus Studie

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Periphere Neuropathie"</b>			
<b>Daten aus Studie</b>			
MIRASOL	N	218	207
	Ereignisse, n (%)	81 (37 %)	47 (23 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [19,143; NA]	NA [24,286; NA]
	HR [95 %-KI] p-Wert	1,41 [0,986; 2,028] 0,0567	
FORWARD 1	N	79	32
	Ereignisse, n (%)	36 (46 %)	9 (28 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	27,29 [7,000; NA]	NA [9,571; NA]
	HR [95 %-KI] p-Wert	1,45 [0,696; 3,024] 0,3043	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

4.5.1.10.1 Zeit bis zum ersten UESI "Periphere Neuropathie" Kaplan-Meier-Plot in Subgruppe Baseline ECOG PS\_0

Kaplan Meier Plot 233.1.3.S.07.03 05000 A09

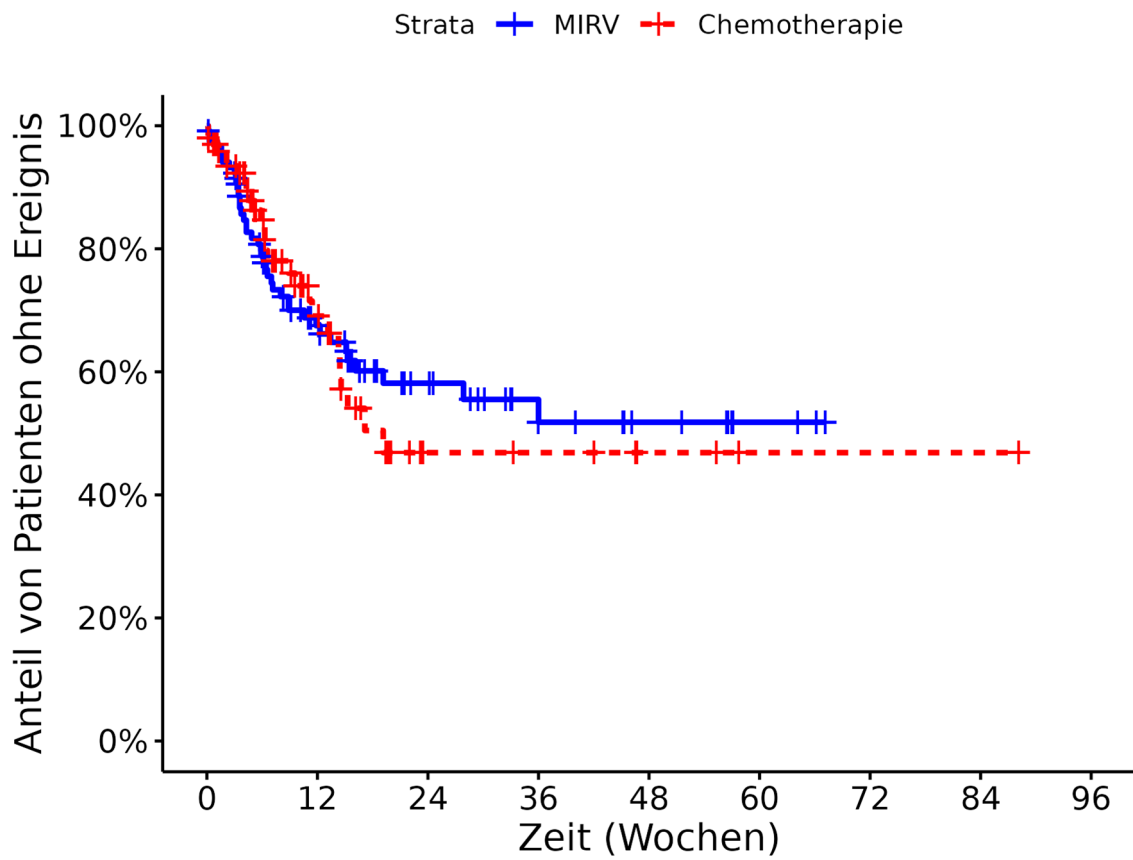


**Patienten unter Risiko**

MIRV	174	78	54	32	24	13	6	1	0
Chemotherapie	133	58	27	10	3	0	0	0	0

4.5.1.10.2 Zeit bis zum ersten UESI "Periphere Neuropathie" Kaplan-Meier-Plot in Subgruppe Baseline ECOG PS\_1

Kaplan Meier Plot 233.1.3.S.07.03 05000 A10

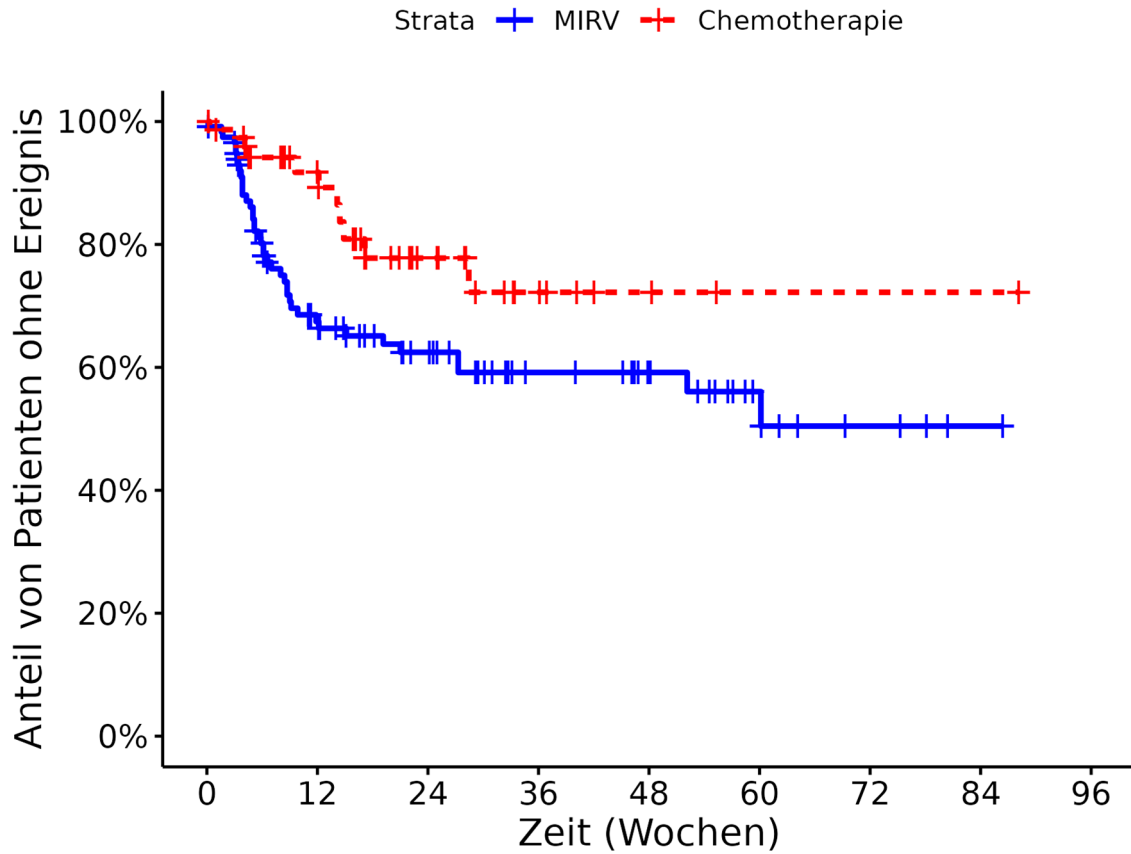


**Patienten unter Risiko**

MIRV	123	53	24	15	9	3	0	0	0
Chemotherapie	103	28	7	6	3	1	1	1	0

4.5.1.1.0.3 Zeit bis zum ersten UESI "Periphere Neuropathie" Kaplan-Meier-Plot in Subgruppe IC-Chemotherapie vor der Randomisierung zugewiesen Pegyliertes liposomales Doxorubicin

Kaplan Meier Plot 233.1.3.S.07.03 12000 A25

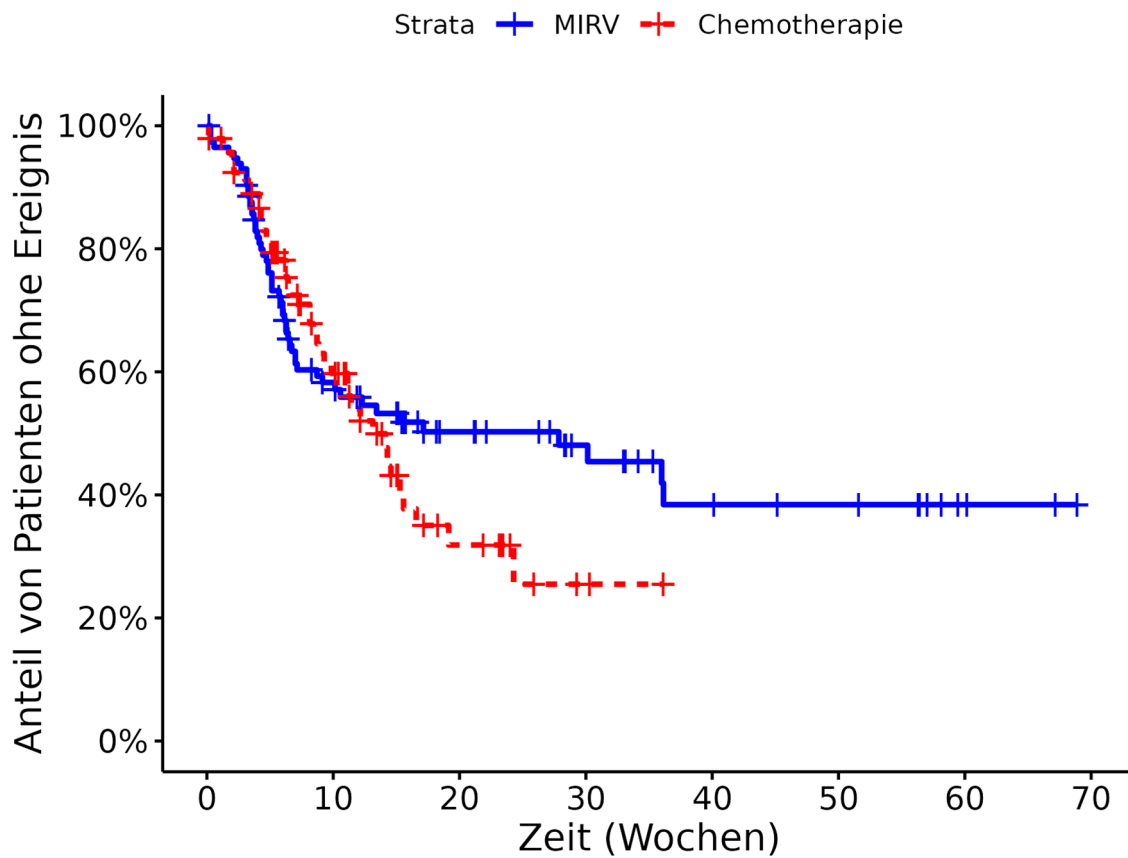


**Patienten unter Risiko**

MIRV	120	61	43	27	20	10	4	1	0
Chemotherapie	90	38	18	7	3	1	1	1	0

4.5.1.10.4 Zeit bis zum ersten UESI "Periphere Neuropathie" Kaplan-Meier-Plot in Subgruppe IC-Chemotherapie vor der Randomisierung zugewiesen Paclitaxel

Kaplan Meier Plot 233.1.3.S.07.03 12000 A26

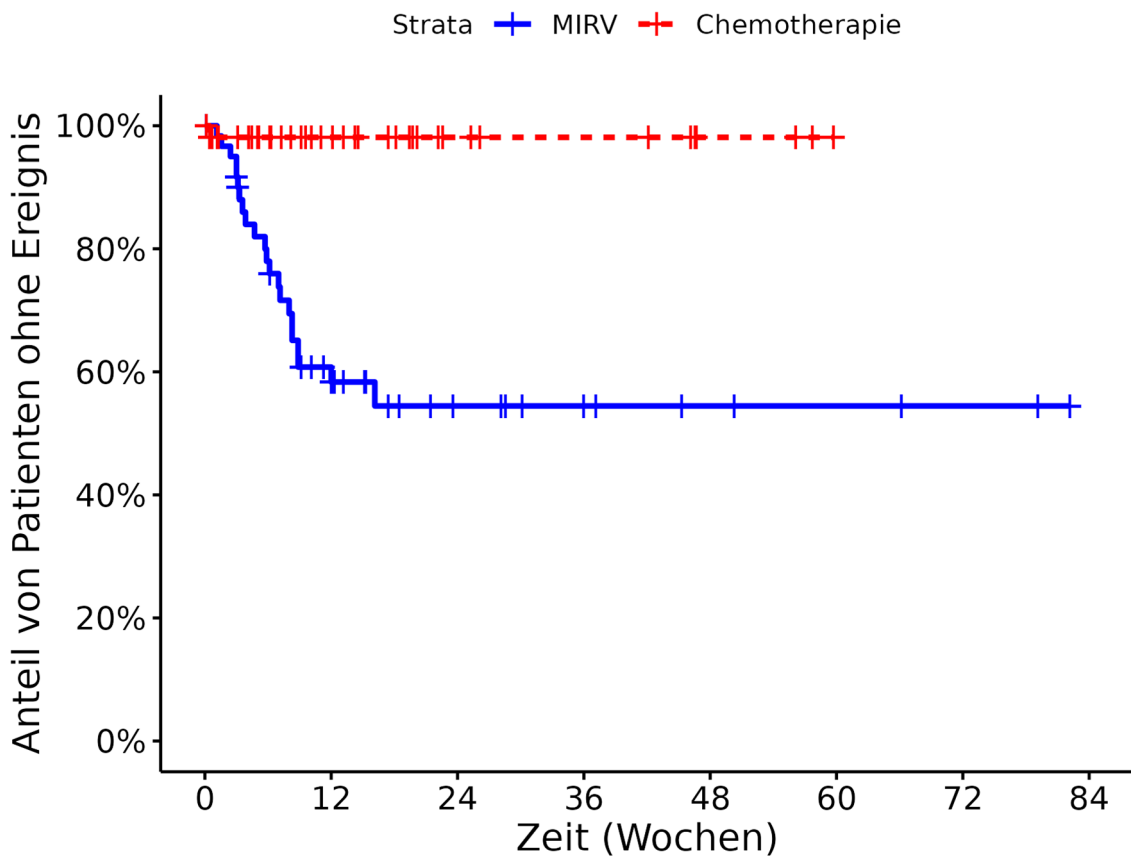


**Patienten unter Risiko**

MIRV	116	50	29	18	11	9	3	0
Chemotherapie	95	37	10	2	0	0	0	0

4.5.1.10.5 Zeit bis zum ersten UESI "Periphere Neuropathie" Kaplan-Meier-Plot in Subgruppe IC-Chemotherapie vor der Randomisierung zugewiesen Topotecan

Kaplan Meier Plot 233.1.3.S.07.03 12000 A27



**Patienten unter Risiko**

MIRV	61	25	10	7	4	3	2	0
Chemotherapie	54	21	10	8	3	0	0	0

## 4.6 UESI "Pneumonitis"

### 4.6.1 Zeit bis zum ersten UESI "Pneumonitis"

#### 4.6.1.1 Zeit bis zum ersten UESI "Pneumonitis": Subgruppenanalyse Alter

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Pneumonitis"</b>			
<b>Alter</b>			
< 65 Jahre	N	155	140
	Ereignisse, n (%)	19 (12 %)	1 (1 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [71,571; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	9,36 [1,234; 70,991] 0,0027	
≥ 65 Jahre	N	142	99
	Ereignisse, n (%)	18 (13 %)	2 (2 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	84,14 [56,714; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	2,97 [0,673; 13,122] 0,1013	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			



#### 4.6.1.2 Zeit bis zum ersten UESI "Pneumonitis": Subgruppenanalyse Region

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Pneumonitis"</b>			
<b>Region</b>			
USA	N	86	56
	Ereignisse, n (%)	10 (12 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [71,571; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
Rest der Welt	N	211	183
	Ereignisse, n (%)	27 (13 %)	3 (2 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	84,14 [84,143; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	3,63 [1,071; 12,275] 0,0164	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

### 4.6.1.3 Zeit bis zum ersten UESI "Pneumonitis": Subgruppenanalyse Stadium bei der Diagnose

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
Zeit bis zum ersten UESI "Pneumonitis"			
Stadium bei der Diagnose			
I-III	N	194	168
	Ereignisse, n (%)	22 (11 %)	3 (2 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	84,14 [71,571; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	2,92 [0,855; 9,946] 0,0541	
IV	N	97	68
	Ereignisse, n (%)	14 (14 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [56,714; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
<p>Analysepopulation: Safety/relevante Biomarker-Population</p> <p>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</p> <p>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</p> <p>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</p> <p>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</p> <p>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</p>			

#### 4.6.1.4 Zeit bis zum ersten UESI "Pneumonitis": Subgruppenanalyse BRCA Status

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Pneumonitis"</b>			
<b>BRCA Status</b>			
Positiv	N	38	37
	Ereignisse, n (%)	7 (18 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [47,429; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
Negativ/Unbekannt	N	259	202
	Ereignisse, n (%)	30 (12 %)	3 (1 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	84,14 [71,571; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	4,24 [1,276; 14,091] 0,0048	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.6.1.5 Zeit bis zum ersten UESI "Pneumonitis": Subgruppenanalyse Baseline ECOG PS

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Pneumonitis"</b>			
<b>Baseline ECOG PS</b>			
0	N	174	133
	Ereignisse, n (%)	26 (15 %)	1 (1 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	84,14 [56,714; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	9,40 [1,256; 70,395] 0,0020	
1	N	123	103
	Ereignisse, n (%)	11 (9 %)	2 (2 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [NA; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	2,61 [0,562; 12,099] 0,1789	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

**4.6.1.6 Zeit bis zum ersten UESI "Pneumonitis": Subgruppenanalyse  
Anzahl vorheriger Therapielinien**

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Pneumonitis"</b>			
<b>Anzahl vorheriger Therapielinien</b>			
1 oder 2	N	171	131
	Ereignisse, n (%)	20 (12 %)	2 (2 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	84,14 [71,571; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	2,77 [0,626; 12,269] 0,1290	
3	N	126	108
	Ereignisse, n (%)	17 (13 %)	1 (1 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [45,429; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	10,26 [1,358; 77,557] 0,0015	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

**4.6.1.7 Zeit bis zum ersten UESI "Pneumonitis": Subgruppenanalyse  
Vorherige Verabreichung von Bevacizumab**

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Pneumonitis"</b>			
<b>Vorherige Verabreichung von Bevacizumab</b>			
Ja	N	173	149
	Ereignisse, n (%)	21 (12 %)	2 (1 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [84,143; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	4,87 [1,122; 21,126] 0,0099	
Nein	N	124	90
	Ereignisse, n (%)	16 (13 %)	1 (1 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [56,714; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	5,74 [0,744; 44,270] 0,0325	
<i>Analysepopulation: Safety/relevante Biomarker-Population</i>			
<i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i>			
<i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i>			
<i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i>			
<i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i>			
<i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i>			

#### 4.6.1.8 Zeit bis zum ersten UESI "Pneumonitis": Subgruppenanalyse Letztes Platin-freies Intervall

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Pneumonitis"</b>			
<b>Letztes Platin-freies Intervall</b>			
≤ 3 Monate	N	112	105
	Ereignisse, n (%)	13 (12 %)	1 (1 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [48,143; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	8,44 [1,096; 64,978] 0,0062	
> 3 Monate	N	185	134
	Ereignisse, n (%)	24 (13 %)	2 (1 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	84,14 [71,571; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	3,66 [0,840; 15,917] 0,0420	
<i>Analysepopulation: Safety/relevante Biomarker-Population</i>			
<i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i>			
<i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i>			
<i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i>			
<i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i>			
<i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i>			

**4.6.1.9 Zeit bis zum ersten UESI "Pneumonitis": Subgruppenanalyse IC-Chemotherapie vor der Randomisierung zugewiesen**

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Pneumonitis"</b>			
<b>IC-Chemotherapie vor der Randomisierung zugewiesen</b>			
Pegyliertes liposomales Doxorubicin	N	120	90
	Ereignisse, n (%)	19 (16 %)	0 (0 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	84,14 [71,571; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	NA [NA; NA] NA	
Paclitaxel	N	116	95
	Ereignisse, n (%)	13 (11 %)	2 (2 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [45,429; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	2,66 [0,547; 12,892] 0,1899	
Topotecan	N	61	54
	Ereignisse, n (%)	5 (8 %)	1 (2 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [47,286; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	2,60 [0,300; 22,627] 0,3398	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			



**4.6.1.10 Zeit bis zum ersten UESI "Pneumonitis": Subgruppenanalyse  
Daten aus Studie**

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum ersten UESI "Pneumonitis"</b>			
<b>Daten aus Studie</b>			
MIRASOL	N	218	207
	Ereignisse, n (%)	26 (12 %)	1 (0,5 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [56,714; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	13,22 [1,780; 98,225] 0,0001	
FORWARD 1	N	79	32
	Ereignisse, n (%)	11 (14 %)	2 (6 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	84,14 [71,571; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	1,30 [0,279; 6,029] 0,7339	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

## 4.7 Zeit bis zum Therapieabbruch aufgrund von UE

### 4.7.1 Zeit bis zum Therapieabbruch aufgrund von UE: Subgruppenanalyse Alter

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum Therapieabbruch aufgrund von UE</b>			
<b>Alter</b>			
< 65 Jahre	N	155	140
	Ereignisse, n (%)	21 (14 %)	23 (16 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [61,143; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	0,43 [0,230; 0,804] 0,0081	
≥ 65 Jahre	N	142	99
	Ereignisse, n (%)	14 (10 %)	25 (25 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [73,857; NA]	55,29 [25,286; NA]
	HR [95 %-KI] p-Wert	0,22 [0,113; 0,448] < 0,0001	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.7.2 Zeit bis zum Therapieabbruch aufgrund von UE: Subgruppenanalyse Region

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum Therapieabbruch aufgrund von UE</b>			
<b>Region</b>			
USA	N	86	56
	Ereignisse, n (%)	9 (10 %)	16 (29 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [61,143; NA]	55,29 [21,143; NA]
	HR [95 %-KI] p-Wert	0,15 [0,057; 0,387] < 0,0001	
Rest der Welt	N	211	183
	Ereignisse, n (%)	26 (12 %)	32 (17 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [73,857; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	0,38 [0,223; 0,661] 0,0005	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschmitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

### 4.7.3 Zeit bis zum Therapieabbruch aufgrund von UE: Subgruppenanalyse Stadium bei der Diagnose

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
Zeit bis zum Therapieabbruch aufgrund von UE			
Stadium bei der Diagnose			
I-III	N	194	168
	Ereignisse, n (%)	18 (9 %)	34 (20 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [NA; NA]	79,14 [55,286; NA]
	HR [95 %-KI] p-Wert	0,25 [0,136; 0,451] < 0,0001	
IV	N	97	68
	Ereignisse, n (%)	17 (18 %)	14 (21 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [56,143; NA]	NA [21,000; NA]
	HR [95 %-KI] p-Wert	0,42 [0,196; 0,890] 0,0262	
<p>Analysepopulation: Safety/relevante Biomarker-Population</p> <p>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</p> <p>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</p> <p>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</p> <p>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</p> <p>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</p>			

#### 4.7.4 Zeit bis zum Therapieabbruch aufgrund von UE: Subgruppenanalyse BRCA Status

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum Therapieabbruch aufgrund von UE</b>			
<b>BRCA Status</b>			
Positiv	N	38	37
	Ereignisse, n (%)	7 (18 %)	7 (19 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	61,14 [56,143; NA]	NA [25,286; NA]
	HR [95 %-KI] p-Wert	0,27 [0,071; 1,012] 0,0457	
Negativ/Unbekannt	N	259	202
	Ereignisse, n (%)	28 (11 %)	41 (20 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [NA; NA]	79,14 [55,286; NA]
	HR [95 %-KI] p-Wert	0,32 [0,196; 0,527] < 0,0001	
<i>Analysepopulation: Safety/relevante Biomarker-Population</i>			
<i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i>			
<i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i>			
<i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i>			
<i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i>			
<i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i>			

#### 4.7.5 Zeit bis zum Therapieabbruch aufgrund von UE: Subgruppenanalyse Baseline ECOG PS

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum Therapieabbruch aufgrund von UE</b>			
<b>Baseline ECOG PS</b>			
0	N	174	133
	Ereignisse, n (%)	17 (10 %)	24 (18 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [NA; NA]	79,14 [NA; NA]
	HR [95 %-KI] p-Wert	0,26 [0,135; 0,507] 0,0001	
1	N	123	103
	Ereignisse, n (%)	18 (15 %)	23 (22 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [57,429; NA]	55,29 [25,286; NA]
	HR [95 %-KI] p-Wert	0,40 [0,214; 0,766] 0,0053	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

**4.7.6 Zeit bis zum Therapieabbruch aufgrund von UE: Subgruppenanalyse  
Anzahl vorheriger Therapielinien**

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum Therapieabbruch aufgrund von UE</b>			
<b>Anzahl vorheriger Therapielinien</b>			
1 oder 2	N	171	131
	Ereignisse, n (%)	19 (11 %)	18 (14 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [NA; NA]	NA [55,286; NA]
	HR [95 %-KI] p-Wert	0,41 [0,208; 0,812] 0,0114	
3	N	126	108
	Ereignisse, n (%)	16 (13 %)	30 (28 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [61,143; NA]	79,14 [21,143; NA]
	HR [95 %-KI] p-Wert	0,25 [0,134; 0,479] < 0,0001	
<i>Analysepopulation: Safety/relevante Biomarker-Population</i>			
<i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i>			
<i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i>			
<i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i>			
<i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i>			
<i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i>			

#### 4.7.7 Zeit bis zum Therapieabbruch aufgrund von UE: Subgruppenanalyse Vorherige Verabreichung von Bevacizumab

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum Therapieabbruch aufgrund von UE</b>			
<b>Vorherige Verabreichung von Bevacizumab</b>			
Ja	N	173	149
	Ereignisse, n (%)	23 (13 %)	26 (17 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [73,857; NA]	NA [55,286; NA]
	HR [95 %-KI] p-Wert	0,42 [0,234; 0,758] 0,0040	
Nein	N	124	90
	Ereignisse, n (%)	12 (10 %)	22 (24 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [NA; NA]	79,14 [26,000; NA]
	HR [95 %-KI] p-Wert	0,22 [0,105; 0,454] < 0,0001	
<i>Analysepopulation: Safety/relevante Biomarker-Population</i>			
<i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i>			
<i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i>			
<i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i>			
<i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i>			
<i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i>			



**4.7.8 Zeit bis zum Therapieabbruch aufgrund von UE: Subgruppenanalyse  
Letztes Platin-freies Intervall**

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum Therapieabbruch aufgrund von UE</b>			
<b>Letztes Platin-freies Intervall</b>			
≤ 3 Monate	N	112	105
	Ereignisse, n (%)	11 (10 %)	26 (25 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [NA; NA]	55,29 [25,286; NA]
	HR [95 %-KI] p-Wert	0,24 [0,119; 0,501] < 0,0001	
> 3 Monate	N	185	134
	Ereignisse, n (%)	24 (13 %)	22 (16 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [73,857; NA]	NA [NA; NA]
	HR [95 %-KI] p-Wert	0,40 [0,216; 0,753] 0,0047	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.7.9 Zeit bis zum Therapieabbruch aufgrund von UE: Subgruppenanalyse IC-Chemotherapie vor der Randomisierung zugewiesen

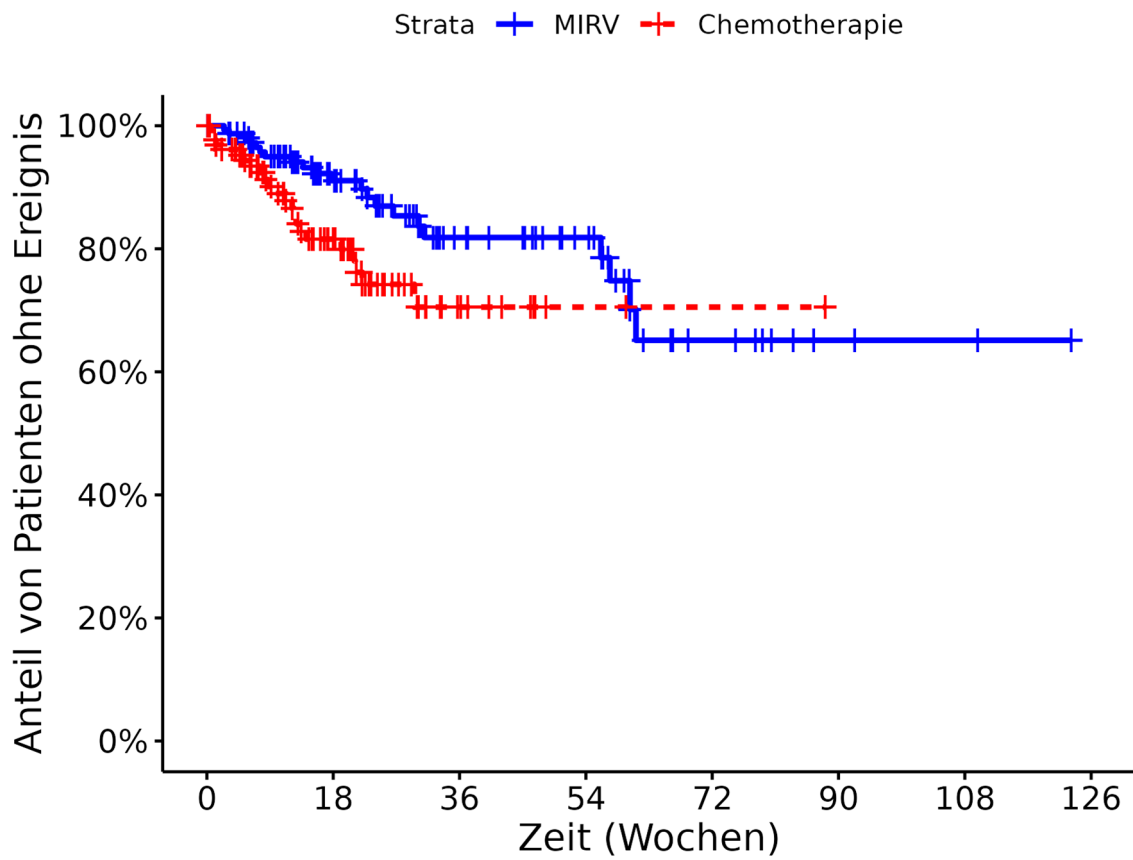
MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum Therapieabbruch aufgrund von UE</b>			
<b>IC-Chemotherapie vor der Randomisierung zugewiesen</b>			
Pegyliertes liposomales Doxorubicin	N	120	90
	Ereignisse, n (%)	13 (11 %)	12 (13 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [73,857; NA]	79,14 [55,286; NA]
	HR [95 %-KI] p-Wert	0,35 [0,154; 0,799] 0,0146	
Paclitaxel	N	116	95
	Ereignisse, n (%)	15 (13 %)	22 (23 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [NA; NA]	NA [29,571; NA]
	HR [95 %-KI] p-Wert	0,41 [0,207; 0,799] 0,0082	
Topotecan	N	61	54
	Ereignisse, n (%)	7 (11 %)	14 (26 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [34,143; NA]	NA [18,714; NA]
	HR [95 %-KI] p-Wert	0,32 [0,125; 0,795] 0,0112	
<p><i>Analysepopulation: Safety/relevante Biomarker-Population</i></p> <p><i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i></p> <p><i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i></p> <p><i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i></p> <p><i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i></p> <p><i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i></p>			

#### 4.7.10 Zeit bis zum Therapieabbruch aufgrund von UE: Subgruppenanalyse Daten aus Studie

MIRASOL + FORWARD 1		Behandlungsarm	
		MIRV	Chemotherapie
<b>Zeit bis zum Therapieabbruch aufgrund von UE</b>			
<b>Daten aus Studie</b>			
MIRASOL	N	218	207
	Ereignisse, n (%)	22 (10 %)	33 (16 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [73,857; NA]	79,14 [55,286; NA]
	HR [95 %-KI] p-Wert	0,39 [0,221; 0,673] 0,0007	
FORWARD 1	N	79	32
	Ereignisse, n (%)	13 (16 %)	15 (47 %)
	50. Perzentil/Median [95 %-KI] (Wochen)	NA [61,143; NA]	18,71 [8,714; NA]
	HR [95 %-KI] p-Wert	0,23 [0,107; 0,487] 0,0002	
<i>Analysepopulation: Safety/relevante Biomarker-Population</i>			
<i>Datenschnitt: MIRASOL 27.10.2023, FORWARD 1 18.03.2020</i>			
<i>Stratifizierungsvariablen: Anzahl vorheriger Therapien und IC-Chemotherapie wie zu Randomisierung festgelegt und Ursprungsstudie</i>			
<i>HR basierend auf einem Cox-Proportional-Hazard-Modell mit Behandlung und Stratifizierungsvariablen als Kovariablen, p-Wert des HR basierend auf einem Log-Rank-Test; KI des Medians basierend auf einer Log-Log-Transformation (nach Brookmeyer und Crowley).</i>			
<i>NA bei Perzentilen: nicht erreicht; NA bei Effektschätzern: Modell nicht konvergiert.</i>			
<i>Ein HR kleiner als Eins bedeutet dabei einen Vorteil für die Behandlung mit MIRV.</i>			

4.7.10.1 Zeit bis zum Therapieabbruch aufgrund von UE Kaplan-Meier-Plot in Subgruppe Alter\_ < 65 Jahre

Kaplan Meier Plot 233.1.3.S.09.03 01000 A01

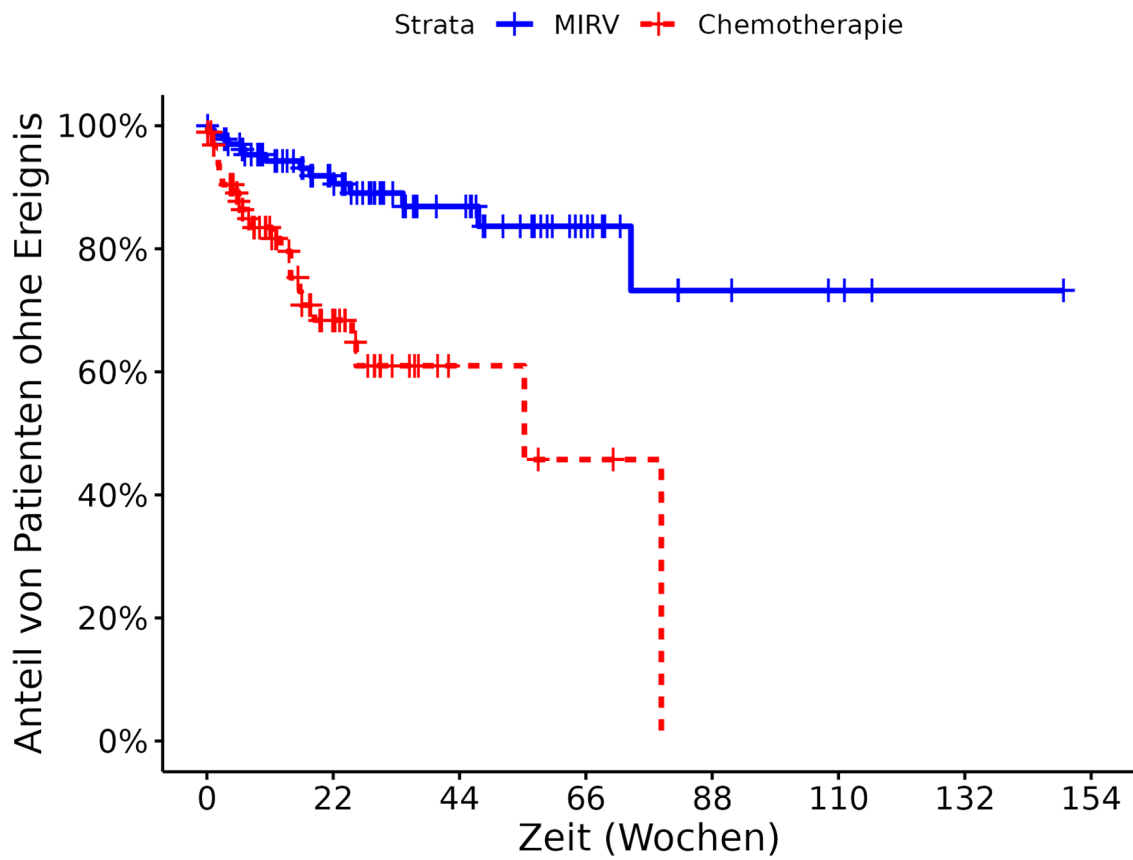


**Patienten unter Risiko**

MIRV	155	79	38	27	9	3	2	0
Chemotherapie	140	55	11	2	1	0	0	0

4.7.10.2 Zeit bis zum Therapieabbruch aufgrund von UE Kaplan-Meier-Plot in Subgruppe Alter  $\geq 65$  Jahre

Kaplan Meier Plot 233.1.3.S.09.03 01000 A02



**Patienten unter Risiko**

MIRV	142	71	34	13	5	3	1	0
Chemotherapie	99	25	4	2	0	0	0	0