

**Dossier zur Nutzenbewertung
gemäß § 35a SGB V**

Lusutrombopag (Mulpleo®)

Shionogi GmbH

Modul 4 A – Anhang 4-G

*Zur Behandlung der schweren Thrombozytopenie bei
Erwachsenen mit chronischer Lebererkrankung, die
sich einem invasiven Eingriff unterziehen müssen*

Medizinischer Nutzen und
medizinischer Zusatznutzen,
Patientengruppen mit therapeutisch
bedeutsamem Zusatznutzen

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Darstellung der Subgruppenanalysen mit und ohne signifikanten Interaktionsterm

Studie L-PLUS 2

Tabelle 4G-1: Subgruppenergebnisse für Studie L-PLUS 2: Vermeidung von Thrombozytentransfusionen und der Gabe einer Notfalltherapie zur Behandlung einer akuten Blutung

L-PLUS 2														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	84	65,5%(55/84)	88	28,4%(25/88)	4,779	[2,506;9,116]	0,371	[0,232;0,509]	2,305	[1,598;3,324]	0	0,71458	0,70096
Age (years)	- >=65	24	62,5%(15/24)	19	31,6%(6/19)	3,611	[1,012;12,888]	0,309	[0,024;0,594]	1,979	[0,953;4,11]	0,04397		
Gender	- Male	65	56,9%(37/65)	69	23,2%(16/69)	4,377	[2,08;9,211]	0,337	[0,181;0,494]	2,455	[1,521;3,962]	7e-05	0,47578	0,78123
Gender	- Female	43	76,7%(33/43)	38	39,5%(15/38)	5,06	[1,935;13,229]	0,373	[0,172;0,573]	1,944	[1,269;2,979]	0,00066		
Race	- White	85	69,4%(59/85)	86	29,1%(25/86)	5,537	[2,875;10,663]	0,403	[0,266;0,541]	2,388	[1,667;3,419]	0	0,42713	0,18718
Race	- Others	23	47,8%(11/23)	21	28,6%(6/21)	2,292	[0,656;8,009]	0,193	[-0,089;0,474]	1,674	[0,752;3,724]	0,19014		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	36	41,7%(15/36)	38	18,4%(7/38)	3,163	[1,102;9,079]	0,232	[0,03;0,435]	2,262	[1,044;4,898]	0,02877	0,97738	0,111
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	71	77,5%(55/71)	68	33,8%(23/68)	6,726	[3,177;14,236]	0,436	[0,288;0,585]	2,29	[1,605;3,267]	0		
Child-Pugh class	- A	72	62,5%(45/72)	63	30,2%(19/63)	3,86	[1,88;7,922]	0,323	[0,164;0,483]	2,072	[1,367;3,142]	0,00017	0,50172	0,34011
Child-Pugh class	- B	33	72,7%(24/33)	43	27,9%(12/43)	6,889	[2,496;19,016]	0,448	[0,246;0,651]	2,606	[1,543;4,4]	1e-04		
Invasive procedure	liver-related	20	55%(11/20)	20	25%(5/20)	3,667	[0,958;14,028]	0,3	[0,011;0,589]	2,2	[0,934;5,18]	0,05281	0,1412	0,34835
Invasive procedure	gi-related	61	70,5%(43/61)	60	26,7%(16/60)	6,569	[2,97;14,53]	0,438	[0,278;0,598]	2,643	[1,686;4,145]	0		
Invasive procedure	Non-liver/gi-related	21	76,2%(16/21)	18	55,6%(10/18)	2,56	[0,652;10,059]	0,206	[-0,087;0,499]	1,371	[0,851;2,211]	0,17295		
Baseline body weight (kg)	- < 75	53	69,8%(37/53)	50	34%(17/50)	4,489	[1,96;10,278]	0,358	[0,178;0,538]	2,053	[1,343;3,14]	0,00028	0,50279	0,93705
Baseline body weight (kg)	- >= 75	55	60%(33/55)	56	23,2%(13/56)	4,962	[2,181;11,289]	0,368	[0,198;0,538]	2,585	[1,532;4,36]	8e-05		
Treatment duration (days)	- < 7	34	82,4%(28/34)	13	46,2%(6/13)	5,444	[1,339;22,129]	0,362	[0,062;0,662]	1,784	[0,972;3,275]	0,01308	0,60068	0,75516
Treatment duration (days)	-7	73	57,5%(42/73)	94	26,6%(25/94)	3,739	[1,949;7,175]	0,309	[0,165;0,454]	2,163	[1,466;3,193]	5e-05		
Region	- EU	44	70,5%(31/44)	50	36%(18/50)	4,239	[1,78;10,095]	0,345	[0,155;0,534]	1,957	[1,291;2,967]	0,00085	0,35736	0,77795
Region	- Other	64	60,9%(39/64)	57	22,8%(13/57)	5,28	[2,38;11,714]	0,381	[0,22;0,543]	2,672	[1,594;4,478]	2e-05		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-2: Subgruppenergebnisse für Studie L-PLUS 2: Vermeidung von Thrombozytentransfusionen vor dem invasiven Eingriff

L-PLUS 2														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	84	65,5%(55/84)	88	29,5%(26/88)	4,523	[2,38;8,593]	0,359	[0,22;0,499]	2,216	[1,549;3,17]	0	0,78525	0,75679
Age (years)	- >=65	24	62,5%(15/24)	19	31,6%(6/19)	3,611	[1,012;12,888]	0,309	[0,024;0,594]	1,979	[0,953;4,11]	0,04397		
Gender	- Male	65	56,9%(37/65)	69	24,6%(17/69)	4,042	[1,937;8,433]	0,323	[0,165;0,48]	2,31	[1,453;3,673]	0,00014	0,59151	0,69971
Gender	- Female	43	76,7%(33/43)	38	39,5%(15/38)	5,06	[1,935;13,229]	0,373	[0,172;0,573]	1,944	[1,269;2,979]	0,00066		
Race	- White	85	69,4%(59/85)	86	30,2%(26/86)	5,237	[2,729;10,048]	0,392	[0,254;0,53]	2,296	[1,617;3,26]	0	0,47834	0,21134
Race	- Others	23	47,8%(11/23)	21	28,6%(6/21)	2,292	[0,656;8,009]	0,193	[-0,089;0,474]	1,674	[0,752;3,724]	0,19014		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	36	41,7%(15/36)	38	18,4%(7/38)	3,163	[1,102;9,079]	0,232	[0,03;0,435]	2,262	[1,044;4,898]	0,02877	0,94448	0,13772
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	71	77,5%(55/71)	68	35,3%(24/68)	6,302	[2,987;13,295]	0,422	[0,272;0,571]	2,195	[1,554;3,1]	0		
Child-Pugh class	- A	72	62,5%(45/72)	63	31,7%(20/63)	3,583	[1,756;7,314]	0,308	[0,147;0,468]	1,969	[1,315;2,948]	0,00036	0,40602	0,28761
Child-Pugh class	- B	33	72,7%(24/33)	43	27,9%(12/43)	6,889	[2,496;19,016]	0,448	[0,246;0,651]	2,606	[1,543;4,4]	1e-04		
Invasive procedure	liver-related	20	55%(11/20)	20	30%(6/20)	2,852	[0,777;10,467]	0,25	[-0,046;0,546]	1,833	[0,842;3,991]	0,10977	0,14504	0,28801
Invasive procedure	gi-related	61	70,5%(43/61)	60	26,7%(16/60)	6,569	[2,97;14,53]	0,438	[0,278;0,598]	2,643	[1,686;4,145]	0		
Invasive procedure	Non-liver/gi-related	21	76,2%(16/21)	18	55,6%(10/18)	2,56	[0,652;10,059]	0,206	[-0,087;0,499]	1,371	[0,851;2,211]	0,17295		
Baseline body weight (kg)	- < 75	53	69,8%(37/53)	50	34%(17/50)	4,489	[1,96;10,278]	0,358	[0,178;0,538]	2,053	[1,343;3,14]	0,00028	0,64166	0,9499
Baseline body weight (kg)	- >= 75	55	60%(33/55)	56	25%(14/56)	4,5	[2,001;10,12]	0,35	[0,178;0,522]	2,4	[1,452;3,966]	0,00019		
Treatment duration (days)	- < 7	34	82,4%(28/34)	13	46,2%(6/13)	5,444	[1,339;22,129]	0,362	[0,062;0,662]	1,784	[0,972;3,275]	0,01308	0,67476	0,71087
Treatment duration (days)	-7	73	57,5%(42/73)	94	27,7%(26/94)	3,543	[1,854;6,773]	0,299	[0,154;0,444]	2,08	[1,42;3,047]	1e-04		
Region	- EU	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Region	- Other	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-3: Subgruppenergebnisse für Studie L-PLUS 2: Vermeidung der Gabe einer Notfalltherapie zur Behandlung einer akuten Blutung

L-PLUS 2														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	84	100%(84/84)	88	98,9%(87/88)	2,897	[0,116;72,115]	0,011	[-0,02;0,043]	1,011	[0,989;1,034]	0,32715	0,82024	0,81784
Age (years)	- >=65	24	100%(24/24)	19	100%(19/19)	-	[NA;NA]	0	[-0,088;0,088]	1	[0,912;1,096]	NaN		
Gender	- Male	65	100%(65/65)	69	100%(69/69)	-	[NA;NA]	0	[-0,029;0,029]	1	[0,971;1,03]	NaN	0,3827	0,49474
Gender	- Female	43	100%(43/43)	38	97,4%(37/38)	3,48	[0,138;87,997]	0,026	[-0,042;0,094]	1,027	[0,975;1,081]	0,28445		
Race	- White	85	100%(85/85)	86	100%(86/86)	-	[NA;NA]	0	[-0,023;0,023]	1	[0,977;1,023]	NaN	0,3319	0,44006
Race	- Others	23	100%(23/23)	21	95,2%(20/21)	3,439	[0,133;89,134]	0,048	[-0,072;0,167]	1,049	[0,955;1,151]	0,28977		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	36	100%(36/36)	38	97,4%(37/38)	2,92	[0,115;74,03]	0,026	[-0,045;0,097]	1,027	[0,975;1,081]	0,3271	0,37532	0,50087
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	71	100%(71/71)	68	100%(68/68)	-	[NA;NA]	0	[-0,028;0,028]	1	[0,972;1,029]	NaN		
Child-Pugh class	- A	72	100%(72/72)	63	100%(63/63)	-	[NA;NA]	0	[-0,029;0,029]	1	[0,971;1,03]	NaN	0,39703	0,53597
Child-Pugh class	- B	33	100%(33/33)	43	97,7%(42/43)	2,365	[0,093;59,928]	0,023	[-0,044;0,09]	1,024	[0,978;1,071]	0,37785		
Invasive procedure	liver-related	20	100%(20/20)	20	100%(20/20)	-	[NA;NA]	0	[-0,092;0,092]	1	[0,908;1,102]	NaN	0,63021	0,73662
Invasive procedure	gi-related	61	100%(61/61)	60	100%(60/60)	-	[NA;NA]	0	[-0,032;0,032]	1	[0,968;1,033]	NaN		
Invasive procedure	Non-liver/gi-related	21	100%(21/21)	18	94,4%(17/18)	3,686	[0,141;96,224]	0,056	[-0,081;0,192]	1,057	[0,948;1,179]	0,27385		
Baseline body weight (kg)	- < 75	53	100%(53/53)	50	98%(49/50)	3,242	[0,129;81,466]	0,02	[-0,033;0,073]	1,02	[0,981;1,061]	0,30086	0,4575	0,53767
Baseline body weight (kg)	- >= 75	55	100%(55/55)	56	100%(56/56)	-	[NA;NA]	0	[-0,035;0,035]	1	[0,965;1,036]	NaN		
Treatment duration (days)	- < 7	34	100%(34/34)	13	100%(13/13)	-	[NA;NA]	0	[-0,105;0,105]	1	[0,894;1,119]	NaN	0,8513	0,8425
Treatment duration (days)	-7	73	100%(73/73)	94	98,9%(93/94)	2,358	[0,095;58,738]	0,011	[-0,021;0,042]	1,011	[0,99;1,032]	0,37675		
Region	- EU	44	100%(44/44)	50	100%(50/50)	-	[NA;NA]	0	[-0,041;0,041]	1	[0,959;1,043]	NaN	0,52609	0,5633
Region	- Other	64	100%(64/64)	57	98,2%(56/57)	3,425	[0,137;85,756]	0,018	[-0,028;0,064]	1,018	[0,983;1,053]	0,28731		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-4: Subgruppenergebnisse für Studie L-PLUS 2: Erfolgreiche Behandlung der schweren Thrombozytopenie

L-PLUS 2														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	84	65,5%(55/84)	88	12,5%(11/88)	13,276	[6,113;28,831]	0,53	[0,407;0,653]	5,238	[2,95;9,301]	0	0,65415	0,66078
Age (years)	- >=65	24	62,5%(15/24)	19	15,8%(3/19)	8,889	[2,015;39,221]	0,467	[0,213;0,721]	3,958	[1,339;11,699]	0,00205		
Gender	- Male	65	53,8%(35/65)	69	10,1%(7/69)	10,333	[4,113;25,96]	0,437	[0,296;0,578]	5,308	[2,539;11,096]	0	0,72109	0,0853
Gender	- Female	43	81,4%(35/43)	38	18,4%(7/38)	19,375	[6,299;59,6]	0,63	[0,46;0,799]	4,419	[2,229;8,758]	0		
Race	- White	85	69,4%(59/85)	86	15,1%(13/86)	12,743	[6,025;26,949]	0,543	[0,419;0,667]	4,592	[2,729;7,726]	0	0,44938	0,38985
Race	- Others	23	47,8%(11/23)	21	4,8%(1/21)	18,333	[2,096;160,346]	0,431	[0,207;0,654]	10,043	[1,415;71,286]	0,00136		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	36	41,7%(15/36)	38	7,9%(3/38)	8,333	[2,155;32,226]	0,338	[0,155;0,52]	5,278	[1,667;16,714]	0,00071	0,88167	0,01643
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	71	77,5%(55/71)	68	16,2%(11/68)	17,812	[7,595;41,774]	0,613	[0,482;0,744]	4,789	[2,748;8,345]	0		
Child-Pugh class	- A	72	63,9%(46/72)	63	12,7%(8/63)	12,163	[5,026;29,44]	0,512	[0,374;0,65]	5,031	[2,574;9,836]	0	0,98904	0,70487
Child-Pugh class	- B	33	69,7%(23/33)	43	14%(6/43)	14,183	[4,545;44,263]	0,557	[0,37;0,745]	4,995	[2,3;10,848]	0		
Invasive procedure	liver-related	20	65%(13/20)	20	5%(1/20)	35,286	[3,868;321,932]	0,6	[0,37;0,83]	13	[1,873;90,212]	7e-05	0,00174	0,07318
Invasive procedure	gi-related	61	68,9%(42/61)	60	8,3%(5/60)	24,316	[8,392;70,455]	0,605	[0,47;0,741]	8,262	[3,51;19,447]	0		
Invasive procedure	Non-liver/gi-related	21	66,7%(14/21)	18	44,4%(8/18)	2,5	[0,682;9,164]	0,222	[-0,083;0,528]	1,5	[0,824;2,729]	0,16296		
Baseline body weight (kg)	- < 75	53	71,7%(38/53)	50	16%(8/50)	13,3	[5,073;34,866]	0,557	[0,399;0,715]	4,481	[2,322;8,646]	0	0,49971	0,56687
Baseline body weight (kg)	- >= 75	55	58,2%(32/55)	56	8,9%(5/56)	14,191	[4,9;41,098]	0,493	[0,342;0,643]	6,516	[2,741;15,491]	0		
Treatment duration (days)	- < 7	34	91,2%(31/34)	13	53,8%(7/13)	8,857	[1,77;44,329]	0,373	[0,086;0,661]	1,693	[1,013;2,831]	0,00362	0,00176	0,58738
Treatment duration (days)	-7	73	53,4%(39/73)	94	7,4%(7/94)	14,256	[5,814;34,956]	0,46	[0,334;0,586]	7,174	[3,409;15,099]	0		
Region	- EU	44	68,2%(30/44)	50	16%(8/50)	11,25	[4,193;30,184]	0,522	[0,351;0,693]	4,261	[2,188;8,298]	0	0,52616	0,98595
Region	- Other	64	62,5%(40/64)	57	10,5%(6/57)	14,167	[5,287;37,963]	0,52	[0,377;0,663]	5,938	[2,721;12,956]	0		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-5: Subgruppenergebnisse für Studie L-PLUS 2: Unerwünschte Ereignisse

L-PLUS 2														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	83	48,2%(40/83)	88	51,1%(45/88)	0,889	[0,488;1,62]	-0,029	[-0,179;0,12]	0,942	[0,696;1,275]	0,70041	0,49156	0,47914
Age (years)	- >=65	24	45,8%(11/24)	19	36,8%(7/19)	1,451	[0,424;4,964]	0,09	[-0,205;0,385]	1,244	[0,598;2,587]	0,55284		
Gender	- Male	64	45,3%(29/64)	69	44,9%(31/69)	1,016	[0,513;2,012]	0,004	[-0,165;0,173]	1,009	[0,693;1,468]	0,96444	0,76178	0,74861
Gender	- Female	43	51,2%(22/43)	38	55,3%(21/38)	0,848	[0,353;2,035]	-0,041	[-0,259;0,177]	0,926	[0,615;1,393]	0,7121		
Race	- White	84	47,6%(40/84)	86	47,7%(41/86)	0,998	[0,547;1,822]	-0,001	[-0,151;0,15]	0,999	[0,729;1,369]	0,99423	0,79176	0,79063
Race	- Others	23	47,8%(11/23)	21	52,4%(11/21)	0,833	[0,255;2,724]	-0,046	[-0,341;0,25]	0,913	[0,506;1,648]	0,76279		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	36	55,6%(20/36)	38	47,4%(18/38)	1,389	[0,556;3,469]	0,082	[-0,145;0,309]	1,173	[0,752;1,83]	0,48126	0,30964	0,31332
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	71	43,7%(31/71)	68	50%(34/68)	0,775	[0,397;1,511]	-0,063	[-0,229;0,102]	0,873	[0,612;1,246]	0,45407		
Child-Pugh class	- A	71	39,4%(28/71)	63	39,7%(25/63)	0,99	[0,495;1,981]	-0,002	[-0,168;0,163]	0,994	[0,653;1,511]	0,97682	0,91635	0,88752
Child-Pugh class	- B	33	60,6%(20/33)	43	62,8%(27/43)	0,912	[0,359;2,317]	-0,022	[-0,242;0,199]	0,965	[0,674;1,382]	0,84592		
Invasive procedure	liver-related	20	50%(10/20)	20	25%(5/20)	3	[0,786;11,445]	0,25	[-0,04;0,54]	2	[0,832;4,805]	0,10247	0,18173	0,12579
Invasive procedure	gi-related	61	50,8%(31/61)	60	58,3%(35/60)	0,738	[0,36;1,513]	-0,075	[-0,252;0,102]	0,871	[0,628;1,208]	0,40659		
Invasive procedure	Non-liver/gi-related	21	42,9%(9/21)	18	55,6%(10/18)	0,6	[0,169;2,135]	-0,127	[-0,439;0,185]	0,771	[0,405;1,469]	0,42899		
Baseline body weight (kg)	- < 75	53	43,4%(23/53)	50	54%(27/50)	0,653	[0,3;1,421]	-0,106	[-0,298;0,086]	0,804	[0,539;1,199]	0,28185	0,15436	0,151
Baseline body weight (kg)	- >= 75	54	51,9%(28/54)	56	42,9%(24/56)	1,436	[0,677;3,045]	0,09	[-0,096;0,276]	1,21	[0,814;1,799]	0,34485		
Treatment duration (days)	- < 7	34	44,1%(15/34)	13	61,5%(8/13)	0,493	[0,134;1,822]	-0,174	[-0,487;0,139]	0,717	[0,404;1,271]	0,2852	0,24859	0,26358
Treatment duration (days)	-7	73	49,3%(36/73)	94	46,8%(44/94)	1,106	[0,599;2,039]	0,025	[-0,128;0,178]	1,054	[0,767;1,447]	0,74773		
Region	- EU	44	45,45%(20/44)	50	44%(22/50)	1,06	[0,45;2,4]	0,015	[-0,187;0,216]	1,103	[0,659;1,620]	0,88745	0,73192	
Region	- Other	63	49,21%(31/63)	57	52,63%(30/57)	0,872	[0,426;1,781]	-0,034	[-0,213;0,145]	0,935	[0,658;1,329]	0,708		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-6: Subgruppenergebnisse für Studie L-PLUS 2: Unerwünschte Ereignisse unter Ausschluss morbiditätsbedingter Folgekomplikationen

L-PLUS 2														
		Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)				
Subgroup	Subgroup factor	N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR	p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
Age (years)	- < 65	83	45,8%(38/83)	88	50%(44/88)	0,844	[0,463;1,54]	-0,042	[-0,192;0,108]	0,916	[0,669;1,253]	0,58119	0,6134	0,5925
Age (years)	- >=65	24	41,7%(10/24)	19	36,8%(7/19)	1,224	[0,356;4,214]	0,048	[-0,245;0,341]	1,131	[0,531;2,407]	0,74795		
Gender	- Male	64	40,6%(26/64)	69	44,9%(31/69)	0,839	[0,421;1,669]	-0,043	[-0,211;0,125]	0,904	[0,609;1,342]	0,61638	0,80517	0,84195
Gender	- Female	43	51,2%(22/43)	38	52,6%(20/38)	0,943	[0,394;2,258]	-0,015	[-0,233;0,203]	0,972	[0,639;1,479]	0,89496		
Race	- White	84	44%(37/84)	86	46,5%(40/86)	0,905	[0,495;1,657]	-0,025	[-0,174;0,125]	0,947	[0,68;1,318]	0,74694	0,9156	0,90114
Race	- Others	23	47,8%(11/23)	21	52,4%(11/21)	0,833	[0,255;2,724]	-0,046	[-0,341;0,25]	0,913	[0,506;1,648]	0,76279		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	36	55,6%(20/36)	38	47,4%(18/38)	1,389	[0,556;3,469]	0,082	[-0,145;0,309]	1,173	[0,752;1,83]	0,48126	0,21882	0,22707
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	71	39,4%(28/71)	68	48,5%(33/68)	0,691	[0,352;1,353]	-0,091	[-0,255;0,073]	0,813	[0,557;1,186]	0,28019		
Child-Pugh class	- A	71	39,4%(28/71)	63	38,1%(24/63)	1,058	[0,527;2,123]	0,013	[-0,152;0,179]	1,035	[0,676;1,586]	0,87364	0,43637	0,37357
Child-Pugh class	- B	33	51,5%(17/33)	43	62,8%(27/43)	0,63	[0,251;1,582]	-0,113	[-0,336;0,111]	0,82	[0,548;1,228]	0,32373		
Invasive procedure	liver-related	20	50%(10/20)	20	25%(5/20)	3	[0,786;11,445]	0,25	[-0,04;0,54]	2	[0,832;4,805]	0,10247	0,13904	0,08719
Invasive procedure	gi-related	61	47,5%(29/61)	60	56,7%(34/60)	0,693	[0,339;1,419]	-0,091	[-0,269;0,086]	0,839	[0,595;1,184]	0,31507		
Invasive procedure	Non-liver/gi-related	21	38,1%(8/21)	18	55,6%(10/18)	0,492	[0,137;1,772]	-0,175	[-0,484;0,135]	0,686	[0,346;1,359]	0,27554		
Baseline body weight (kg)	- < 75	53	41,5%(22/53)	50	52%(26/50)	0,655	[0,301;1,427]	-0,105	[-0,297;0,087]	0,798	[0,527;1,21]	0,28611	0,25149	0,24702
Baseline body weight (kg)	- >= 75	54	48,1%(26/54)	56	42,9%(24/56)	1,238	[0,584;2,626]	0,053	[-0,133;0,239]	1,123	[0,746;1,693]	0,57743		
Treatment duration (days)	- < 7	34	41,2%(14/34)	13	61,5%(8/13)	0,438	[0,118;1,621]	-0,204	[-0,516;0,108]	0,669	[0,372;1,205]	0,21079	0,22226	0,23129
Treatment duration (days)	-7	73	46,6%(34/73)	94	45,7%(43/94)	1,034	[0,56;1,909]	0,008	[-0,144;0,161]	1,018	[0,732;1,416]	0,91493		
Region	- EU	44	40,9%(18/44)	50	44%(22/50)	0,881	[0,388;2,001]	-0,031	[-0,231;0,169]	0,93	[0,579;1,492]	0,76232	0,98315	0,98833
Region	- Other	63	47,6%(30/63)	57	50,9%(29/57)	0,878	[0,429;1,798]	-0,033	[-0,212;0,146]	0,936	[0,651;1,346]	0,72145		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-7: Subgruppenergebnisse für Studie L-PLUS 2: Schwere unerwünschte Ereignisse

L-PLUS 2														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	83	4,8%(4/83)	88	4,5%(4/88)	1,063	[0,257;4,397]	0,003	[-0,061;0,066]	1,06	[0,274;4,102]	0,93246	0,43006	0,42339
Age (years)	- >=65	24	0%(0/24)	19	5,3%(1/19)	0,252	[0,01;6,537]	-0,055	[-0,183;0,073]	0,267	[0,011;6,199]	0,37367		
Gender	- Male	64	3,1%(2/64)	69	4,3%(3/69)	0,71	[0,115;4,391]	-0,012	[-0,077;0,052]	0,719	[0,124;4,163]	0,71106	0,87602	0,91796
Gender	- Female	43	4,7%(2/43)	38	5,3%(2/38)	0,878	[0,118;6,556]	-0,006	[-0,101;0,089]	0,884	[0,131;5,972]	0,89905		
Race	- White	84	4,8%(4/84)	86	5,8%(5/86)	0,81	[0,21;3,126]	-0,011	[-0,078;0,057]	0,819	[0,228;2,946]	0,75939	n.d.	n.d.
Race	- Others	23	0%(0/23)	21	0%(0/21)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	36	2,8%(1/36)	38	2,6%(1/38)	1,057	[0,064;17,56]	0,001	[-0,073;0,075]	1,056	[0,069;16,251]	0,96908	0,80727	0,73432
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	71	4,2%(3/71)	68	5,9%(4/68)	0,706	[0,152;3,277]	-0,017	[-0,089;0,056]	0,718	[0,167;3,092]	0,65519		
Child-Pugh class	- A	71	0%(0/71)	63	1,6%(1/63)	0,291	[0,012;7,282]	-0,016	[-0,058;0,025]	0,296	[0,012;7,145]	0,42513	0,66538	0,80413
Child-Pugh class	- B	33	6,1%(2/33)	43	9,3%(4/43)	0,629	[0,108;3,662]	-0,032	[-0,151;0,087]	0,652	[0,127;3,344]	0,60344		
Invasive procedure	liver-related	20	5%(1/20)	20	0%(0/20)	3,154	[0,121;82,165]	0,048	[-0,08;0,176]	3	[0,129;69,515]	0,46872	0,70861	0,67985
Invasive procedure	gi-related	61	3,3%(2/61)	60	5%(3/60)	0,644	[0,104;3,998]	-0,017	[-0,088;0,054]	0,656	[0,114;3,786]	0,63433		
Invasive procedure	Non-liver/gi-related	21	4,8%(1/21)	18	5,6%(1/18)	0,85	[0,049;14,639]	-0,008	[-0,148;0,132]	0,857	[0,058;12,746]	0,91081		
Baseline body weight (kg)	- < 75	53	1,9%(1/53)	50	4%(2/50)	0,462	[0,041;5,255]	-0,021	[-0,087;0,044]	0,472	[0,044;5,042]	0,52385	0,58623	0,67133
Baseline body weight (kg)	- >= 75	54	5,6%(3/54)	56	5,4%(3/56)	1,039	[0,2;5,389]	0,002	[-0,083;0,087]	1,037	[0,219;4,916]	0,96346		
Treatment duration (days)	- < 7	34	2,9%(1/34)	13	7,7%(1/13)	0,364	[0,021;6,283]	-0,048	[-0,203;0,108]	0,382	[0,026;5,673]	0,4704	0,55356	0,5797
Treatment duration (days)	-7	73	4,1%(3/73)	94	4,3%(4/94)	0,964	[0,209;4,45]	-0,001	[-0,063;0,06]	0,966	[0,223;4,181]	0,96282		
Region	- EU	44	4,55%(2/44)	50	6%(3/50)	0,746	[0,119;4,831]	-0,015	[-0,105;0,076]	0,758	[0,133;4,328]	0,7548	0,89345	
Region	- Other	63	3,17%(2/63)	57	3,51%(2/57)	0,902	[0,123;6,619]	-0,003	[-0,068;0,061]	0,905	[0,132;6,214]	0,9189		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-8: Subgruppenergebnisse für Studie L-PLUS 2: Schwere unerwünschte Ereignisse unter Ausschluss morbiditätsbedingter Folgekomplikationen

L-PLUS 2														
		Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)				
Subgroup	Subgroup factor	N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR	p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
Age (years)	- < 65	83	4,8%(4/83)	88	3,4%(3/88)	1,435	[0,311;6,612]	0,014	[-0,046;0,074]	1,414	[0,326;6,127]	0,64183	0,34658	0,33513
Age (years)	- >=65	24	0%(0/24)	19	5,3%(1/19)	0,252	[0,01;6,537]	-0,055	[-0,183;0,073]	0,267	[0,011;6,199]	0,37367		
Gender	- Male	64	3,1%(2/64)	69	2,9%(2/69)	1,081	[0,148;7,907]	0,002	[-0,056;0,06]	1,078	[0,156;7,429]	0,9391	0,88615	0,88761
Gender	- Female	43	4,7%(2/43)	38	5,3%(2/38)	0,878	[0,118;6,556]	-0,006	[-0,101;0,089]	0,884	[0,131;5,972]	0,89905		
Race	- White	84	4,8%(4/84)	86	4,7%(4/86)	1,025	[0,248;4,239]	0,001	[-0,063;0,065]	1,024	[0,265;3,961]	0,97281	n.d.	n.d.
Race	- Others	23	0%(0/23)	21	0%(0/21)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	36	2,8%(1/36)	38	2,6%(1/38)	1,057	[0,064;17,56]	0,001	[-0,073;0,075]	1,056	[0,069;16,251]	0,96908	0,95169	0,95308
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	71	4,2%(3/71)	68	4,4%(3/68)	0,956	[0,186;4,908]	-0,002	[-0,069;0,066]	0,958	[0,2;4,582]	0,95689		
Child-Pugh class	- A	71	0%(0/71)	63	0%(0/63)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Child-Pugh class	- B	33	6,1%(2/33)	43	9,3%(4/43)	0,629	[0,108;3,662]	-0,032	[-0,151;0,087]	0,652	[0,127;3,344]	0,60344		
Invasive procedure	liver-related	20	5%(1/20)	20	0%(0/20)	3,154	[0,121;82,165]	0,048	[-0,08;0,176]	3	[0,129;69,515]	0,46872	0,80791	0,77841
Invasive procedure	gi-related	61	3,3%(2/61)	60	3,3%(2/60)	0,983	[0,134;7,215]	-0,001	[-0,064;0,063]	0,984	[0,143;6,758]	0,98659		
Invasive procedure	Non-liver/gi-related	21	4,8%(1/21)	18	5,6%(1/18)	0,85	[0,049;14,639]	-0,008	[-0,148;0,132]	0,857	[0,058;12,746]	0,91081		
Baseline body weight (kg)	- < 75	53	1,9%(1/53)	50	4%(2/50)	0,462	[0,041;5,255]	-0,021	[-0,087;0,044]	0,472	[0,044;5,042]	0,52385	0,42728	0,42914
Baseline body weight (kg)	- >= 75	54	5,6%(3/54)	56	3,6%(2/56)	1,588	[0,255;9,898]	0,02	[-0,058;0,098]	1,556	[0,27;8,949]	0,61747		
Treatment duration (days)	- < 7	34	2,9%(1/34)	13	7,7%(1/13)	0,364	[0,021;6,283]	-0,048	[-0,203;0,108]	0,382	[0,026;5,673]	0,4704	0,44531	0,4982
Treatment duration (days)	-7	73	4,1%(3/73)	94	3,2%(3/94)	1,3	[0,255;6,637]	0,009	[-0,049;0,067]	1,288	[0,268;6,194]	0,75184		
Region	- EU	44	4,5%(2/44)	50	6%(3/50)	0,746	[0,119;4,683]	-0,015	[-0,105;0,076]	0,758	[0,133;4,328]	0,75385	0,56236	0,59022
Region	- Other	63	3,2%(2/63)	57	1,8%(1/57)	1,836	[0,162;20,808]	0,014	[-0,041;0,069]	1,81	[0,169;19,426]	0,61875		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-9: Subgruppenergebnisse für Studie L-PLUS 2: Schwerwiegende unerwünschte Ereignisse

L-PLUS 2														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	83	7,2%(6/83)	88	5,7%(5/88)	1,294	[0,379;4,411]	0,015	[-0,058;0,089]	1,272	[0,404;4,011]	0,68024	0,37764	0,37725
Age (years)	- >=65	24	4,2%(1/24)	19	10,5%(2/19)	0,37	[0,031;4,417]	-0,064	[-0,223;0,096]	0,396	[0,039;4,043]	0,41625		
Gender	- Male	64	6,2%(4/64)	69	7,2%(5/69)	0,853	[0,219;3,329]	-0,01	[-0,095;0,075]	0,862	[0,242;3,071]	0,8192	0,6947	0,69239
Gender	- Female	43	7%(3/43)	38	5,3%(2/38)	1,35	[0,213;8,543]	0,017	[-0,087;0,121]	1,326	[0,234;7,516]	0,74912		
Race	- White	84	7,1%(6/84)	86	7%(6/86)	1,026	[0,317;3,317]	0,002	[-0,075;0,079]	1,024	[0,344;3,048]	0,96628	0,9386	0,93546
Race	- Others	23	4,3%(1/23)	21	4,8%(1/21)	0,909	[0,053;15,516]	-0,004	[-0,128;0,119]	0,913	[0,061;13,694]	0,94749		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	36	5,6%(2/36)	38	5,3%(2/38)	1,059	[0,141;7,944]	0,003	[-0,1;0,106]	1,056	[0,157;7,101]	0,95566	0,93237	0,93059
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	71	7%(5/71)	68	7,4%(5/68)	0,955	[0,264;3,456]	-0,003	[-0,089;0,083]	0,958	[0,29;3,161]	0,94351		
Child-Pugh class	- A	71	0%(0/71)	63	1,6%(1/63)	0,291	[0,012;7,282]	-0,016	[-0,058;0,025]	0,296	[0,012;7,145]	0,42513	0,44918	0,7408
Child-Pugh class	- B	33	15,2%(5/33)	43	14%(6/43)	1,101	[0,305;3,978]	0,012	[-0,148;0,172]	1,086	[0,363;3,251]	0,88303		
Invasive procedure	liver-related	20	5%(1/20)	20	0%(0/20)	3,154	[0,121;82,165]	0,048	[-0,08;0,176]	3	[0,129;69,515]	0,46872	0,73808	0,70186
Invasive procedure	gi-related	61	6,6%(4/61)	60	8,3%(5/60)	0,772	[0,197;3,026]	-0,018	[-0,111;0,076]	0,787	[0,222;2,79]	0,70971		
Invasive procedure	Non-liver/gi-related	21	9,5%(2/21)	18	11,1%(2/18)	0,842	[0,106;6,672]	-0,016	[-0,208;0,176]	0,857	[0,134;5,485]	0,87061		
Baseline body weight (kg)	- < 75	53	3,8%(2/53)	50	4%(2/50)	0,941	[0,127;6,949]	-0,002	[-0,077;0,072]	0,943	[0,138;6,445]	0,9526	0,9342	0,94038
Baseline body weight (kg)	- >= 75	54	9,3%(5/54)	56	8,9%(5/56)	1,041	[0,284;3,82]	0,003	[-0,104;0,111]	1,037	[0,318;3,381]	0,95191		
Treatment duration (days)	- < 7	34	5,9%(2/34)	13	15,4%(2/13)	0,344	[0,043;2,741]	-0,095	[-0,306;0,116]	0,382	[0,06;2,439]	0,29635	0,28075	0,33666
Treatment duration (days)	-7	73	6,8%(5/73)	94	5,3%(5/94)	1,309	[0,364;4,703]	0,015	[-0,058;0,089]	1,288	[0,387;4,281]	0,67931		
Region	- EU	44	9,09%(4/44)	50	10%(5/50)	0,9	[0,226;3,585]	-0,009	[-0,128;0,110]	0,909	[0,260;3,176]	0,88127	0,71534	
Region	- Other	63	4,76%(3/63)	57	3,51%(2/57)	1,375	[0,221;8,539]	0,013	[-0,059;0,084]	1,357	[0,235;7,833]	0,73277		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-10: Subgruppenergebnisse für Studie L-PLUS 2: Schwerwiegende unerwünschte Ereignisse unter Ausschluss morbiditätsbedingter Folgekomplikationen

L-PLUS 2														
		Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)				
Subgroup	Subgroup factor	N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR	p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
Age (years)	- < 65	83	6%(5/83)	88	5,7%(5/88)	1,064	[0,297;3,818]	0,003	[-0,067;0,074]	1,06	[0,318;3,53]	0,92405	0,24867	0,2135
Age (years)	- >=65	24	0%(0/24)	19	10,5%(2/19)	0,143	[0,006;3,164]	-0,105	[-0,26;0,05]	0,16	[0,008;3,147]	0,16058		
Gender	- Male	64	3,1%(2/64)	69	7,2%(5/69)	0,413	[0,077;2,208]	-0,041	[-0,116;0,033]	0,431	[0,087;2,145]	0,28754	0,35131	0,37381
Gender	- Female	43	7%(3/43)	38	5,3%(2/38)	1,35	[0,213;8,543]	0,017	[-0,087;0,121]	1,326	[0,234;7,516]	0,74912		
Race	- White	84	4,8%(4/84)	86	7%(6/86)	0,667	[0,181;2,452]	-0,022	[-0,093;0,048]	0,683	[0,2;2,333]	0,53947	0,84829	0,80408
Race	- Others	23	4,3%(1/23)	21	4,8%(1/21)	0,909	[0,053;15,516]	-0,004	[-0,128;0,119]	0,913	[0,061;13,694]	0,94749		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	36	5,6%(2/36)	38	5,3%(2/38)	1,059	[0,141;7,944]	0,003	[-0,1;0,106]	1,056	[0,157;7,101]	0,95566	0,6138	0,60862
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	71	4,2%(3/71)	68	7,4%(5/68)	0,556	[0,128;2,422]	-0,031	[-0,109;0,046]	0,575	[0,143;2,312]	0,42869		
Child-Pugh class	- A	71	0%(0/71)	63	1,6%(1/63)	0,291	[0,012;7,282]	-0,016	[-0,058;0,025]	0,296	[0,012;7,145]	0,42513	0,65294	0,66397
Child-Pugh class	- B	33	9,1%(3/33)	43	14%(6/43)	0,617	[0,142;2,674]	-0,049	[-0,191;0,094]	0,652	[0,176;2,414]	0,51551		
Invasive procedure	liver-related	20	5%(1/20)	20	0%(0/20)	3,154	[0,121;82,165]	0,048	[-0,08;0,176]	3	[0,129;69,515]	0,46872	0,59201	0,49132
Invasive procedure	gi-related	61	4,9%(3/61)	60	8,3%(5/60)	0,569	[0,13;2,495]	-0,034	[-0,123;0,054]	0,59	[0,148;2,361]	0,44969		
Invasive procedure	Non-liver/gi-related	21	4,8%(1/21)	18	11,1%(2/18)	0,4	[0,033;4,819]	-0,063	[-0,235;0,108]	0,429	[0,042;4,345]	0,45821		
Baseline body weight (kg)	- < 75	53	1,9%(1/53)	50	4%(2/50)	0,462	[0,041;5,255]	-0,021	[-0,087;0,044]	0,472	[0,044;5,042]	0,52385	0,68012	0,92239
Baseline body weight (kg)	- >= 75	54	7,4%(4/54)	56	8,9%(5/56)	0,816	[0,207;3,216]	-0,015	[-0,117;0,087]	0,83	[0,235;2,926]	0,77106		
Treatment duration (days)	- < 7	34	2,9%(1/34)	13	15,4%(2/13)	0,167	[0,014;2,021]	-0,124	[-0,329;0,08]	0,191	[0,019;1,933]	0,11851	0,21154	0,25086
Treatment duration (days)	-7	73	5,5%(4/73)	94	5,3%(5/94)	1,032	[0,267;3,988]	0,002	[-0,068;0,071]	1,03	[0,287;3,7]	0,9637		
Region	- EU	44	4,5%(2/44)	50	10%(5/50)	0,429	[0,079;2,329]	-0,055	[-0,158;0,049]	0,455	[0,093;2,227]	0,31483	0,36542	0,28854
Region	- Other	63	4,8%(3/63)	57	3,5%(2/57)	1,375	[0,221;8,539]	0,013	[-0,059;0,084]	1,357	[0,235;7,833]	0,73156		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-11: Subgruppenergebnisse für Studie L-PLUS 2: Blutungsereignisse

L-PLUS 2														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	83	3,6%(3/83)	88	5,7%(5/88)	0,622	[0,144;2,691]	-0,021	[-0,084;0,042]	0,636	[0,157;2,579]	0,52229	0,62128	0,63886
Age (years)	- >=65	24	0%(0/24)	19	5,3%(1/19)	0,252	[0,01;6,537]	-0,055	[-0,183;0,073]	0,267	[0,011;6,199]	0,37367		
Gender	- Male	64	4,7%(3/64)	69	2,9%(2/69)	1,648	[0,266;10,194]	0,018	[-0,047;0,083]	1,617	[0,279;9,368]	0,58786	0,10419	0,05388
Gender	- Female	43	0%(0/43)	38	10,5%(4/38)	0,088	[0,005;1,693]	-0,104	[-0,209;0,001]	0,098	[0,005;1,772]	0,04683		
Race	- White	84	3,6%(3/84)	86	3,5%(3/86)	1,025	[0,201;5,226]	0,001	[-0,055;0,056]	1,024	[0,213;4,93]	0,97659	0,22254	0,11255
Race	- Others	23	0%(0/23)	21	14,3%(3/21)	0,112	[0,005;2,316]	-0,138	[-0,301;0,025]	0,131	[0,007;2,395]	0,09644		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	36	0%(0/36)	38	7,9%(3/38)	0,139	[0,007;2,788]	-0,076	[-0,173;0,021]	0,151	[0,008;2,817]	0,13687	0,27554	0,22101
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	71	4,2%(3/71)	68	4,4%(3/68)	0,956	[0,186;4,908]	-0,002	[-0,069;0,066]	0,958	[0,2;4,582]	0,95689		
Child-Pugh class	- A	71	1,4%(1/71)	63	4,8%(3/63)	0,286	[0,029;2,819]	-0,034	[-0,093;0,026]	0,296	[0,032;2,772]	0,2549	0,45554	0,69793
Child-Pugh class	- B	33	6,1%(2/33)	43	7%(3/43)	0,86	[0,135;5,469]	-0,009	[-0,121;0,102]	0,869	[0,154;4,904]	0,87313		
Invasive procedure	liver-related	20	0%(0/20)	20	0%(0/20)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Invasive procedure	gi-related	61	3,3%(2/61)	60	8,3%(5/60)	0,373	[0,069;2,002]	-0,051	[-0,134;0,032]	0,393	[0,079;1,95]	0,23375		
Invasive procedure	Non-liver/gi-related	21	4,8%(1/21)	18	5,6%(1/18)	0,85	[0,049;14,639]	-0,008	[-0,148;0,132]	0,857	[0,058;12,746]	0,91081		
Baseline body weight (kg)	- < 75	53	0%(0/53)	50	8%(4/50)	0,097	[0,005;1,842]	-0,079	[-0,161;0,003]	0,105	[0,006;1,901]	0,05753	0,11845	0,08784
Baseline body weight (kg)	- >= 75	54	5,6%(3/54)	56	3,6%(2/56)	1,588	[0,255;9,898]	0,02	[-0,058;0,098]	1,556	[0,27;8,949]	0,61747		
Treatment duration (days)	- < 7	34	0%(0/34)	13	7,7%(1/13)	0,121	[0,005;3,163]	-0,093	[-0,26;0,074]	0,133	[0,006;3,081]	0,1378	0,31559	0,37436
Treatment duration (days)	-7	73	4,1%(3/73)	94	5,3%(5/94)	0,763	[0,176;3,302]	-0,012	[-0,076;0,052]	0,773	[0,191;3,128]	0,71657		
Region	- EU	44	0%(0/44)	50	2%(1/50)	0,371	[0,015;9,337]	-0,020	[-0,059;0,019]	0,378	[0,016;9,043]	0,54794	0,83750	
Region	- Other	63	4,76%(3/63)	57	8,77%(5/57)	0,520	[0,119;2,281]	-0,040	[-0,130;0,050]	0,543	[0,136;2,170]	0,38757		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-12: Subgruppenergebnisse für Studie L-PLUS 2: Thrombose- und Embolieereignisse

L-PLUS 2														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	83	1,2%(1/83)	88	1,1%(1/88)	1,061	[0,065;17,242]	0,001	[-0,032;0,033]	1,06	[0,067;16,677]	0,96681	0,8824	0,85773
Age (years)	- >=65	24	4,2%(1/24)	19	5,3%(1/19)	0,783	[0,046;13,39]	-0,011	[-0,139;0,117]	0,792	[0,053;11,847]	0,86536		
Gender	- Male	64	3,1%(2/64)	69	1,4%(1/69)	2,194	[0,194;24,792]	0,017	[-0,034;0,068]	2,156	[0,2;23,211]	0,5155	0,32524	0,3129
Gender	- Female	43	0%(0/43)	38	2,6%(1/38)	0,287	[0,011;7,266]	-0,027	[-0,095;0,041]	0,295	[0,012;7,044]	0,4217		
Race	- White	84	2,4%(2/84)	86	1,2%(1/86)	2,073	[0,184;23,304]	0,012	[-0,028;0,052]	2,048	[0,189;22,159]	0,54643	0,34521	0,35806
Race	- Others	23	0%(0/23)	21	4,8%(1/21)	0,291	[0,011;7,537]	-0,047	[-0,167;0,072]	0,306	[0,013;7,115]	0,43151		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	36	0%(0/36)	38	0%(0/38)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	71	2,8%(2/71)	68	2,9%(2/68)	0,957	[0,131;6,989]	-0,001	[-0,057;0,054]	0,958	[0,139;6,609]	0,96506		
Child-Pugh class	- A	71	0%(0/71)	63	1,6%(1/63)	0,291	[0,012;7,282]	-0,016	[-0,058;0,025]	0,296	[0,012;7,145]	0,42513	0,28174	0,30322
Child-Pugh class	- B	33	6,1%(2/33)	43	2,3%(1/43)	2,71	[0,235;31,241]	0,037	[-0,056;0,13]	2,606	[0,247;27,524]	0,4072		
Invasive procedure	liver-related	20	0%(0/20)	20	5%(1/20)	0,317	[0,012;8,26]	-0,048	[-0,176;0,08]	0,333	[0,014;7,724]	0,46872	0,63122	0,63341
Invasive procedure	gi-related	61	1,6%(1/61)	60	0%(0/60)	3	[0,12;75,113]	0,016	[-0,028;0,06]	2,952	[0,123;71,05]	0,48308		
Invasive procedure	Non-liver/gi-related	21	4,8%(1/21)	18	5,6%(1/18)	0,85	[0,049;14,639]	-0,008	[-0,148;0,132]	0,857	[0,058;12,746]	0,91081		
Baseline body weight (kg)	- < 75	53	1,9%(1/53)	50	0%(0/50)	2,886	[0,115;72,502]	0,018	[-0,034;0,069]	2,833	[0,118;67,972]	0,50068	0,4015	0,38701
Baseline body weight (kg)	- >= 75	54	1,9%(1/54)	56	3,6%(2/56)	0,509	[0,045;5,788]	-0,017	[-0,078;0,043]	0,519	[0,048;5,553]	0,57989		
Treatment duration (days)	- < 7	34	2,9%(1/34)	13	7,7%(1/13)	0,364	[0,021;6,283]	-0,048	[-0,203;0,108]	0,382	[0,026;5,673]	0,4704	0,53664	0,52796
Treatment duration (days)	-7	73	1,4%(1/73)	94	1,1%(1/94)	1,292	[0,079;21,005]	0,003	[-0,031;0,037]	1,288	[0,082;20,241]	0,85688		
Region	- EU	44	4,55%(2/44)	50	2%(1/50)	2,33	[0,204;26,652]	0,025	[-0,047;0,098]	2,273	[0,213;24,216]	0,49645	0,31841	
Region	- Other	63	0%(0/63)	57	1,75%(1/57)	0,297	[0,012;7,428]	-0,018	[-0,052;0,017]	0,302	[0,013;7,270]	0,46075		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Studie L-PLUS 1

Tabelle 4G-13: Subgruppenergebnisse für Studie L-PLUS 1: Vermeidung von Thrombozytentransfusionen und der Gabe einer Notfalltherapie zur Behandlung einer akuten Blutung

L-PLUS 1														
		Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)				
Subgroup	Subgroup factor	N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR	p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
Age (years)	- < 65	15	73,3%(11/15)	19	15,8%(3/19)	14,667	[2,727;78,877]	0,575	[0,298;0,853]	4,644	[1,574;13,708]	0,00071	0,5527	0,61126
Age (years)	- >=65	34	76,5%(26/34)	29	10,3%(3/29)	28,167	[6,714;118,164]	0,661	[0,481;0,842]	7,392	[2,491;21,933]	0		
Gender	- Male	22	72,7%(16/22)	30	13,3%(4/30)	17,333	[4,231;71,005]	0,594	[0,372;0,816]	5,455	[2,115;14,069]	1e-05	0,76382	0,64196
Gender	- Female	27	77,8%(21/27)	18	11,1%(2/18)	28	[4,977;157,532]	0,667	[0,453;0,88]	7	[1,866;26,259]	1e-05		
Race	- White	-	-	-	-	n,d,	n,d,	n,d,	n,d,	n,d,	n,d,	n,d,	n,d,	n,d,
Race	- Others	49	75,5%(37/49)	48	12,5%(6/48)	21,583	[7,366;63,24]	0,63	[0,478;0,783]	6,041	[2,81;12,985]	0		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	7	57,1%(4/7)	10	0%(0/10)	27	[1,143;637,856]	0,517	[0,152;0,882]	12,375	[0,771;198,712]	0,01151	0,53465	0,58881
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	42	78,6%(33/42)	38	15,8%(6/38)	19,556	[6,243;61,251]	0,628	[0,458;0,798]	4,976	[2,348;10,546]	0		
Child-Pugh class	- A	27	70,4%(19/27)	22	13,6%(3/22)	15,042	[3,454;65,512]	0,567	[0,343;0,791]	5,16	[1,753;15,192]	7e-05	0,68363	0,37605
Child-Pugh class	- B	22	81,8%(18/22)	26	11,5%(3/26)	34,5	[6,834;174,164]	0,703	[0,5;0,905]	7,091	[2,402;20,93]	0		
Invasive procedure	liver-related	38	78,9%(30/38)	33	12,1%(4/33)	27,188	[7,378;100,184]	0,668	[0,497;0,839]	6,513	[2,562;16,561]	0	0,73345	0,5647
Invasive procedure	gi-related	10	70%(7/10)	14	14,3%(2/14)	14	[1,862;105,268]	0,557	[0,219;0,895]	4,9	[1,276;18,821]	0,00544		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n,d,	n,d,	n,d,	n,d,	n,d,	n,d,	n,d,		
Baseline body weight (kg)	- < 75	44	75%(33/44)	38	10,5%(4/38)	25,5	[7,375;88,167]	0,645	[0,484;0,806]	7,125	[2,776;18,286]	0	0,4844	0,8474
Baseline body weight (kg)	- >= 75	5	80%(4/5)	10	20%(2/10)	16	[1,093;234,248]	0,6	[0,171;1,029]	4	[1,074;14,896]	0,02535		
Treatment duration (days)	- < 7	8	100%(8/8)	2	100%(2/2)	-	[NA;NA]	0	[-0,447;0,447]	1	[0,526;1,901]	NaN	0,00031	0,00846
Treatment duration (days)	-7	40	72,5%(29/40)	46	8,7%(4/46)	27,682	[8,024;95,5]	0,638	[0,477;0,799]	8,338	[3,206;21,681]	0		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-14: Subgruppenergebnisse für Studie L-PLUS 1: Vermeidung von Thrombozytentransfusionen vor dem invasiven Eingriff

L-PLUS 1														
		Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)				
Subgroup	Subgroup factor	N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR	p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
Age (years)	- < 65	15	73,3%(11/15)	19	15,8%(3/19)	14,667	[2,727;78,877]	0,575	[0,298;0,853]	4,644	[1,574;13,708]	0,00071	0,52053	0,48882
Age (years)	- >=65	34	79,4%(27/34)	29	10,3%(3/29)	33,429	[7,796;143,336]	0,691	[0,515;0,866]	7,676	[2,594;22,719]	0		
Gender	- Male	22	72,7%(16/22)	30	13,3%(4/30)	17,333	[4,231;71,005]	0,594	[0,372;0,816]	5,455	[2,115;14,069]	1e-05	0,72109	0,47578
Gender	- Female	27	81,5%(22/27)	18	11,1%(2/18)	35,2	[6,045;204,954]	0,704	[0,497;0,91]	7,333	[1,961;27,423]	0		
Race	- White	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	49	77,6%(38/49)	48	12,5%(6/48)	24,182	[8,153;71,723]	0,651	[0,501;0,8]	6,204	[2,891;13,312]	0		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	7	57,1%(4/7)	10	0%(0/10)	27	[1,143;637,856]	0,517	[0,152;0,882]	12,375	[0,771;198,712]	0,01151	0,54805	0,50916
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	42	81%(34/42)	38	15,8%(6/38)	22,667	[7,082;72,55]	0,652	[0,486;0,818]	5,127	[2,425;10,841]	0		
Child-Pugh class	- A	27	74,1%(20/27)	22	13,6%(3/22)	18,095	[4,073;80,382]	0,604	[0,386;0,823]	5,432	[1,854;15,916]	2e-05	0,73206	0,51529
Child-Pugh class	- B	22	81,8%(18/22)	26	11,5%(3/26)	34,5	[6,834;174,164]	0,703	[0,5;0,905]	7,091	[2,402;20,93]	0		
Invasive procedure	liver-related	38	78,9%(30/38)	33	12,1%(4/33)	27,188	[7,378;100,184]	0,668	[0,497;0,839]	6,513	[2,562;16,561]	0	0,85471	0,95113
Invasive procedure	gi-related	10	80%(8/10)	14	14,3%(2/14)	24	[2,783;206,961]	0,657	[0,349;0,965]	5,6	[1,496;20,963]	0,00128		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	44	77,3%(34/44)	38	10,5%(4/38)	28,9	[8,254;101,193]	0,667	[0,51;0,825]	7,341	[2,866;18,806]	0	0,46169	0,77383
Baseline body weight (kg)	- >= 75	5	80%(4/5)	10	20%(2/10)	16	[1,093;234,248]	0,6	[0,171;1,029]	4	[1,074;14,896]	0,02535		
Treatment duration (days)	- < 7	8	100%(8/8)	2	100%(2/2)	-	[NA;NA]	0	[-0,447;0,447]	1	[0,526;1,901]	NaN	0,00024	0,00607
Treatment duration (days)	-7	40	75%(30/40)	46	8,7%(4/46)	31,5	[9,019;110,013]	0,663	[0,506;0,82]	8,625	[3,325;22,376]	0		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-15: Subgruppenergebnisse für Studie L-PLUS 1: Vermeidung der Gabe einer Notfalltherapie zur Behandlung einer akuten Blutung

L-PLUS 1														
		Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)				
Subgroup	Subgroup factor	N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR	p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
Age (years)	- < 65	15	100%(15/15)	19	94,7%(18/19)	2,514	[0,095;66,199]	0,053	[-0,091;0,196]	1,054	[0,951;1,169]	0,36712	0,17397	0,32739
Age (years)	- >=65	34	97,1%(33/34)	29	100%(29/29)	0,379	[0,015;9,652]	-0,029	[-0,111;0,052]	0,971	[0,917;1,029]	0,35187		
Gender	- Male	22	100%(22/22)	30	96,7%(29/30)	2,288	[0,089;58,852]	0,033	[-0,063;0,13]	1,034	[0,969;1,104]	0,3872	0,16166	0,34685
Gender	- Female	27	96,3%(26/27)	18	100%(18/18)	0,477	[0,018;12,379]	-0,037	[-0,147;0,073]	0,964	[0,896;1,036]	0,40896		
Race	- White	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	49	98%(48/49)	48	97,9%(47/48)	1,021	[0,062;16,809]	0	[-0,056;0,057]	1	[0,944;1,06]	0,98825		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	7	100%(7/7)	10	100%(10/10)	-	[NA;NA]	0	[-0,208;0,208]	1	[0,791;1,264]	NaN	0,98087	0,97856
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	42	97,6%(41/42)	38	97,4%(37/38)	1,108	[0,067;18,354]	0,003	[-0,066;0,071]	1,003	[0,934;1,076]	0,94284		
Child-Pugh class	- A	27	96,3%(26/27)	22	100%(22/22)	0,393	[0,015;10,121]	-0,037	[-0,14;0,065]	0,964	[0,896;1,036]	0,36176	0,16083	0,3171
Child-Pugh class	- B	22	100%(22/22)	26	96,2%(25/26)	2,647	[0,103;68,298]	0,038	[-0,067;0,143]	1,039	[0,964;1,121]	0,35258		
Invasive procedure	liver-related	38	100%(38/38)	33	100%(33/33)	-	[NA;NA]	0	[-0,054;0,054]	1	[0,946;1,057]	NaN	n.d.	n.d.
Invasive procedure	gi-related	10	90%(9/10)	14	92,9%(13/14)	0,692	[0,038;12,572]	-0,029	[-0,258;0,201]	0,969	[0,753;1,248]	0,80284		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	44	97,7%(43/44)	38	97,4%(37/38)	1,162	[0,07;19,235]	0,004	[-0,064;0,071]	1,004	[0,937;1,075]	0,91634	0,97957	0,97608
Baseline body weight (kg)	- >= 75	5	100%(5/5)	10	100%(10/10)	-	[NA;NA]	0	[-0,253;0,253]	1	[0,743;1,346]	NaN		
Treatment duration (days)	- < 7	8	100%(8/8)	2	100%(2/2)	-	[NA;NA]	0	[-0,447;0,447]	1	[0,526;1,901]	NaN	0,99273	0,98961
Treatment duration (days)	-7	40	97,5%(39/40)	46	97,8%(45/46)	0,867	[0,052;14,32]	-0,003	[-0,067;0,061]	0,997	[0,933;1,064]	0,92028		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-16: Subgruppenergebnisse für Studie L-PLUS 1: Erfolgreiche Behandlung der schweren Thrombozytopenie

L-PLUS 1														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	15	73,3%(11/15)	19	5,3%(1/19)	49,5	[4,883;501,751]	0,681	[0,435;0,926]	13,933	[2,018;96,181]	4e-05	0,8494	0,92154
Age (years)	- >=65	34	76,5%(26/34)	29	6,9%(2/29)	43,875	[8,507;226,275]	0,696	[0,526;0,866]	11,088	[2,874;42,78]	0		
Gender	- Male	22	72,7%(16/22)	30	6,7%(2/30)	37,333	[6,724;207,27]	0,661	[0,454;0,867]	10,909	[2,791;42,638]	0	0,83525	0,66958
Gender	- Female	27	77,8%(21/27)	18	5,6%(1/18)	59,5	[6,518;543,183]	0,722	[0,533;0,911]	14	[2,062;95,054]	0		
Race	- White	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	49	75,5%(37/49)	48	6,2%(3/48)	46,25	[12,137;176,248]	0,693	[0,554;0,831]	12,082	[3,993;36,557]	0		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	7	57,1%(4/7)	10	0%(0/10)	27	[1,143;637,856]	0,517	[0,152;0,882]	12,375	[0,771;198,712]	0,01151	0,88624	0,34526
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	42	78,6%(33/42)	38	7,9%(3/38)	42,778	[10,65;171,832]	0,707	[0,556;0,858]	9,952	[3,321;29,822]	0		
Child-Pugh class	- A	27	70,4%(19/27)	22	9,1%(2/22)	23,75	[4,462;126,401]	0,613	[0,403;0,823]	7,741	[2,019;29,677]	2e-05	0,39986	0,23232
Child-Pugh class	- B	22	81,8%(18/22)	26	3,8%(1/26)	112,5	[11,582;1092,773]	0,78	[0,602;0,957]	21,273	[3,082;146,848]	0		
Invasive procedure	liver-related	38	76,3%(29/38)	33	9,1%(3/33)	32,222	[7,924;131,033]	0,672	[0,505;0,839]	8,395	[2,813;25,052]	0	0,50031	0,6745
Invasive procedure	gi-related	10	80%(8/10)	14	0%(0/14)	98,6	[4,216;2306,004]	0,739	[0,476;1,003]	23,182	[1,491;360,455]	9e-05		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	44	75%(33/44)	38	5,3%(2/38)	54	[11,134;261,891]	0,697	[0,551;0,844]	14,25	[3,659;55,503]	0	0,62936	0,98889
Baseline body weight (kg)	- >= 75	5	80%(4/5)	10	10%(1/10)	36	[1,772;731,562]	0,7	[0,303;1,097]	8	[1,184;54,043]	0,00671		
Treatment duration (days)	- < 7	8	100%(8/8)	2	100%(2/2)	-	[NA;NA]	0	[-0,447;0,447]	1	[0,526;1,901]	NaN	0,00081	0,00336
Treatment duration (days)	-7	40	72,5%(29/40)	46	2,2%(1/46)	118,636	[14,533;968,462]	0,703	[0,559;0,848]	33,35	[4,755;233,919]	0		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-17: Subgruppenergebnisse für Studie L-PLUS 1: Unerwünschte Ereignisse

L-PLUS 1														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	14	85,7%(12/14)	19	100%(19/19)	0,128	[0,006;2,898]	-0,143	[-0,343;0,058]	0,862	[0,702;1,059]	0,08916	0,27612	0,29973
Age (years)	- >=65	34	97,1%(33/34)	29	100%(29/29)	0,379	[0,015;9,652]	-0,029	[-0,111;0,052]	0,971	[0,917;1,029]	0,35187		
Gender	- Male	21	95,2%(20/21)	30	100%(30/30)	0,224	[0,009;5,773]	-0,048	[-0,162;0,067]	0,953	[0,869;1,047]	0,22739	0,70004	0,76535
Gender	- Female	27	92,6%(25/27)	18	100%(18/18)	0,276	[0,012;6,088]	-0,074	[-0,202;0,054]	0,927	[0,835;1,03]	0,2375		
Race	- White	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	48	93,8%(45/48)	48	100%(48/48)	0,134	[0,007;2,667]	-0,062	[-0,14;0,015]	0,938	[0,873;1,008]	0,07845		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	7	100%(7/7)	10	100%(10/10)	-	[NA;NA]	0	[-0,208;0,208]	1	[0,791;1,264]	NaN	0,55652	0,52755
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	41	92,7%(38/41)	38	100%(38/38)	0,143	[0,007;2,86]	-0,073	[-0,164;0,018]	0,928	[0,852;1,01]	0,08912		
Child-Pugh class	- A	26	92,3%(24/26)	22	100%(22/22)	0,218	[0,01;4,785]	-0,077	[-0,201;0,048]	0,925	[0,829;1,031]	0,18389	0,64702	0,71101
Child-Pugh class	- B	22	95,5%(21/22)	26	100%(26/26)	0,27	[0,01;6,98]	-0,045	[-0,158;0,068]	0,956	[0,874;1,045]	0,27193		
Invasive procedure	liver-related	38	94,7%(36/38)	33	100%(33/33)	0,218	[0,01;4,705]	-0,053	[-0,14;0,034]	0,948	[0,88;1,021]	0,18127	0,66318	0,69832
Invasive procedure	gi-related	10	90%(9/10)	14	100%(14/14)	0,218	[0,008;5,942]	-0,1	[-0,322;0,122]	0,905	[0,744;1,101]	0,22679		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	44	93,2%(41/44)	38	100%(38/38)	0,154	[0,008;3,079]	-0,068	[-0,154;0,018]	0,933	[0,862;1,009]	0,10102	0,70786	0,65964
Baseline body weight (kg)	- >= 75	4	100%(4/4)	10	100%(10/10)	-	[NA;NA]	0	[-0,29;0,29]	1	[0,702;1,424]	NaN		
Treatment duration (days)	- < 7	8	100%(8/8)	2	100%(2/2)	-	[NA;NA]	0	[-0,447;0,447]	1	[0,526;1,901]	NaN	0,81622	0,74711
Treatment duration (days)	-7	40	92,5%(37/40)	46	100%(46/46)	0,115	[0,006;2,301]	-0,075	[-0,165;0,015]	0,926	[0,849;1,01]	0,05867		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-18: Subgruppenergebnisse für Studie L-PLUS 1: Unerwünschte Ereignisse unter Ausschluss morbiditätsbedingter Folgekomplikationen

L-PLUS 1														
		Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)				
Subgroup	Subgroup factor	N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR	p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
Age (years)	- < 65	14	85,7%(12/14)	19	100%(19/19)	0,128	[0,006;2,898]	-0,143	[-0,343;0,058]	0,862	[0,702;1,059]	0,08916	0,27612	0,29973
Age (years)	- >=65	34	97,1%(33/34)	29	100%(29/29)	0,379	[0,015;9,652]	-0,029	[-0,111;0,052]	0,971	[0,917;1,029]	0,35187		
Gender	- Male	21	95,2%(20/21)	30	100%(30/30)	0,224	[0,009;5,773]	-0,048	[-0,162;0,067]	0,953	[0,869;1,047]	0,22739	0,70004	0,76535
Gender	- Female	27	92,6%(25/27)	18	100%(18/18)	0,276	[0,012;6,088]	-0,074	[-0,202;0,054]	0,927	[0,835;1,03]	0,2375		
Race	- White	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	48	93,8%(45/48)	48	100%(48/48)	0,134	[0,007;2,667]	-0,062	[-0,14;0,015]	0,938	[0,873;1,008]	0,07845		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	7	100%(7/7)	10	100%(10/10)	#NV	[NA;NA]	0	[-0,208;0,208]	1	[0,791;1,264]	NaN	0,55652	0,52755
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	41	92,7%(38/41)	38	100%(38/38)	0,143	[0,007;2,86]	-0,073	[-0,164;0,018]	0,928	[0,852;1,01]	0,08912		
Child-Pugh class	- A	26	92,3%(24/26)	22	100%(22/22)	0,218	[0,01;4,785]	-0,077	[-0,201;0,048]	0,925	[0,829;1,031]	0,18389	0,64702	0,71101
Child-Pugh class	- B	22	95,5%(21/22)	26	100%(26/26)	0,27	[0,01;6,98]	-0,045	[-0,158;0,068]	0,956	[0,874;1,045]	0,27193		
Invasive procedure	liver-related	38	94,7%(36/38)	33	100%(33/33)	0,218	[0,01;4,705]	-0,053	[-0,14;0,034]	0,948	[0,88;1,021]	0,18127	n.d.	n.d.
Invasive procedure	gi-related	10	90%(9/10)	14	100%(14/14)	0,218	[0,008;5,942]	-0,1	[-0,322;0,122]	0,905	[0,744;1,101]	0,22679		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	44	93,2%(41/44)	38	100%(38/38)	0,154	[0,008;3,079]	-0,068	[-0,154;0,018]	0,933	[0,862;1,009]	0,10102	0,70786	0,65964
Baseline body weight (kg)	- >= 75	4	100%(4/4)	10	100%(10/10)	#NV	[NA;NA]	0	[-0,29;0,29]	1	[0,702;1,424]	NaN		
Treatment duration (days)	- < 7	8	100%(8/8)	2	100%(2/2)	#NV	[NA;NA]	0	[-0,447;0,447]	1	[0,526;1,901]	NaN	0,81622	0,74711
Treatment duration (days)	-7	40	92,5%(37/40)	46	100%(46/46)	0,115	[0,006;2,301]	-0,075	[-0,165;0,015]	0,926	[0,849;1,01]	0,05867		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-19: Subgruppenergebnisse für Studie L-PLUS 1: Schwere unerwünschte Ereignisse

L-PLUS 1														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	14	35,7%(5/14)	19	36,8%(7/19)	0,952	[0,226;4,006]	-0,011	[-0,343;0,32]	0,969	[0,388;2,425]	0,94693	0,80942	0,73984
Age (years)	- >=65	34	47,1%(16/34)	29	55,2%(16/29)	0,722	[0,267;1,952]	-0,081	[-0,328;0,166]	0,853	[0,525;1,385]	0,52084		
Gender	- Male	21	33,3%(7/21)	30	46,7%(14/30)	0,571	[0,18;1,817]	-0,133	[-0,403;0,136]	0,714	[0,349;1,461]	0,341	0,4299	0,4576
Gender	- Female	27	51,9%(14/27)	18	50%(9/18)	1,077	[0,327;3,551]	0,019	[-0,28;0,317]	1,037	[0,576;1,867]	0,9031		
Race	- White	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	48	43,8%(21/48)	48	47,9%(23/48)	0,845	[0,378;1,888]	-0,042	[-0,241;0,158]	0,913	[0,591;1,412]	0,68205		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	7	28,6%(2/7)	10	40%(4/10)	0,6	[0,076;4,76]	-0,114	[-0,566;0,338]	0,714	[0,177;2,884]	0,62748	0,72752	0,76422
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	41	46,3%(19/41)	38	50%(19/38)	0,864	[0,357;2,09]	-0,037	[-0,257;0,184]	0,927	[0,586;1,465]	0,74505		
Child-Pugh class	- A	26	42,3%(11/26)	22	45,5%(10/22)	0,88	[0,28;2,764]	-0,031	[-0,313;0,25]	0,931	[0,49;1,767]	0,82667	0,95738	0,94538
Child-Pugh class	- B	22	45,5%(10/22)	26	50%(13/26)	0,833	[0,267;2,601]	-0,045	[-0,329;0,238]	0,909	[0,5;1,653]	0,75345		
Invasive procedure	liver-related	38	52,6%(20/38)	33	57,6%(19/33)	0,819	[0,32;2,094]	-0,049	[-0,281;0,182]	0,914	[0,6;1,392]	0,67624	n.d.	n.d.
Invasive procedure	gi-related	10	10%(1/10)	14	28,6%(4/14)	0,278	[0,026;2,969]	-0,186	[-0,487;0,115]	0,35	[0,046;2,68]	0,26939		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	44	40,9%(18/44)	38	52,6%(20/38)	0,623	[0,26;1,496]	-0,117	[-0,332;0,098]	0,777	[0,488;1,239]	0,28846	0,05561	0,0453
Baseline body weight (kg)	- >= 75	4	75%(3/4)	10	30%(3/10)	7	[0,501;97,751]	0,45	[-0,061;0,961]	2,5	[0,83;7,532]	0,12428		
Treatment duration (days)	- < 7	8	37,5%(3/8)	2	50%(1/2)	0,6	[0,027;13,582]	-0,125	[-0,895;0,645]	0,75	[0,144;3,903]	0,74689	0,79499	0,81188
Treatment duration (days)	-7	40	45%(18/40)	46	47,8%(22/46)	0,893	[0,381;2,089]	-0,028	[-0,239;0,183]	0,941	[0,596;1,485]	0,79326		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-20: Subgruppenergebnisse für Studie L-PLUS 1: Schwere unerwünschte Ereignisse ohne Morbidität

L-PLUS 1														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	14	35,7%(5/14)	19	31,6%(6/19)	1,204	[0,28;5,182]	0,041	[-0,285;0,368]	1,131	[0,431;2,97]	0,80332	0,5324	0,46749
Age (years)	- >=65	34	44,1%(15/34)	29	55,2%(16/29)	0,641	[0,237;1,738]	-0,111	[-0,357;0,136]	0,8	[0,485;1,319]	0,38169		
Gender	- Male	21	33,3%(7/21)	30	43,3%(13/30)	0,654	[0,205;2,085]	-0,1	[-0,369;0,169]	0,769	[0,371;1,597]	0,4716	0,64191	0,69222
Gender	- Female	27	48,1%(13/27)	18	50%(9/18)	0,929	[0,282;3,062]	-0,019	[-0,317;0,28]	0,963	[0,526;1,764]	0,9031		
Race	- White	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	48	41,7%(20/48)	48	45,8%(22/48)	0,844	[0,377;1,892]	-0,042	[-0,24;0,157]	0,909	[0,577;1,432]	0,68072		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	7	28,6%(2/7)	10	40%(4/10)	0,6	[0,076;4,76]	-0,114	[-0,566;0,338]	0,714	[0,177;2,884]	0,62748	0,72891	0,75829
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	41	43,9%(18/41)	38	47,4%(18/38)	0,87	[0,358;2,11]	-0,035	[-0,254;0,185]	0,927	[0,573;1,5]	0,75728		
Child-Pugh class	- A	26	42,3%(11/26)	22	45,5%(10/22)	0,88	[0,28;2,764]	-0,031	[-0,313;0,25]	0,931	[0,49;1,767]	0,82667	0,91537	0,91758
Child-Pugh class	- B	22	40,9%(9/22)	26	46,2%(12/26)	0,808	[0,256;2,545]	-0,052	[-0,333;0,228]	0,886	[0,462;1,701]	0,71514		
Invasive procedure	liver-related	38	50%(19/38)	33	57,6%(19/33)	0,737	[0,288;1,884]	-0,076	[-0,308;0,156]	0,868	[0,564;1,338]	0,52325	n.d.	n.d.
Invasive procedure	gi-related	10	10%(1/10)	14	21,4%(3/14)	0,407	[0,036;4,621]	-0,114	[-0,398;0,17]	0,467	[0,056;3,86]	0,4589		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	44	38,6%(17/44)	38	50%(19/38)	0,63	[0,261;1,516]	-0,114	[-0,328;0,101]	0,773	[0,474;1,261]	0,30115	0,05653	0,04615
Baseline body weight (kg)	- >= 75	4	75%(3/4)	10	30%(3/10)	7	[0,501;97,751]	0,45	[-0,061;0,961]	2,5	[0,83;7,532]	0,12428		
Treatment duration (days)	- < 7	8	37,5%(3/8)	2	50%(1/2)	0,6	[0,027;13,582]	-0,125	[-0,895;0,645]	0,75	[0,144;3,903]	0,74689	0,80515	0,81939
Treatment duration (days)	-7	40	42,5%(17/40)	46	45,7%(21/46)	0,88	[0,375;2,067]	-0,032	[-0,242;0,179]	0,931	[0,577;1,503]	0,76906		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-21: Subgruppenergebnisse für Studie L-PLUS 1: Schwerwiegende unerwünschte Ereignisse

L-PLUS 1														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	14	0%(0/14)	19	5,3%(1/19)	0,425	[0,016;11,23]	-0,042	[-0,189;0,105]	0,444	[0,019;10,164]	0,5992	0,81914	0,74551
Age (years)	- >=65	34	2,9%(1/34)	29	10,3%(3/29)	0,263	[0,026;2,675]	-0,074	[-0,199;0,051]	0,284	[0,031;2,587]	0,22969		
Gender	- Male	21	0%(0/21)	30	10%(3/30)	0,183	[0,009;3,731]	-0,09	[-0,218;0,037]	0,201	[0,011;3,704]	0,22073	0,55433	0,43989
Gender	- Female	27	3,7%(1/27)	18	5,6%(1/18)	0,654	[0,038;11,173]	-0,019	[-0,146;0,109]	0,667	[0,044;9,988]	0,76776		
Race	- White	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	48	2,1%(1/48)	48	8,3%(4/48)	0,234	[0,025;2,176]	-0,062	[-0,151;0,026]	0,25	[0,029;2,156]	0,1682		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	7	0%(0/7)	10	20%(2/10)	0,227	[0,009;5,512]	-0,165	[-0,464;0,134]	0,275	[0,015;4,981]	0,33081	0,78463	0,38949
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	41	2,4%(1/41)	38	5,3%(2/38)	0,45	[0,039;5,175]	-0,028	[-0,114;0,057]	0,463	[0,044;4,906]	0,51172		
Child-Pugh class	- A	26	0%(0/26)	22	4,5%(1/22)	0,27	[0,01;6,98]	-0,047	[-0,16;0,066]	0,284	[0,012;6,639]	0,40099	0,86725	0,81142
Child-Pugh class	- B	22	4,5%(1/22)	26	11,5%(3/26)	0,365	[0,035;3,787]	-0,07	[-0,22;0,081]	0,394	[0,044;3,523]	0,38243		
Invasive procedure	liver-related	38	2,6%(1/38)	33	9,1%(3/33)	0,27	[0,027;2,733]	-0,065	[-0,175;0,046]	0,289	[0,032;2,651]	0,23906	n.d.	n.d.
Invasive procedure	gi-related	10	0%(0/10)	14	7,1%(1/14)	0,429	[0,016;11,627]	-0,055	[-0,25;0,141]	0,455	[0,02;10,137]	0,60609		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	44	2,3%(1/44)	38	7,9%(3/38)	0,271	[0,027;2,724]	-0,056	[-0,153;0,04]	0,288	[0,031;2,654]	0,23859	0,62535	0,90951
Baseline body weight (kg)	- >= 75	4	0%(0/4)	10	10%(1/10)	0,704	[0,024;20,906]	-0,036	[-0,368;0,296]	0,733	[0,036;15,042]	0,83846		
Treatment duration (days)	- < 7	8	0%(0/8)	2	0%(0/2)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Treatment duration (days)	-7	40	2,5%(1/40)	46	8,7%(4/46)	0,269	[0,029;2,514]	-0,062	[-0,157;0,033]	0,288	[0,033;2,468]	0,2207		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-22: Subgruppenergebnisse für Studie L-PLUS 1: Schwerwiegende unerwünschte Ereignisse ohne Morbidität

L-PLUS 1														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	14	0%(0/14)	19	0%(0/19)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Age (years)	- >=65	34	0%(0/34)	29	10,3%(3/29)	0,11	[0,005;2,218]	-0,102	[-0,224;0,019]	0,122	[0,007;2,277]	0,08684		
Gender	- Male	21	0%(0/21)	30	6,7%(2/30)	0,265	[0,012;5,812]	-0,058	[-0,172;0,056]	0,282	[0,014;5,586]	0,36861	0,92034	0,97299
Gender	- Female	27	0%(0/27)	18	5,6%(1/18)	0,212	[0,008;5,505]	-0,061	[-0,192;0,07]	0,226	[0,01;5,263]	0,30856		
Race	- White	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	48	0%(0/48)	48	6,2%(3/48)	0,134	[0,007;2,667]	-0,061	[-0,139;0,016]	0,143	[0,008;2,693]	0,12563		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	7	0%(0/7)	10	20%(2/10)	0,227	[0,009;5,512]	-0,165	[-0,464;0,134]	0,275	[0,015;4,981]	0,33081	0,9564	0,37927
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	41	0%(0/41)	38	2,6%(1/38)	0,301	[0,012;7,621]	-0,027	[-0,095;0,042]	0,31	[0,013;7,375]	0,44156		
Child-Pugh class	- A	26	0%(0/26)	22	4,5%(1/22)	0,27	[0,01;6,98]	-0,047	[-0,16;0,066]	0,284	[0,012;6,639]	0,40099	0,93186	0,78111
Child-Pugh class	- B	22	0%(0/22)	26	7,7%(2/26)	0,218	[0,01;4,785]	-0,071	[-0,195;0,054]	0,235	[0,012;4,646]	0,29306		
Invasive procedure	liver-related	38	0%(0/38)	33	9,1%(3/33)	0,113	[0,006;2,275]	-0,09	[-0,198;0,018]	0,125	[0,007;2,326]	0,09146	n.d.	n.d.
Invasive procedure	gi-related	10	0%(0/10)	14	0%(0/14)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	44	0%(0/44)	38	5,3%(2/38)	0,164	[0,008;3,526]	-0,053	[-0,136;0,03]	0,173	[0,009;3,502]	0,19182	0,50667	0,92223
Baseline body weight (kg)	- >= 75	4	0%(0/4)	10	10%(1/10)	0,704	[0,024;20,906]	-0,036	[-0,368;0,296]	0,733	[0,036;15,042]	0,83846		
Treatment duration (days)	- < 7	8	0%(0/8)	2	0%(0/2)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Treatment duration (days)	-7	40	0%(0/40)	46	6,5%(3/46)	0,153	[0,008;3,063]	-0,062	[-0,145;0,02]	0,164	[0,009;3,077]	0,16182		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-23: Subgruppenergebnisse für Studie L-PLUS 1: Blutungsereignisse

L-PLUS 1														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	14	28,6%(4/14)	19	15,8%(3/19)	2,133	[0,393;11,592]	0,128	[-0,16;0,416]	1,81	[0,479;6,83]	0,37471	0,03162	0,03088
Age (years)	- >=65	34	8,8%(3/34)	29	34,5%(10/29)	0,184	[0,045;0,754]	-0,257	[-0,454;-0,059]	0,256	[0,078;0,842]	0,01213		
Gender	- Male	21	9,5%(2/21)	30	20%(6/30)	0,421	[0,076;2,327]	-0,105	[-0,295;0,086]	0,476	[0,106;2,134]	0,31132	1	0,55535
Gender	- Female	27	18,5%(5/27)	18	38,9%(7/18)	0,357	[0,092;1,387]	-0,204	[-0,472;0,065]	0,476	[0,179;1,269]	0,13007		
Race	- White	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	48	14,6%(7/48)	48	27,1%(13/48)	0,46	[0,165;1,279]	-0,125	[-0,286;0,036]	0,538	[0,235;1,231]	0,13159		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	7	14,3%(1/7)	10	40%(4/10)	0,25	[0,021;2,945]	-0,257	[-0,656;0,142]	0,357	[0,05;2,553]	0,25214	0,62131	0,45496
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	41	14,6%(6/41)	38	23,7%(9/38)	0,552	[0,176;1,735]	-0,091	[-0,264;0,083]	0,618	[0,243;1,572]	0,30549		
Child-Pugh class	- A	26	15,4%(4/26)	22	27,3%(6/22)	0,485	[0,117;2,005]	-0,119	[-0,351;0,113]	0,564	[0,182;1,747]	0,31225	0,89858	0,932
Child-Pugh class	- B	22	13,6%(3/22)	26	26,9%(7/26)	0,429	[0,096;1,91]	-0,133	[-0,356;0,09]	0,506	[0,148;1,729]	0,25873		
Invasive procedure	liver-related	38	13,2%(5/38)	33	24,2%(8/33)	0,473	[0,138;1,624]	-0,111	[-0,292;0,071]	0,543	[0,197;1,498]	0,22839	n.d.	n.d.
Invasive procedure	gi-related	10	20%(2/10)	14	35,7%(5/14)	0,45	[0,068;2,998]	-0,157	[-0,51;0,196]	0,56	[0,135;2,328]	0,40371		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	44	15,9%(7/44)	38	31,6%(12/38)	0,41	[0,142;1,181]	-0,157	[-0,34;0,026]	0,504	[0,221;1,149]	0,09353	0,81465	0,53048
Baseline body weight (kg)	- >= 75	4	0%(0/4)	10	10%(1/10)	0,704	[0,024;20,906]	-0,036	[-0,368;0,296]	0,733	[0,036;15,042]	0,83846		
Treatment duration (days)	- < 7	8	12,5%(1/8)	2	0%(0/2)	1	[0,03;33,318]	0	[-0,487;0,487]	1	[0,054;18,574]	1	0,684	0,61282
Treatment duration (days)	-7	40	15%(6/40)	46	28,3%(13/46)	0,448	[0,152;1,318]	-0,133	[-0,303;0,038]	0,531	[0,222;1,266]	0,13928		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-24: Subgruppenergebnisse für Studie L-PLUS 1: Thrombose- und Embolieereignisse

L-PLUS 1														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	14	0%(0/14)	19	5,3%(1/19)	0,425	[0,016;11,23]	-0,042	[-0,189;0,105]	0,444	[0,019;10,164]	0,5992	0,43921	0,42629
Age (years)	- >=65	34	2,9%(1/34)	29	0%(0/29)	2,642	[0,104;67,363]	0,026	[-0,055;0,107]	2,571	[0,109;60,807]	0,54216		
Gender	- Male	21	0%(0/21)	30	3,3%(1/30)	0,457	[0,018;11,778]	-0,026	[-0,124;0,072]	0,47	[0,02;11,001]	0,62907	0,51897	0,4802
Gender	- Female	27	3,7%(1/27)	18	0%(0/18)	2,094	[0,081;54,297]	0,027	[-0,083;0,137]	2,036	[0,087;47,37]	0,64962		
Race	- White	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	48	2,1%(1/48)	48	2,1%(1/48)	1	[0,061;16,463]	0	[-0,057;0,057]	1	[0,064;15,53]	1		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	7	0%(0/7)	10	0%(0/10)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	41	2,4%(1/41)	38	2,6%(1/38)	0,925	[0,056;15,328]	-0,002	[-0,071;0,067]	0,927	[0,06;14,303]	0,95659		
Child-Pugh class	- A	26	0%(0/26)	22	4,5%(1/22)	0,27	[0,01;6,98]	-0,047	[-0,16;0,066]	0,284	[0,012;6,639]	0,40099	0,26828	0,25179
Child-Pugh class	- B	22	4,5%(1/22)	26	0%(0/26)	3,698	[0,143;95,438]	0,047	[-0,066;0,16]	3,522	[0,151;82,341]	0,40099		
Invasive procedure	liver-related	38	2,6%(1/38)	33	3%(1/33)	0,865	[0,052;14,393]	-0,004	[-0,082;0,074]	0,868	[0,057;13,346]	0,91933	n.d.	n.d.
Invasive procedure	gi-related	10	0%(0/10)	14	0%(0/14)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	44	2,3%(1/44)	38	2,6%(1/38)	0,86	[0,052;14,241]	-0,004	[-0,071;0,064]	0,864	[0,056;13,343]	0,91634	n.d.	n.d.
Baseline body weight (kg)	- >= 75	4	0%(0/4)	10	0%(0/10)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Treatment duration (days)	- < 7	8	0%(0/8)	2	0%(0/2)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Treatment duration (days)	-7	40	2,5%(1/40)	46	2,2%(1/46)	1,154	[0,07;19,065]	0,003	[-0,061;0,067]	1,15	[0,074;17,796]	0,92028		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Studie M0626

Tabelle 4G-25: Subgruppenergebnisse für Studie M0626: Vermeidung von Thrombozytentransfusionen und der Gabe einer Notfalltherapie zur Behandlung einer akuten Blutung

M0626														
		Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)				
Subgroup	Subgroup factor	N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR	p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
Age (years)	- < 65	7	85,7%(6/7)	3	66,7%(2/3)	3	[0,122;73,642]	0,19	[-0,403;0,784]	1,286	[0,547;3,024]	0,49015	0,06325	0,14132
Age (years)	- >=65	9	77,8%(7/9)	12	8,3%(1/12)	38,5	[2,915;508,463]	0,694	[0,381;1,008]	9,333	[1,384;62,949]	0,00118		
Gender	- Male	9	77,8%(7/9)	8	37,5%(3/8)	5,833	[0,696;48,873]	0,403	[-0,029;0,834]	2,074	[0,794;5,419]	0,09213	0,20998	0,20406
Gender	- Female	7	85,7%(6/7)	7	0%(0/7)	65	[2,239;1887,351]	0,75	[0,432;1,068]	13	[0,87;194,281]	0,0025		
Race	- White	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	16	81,2%(13/16)	15	20%(3/15)	17,333	[2,916;103,021]	0,612	[0,334;0,891]	4,062	[1,437;11,484]	0,00065		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	3	0%(0/3)	4	0%(0/4)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	13	100%(13/13)	11	27,3%(3/11)	65,571	[2,999;1433,821]	0,727	[0,452;1,002]	3,286	[1,371;7,873]	0,00017		
Child-Pugh class	- A	9	77,8%(7/9)	9	22,2%(2/9)	12,25	[1,327;113,06]	0,556	[0,171;0,94]	3,5	[0,982;12,477]	0,01842	0,73351	0,63401
Child-Pugh class	- B	7	85,7%(6/7)	6	16,7%(1/6)	30	[1,471;611,797]	0,69	[0,295;1,086]	5,143	[0,838;31,569]	0,01279		
Invasive procedure	liver-related	15	86,7%(13/15)	15	20%(3/15)	26	[3,686;183,418]	0,667	[0,401;0,932]	4,333	[1,545;12,155]	0,00025	n.d.	n.d.
Invasive procedure	gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	14	78,6%(11/14)	11	18,2%(2/11)	16,5	[2,246;121,228]	0,604	[0,291;0,917]	4,321	[1,198;15,591]	0,0027	0,69614	0,66518
Baseline body weight (kg)	- >= 75	2	100%(2/2)	4	25%(1/4)	11,667	[0,322;422,139]	0,75	[0,168;1,332]	3	[0,812;11,081]	0,08326		
Treatment duration (days)	- < 7	4	75%(3/4)	-	-	2,333	[0,03;182,909]	0,2	[-0,859;1,259]	1,4	[0,182;10,791]	0,69854	0,35128	0,43954
Treatment duration (days)	-7	12	83,3%(10/12)	15	20%(3/15)	20	[2,772;144,31]	0,633	[0,341;0,926]	4,167	[1,468;11,827]	0,00107		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-26: Subgruppenergebnisse für Studie M0626: Vermeidung von Thrombozytentransfusionen vor dem invasiven Eingriff

M0626														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	7	85,7%(6/7)	3	66,7%(2/3)	3	[0,122;73,642]	0,19	[-0,403;0,784]	1,286	[0,547;3,024]	0,49015	0,06325	0,14132
Age (years)	- >=65	9	77,8%(7/9)	12	8,3%(1/12)	38,5	[2,915;508,463]	0,694	[0,381;1,008]	9,333	[1,384;62,949]	0,00118		
Gender	- Male	9	77,8%(7/9)	8	37,5%(3/8)	5,833	[0,696;48,873]	0,403	[-0,029;0,834]	2,074	[0,794;5,419]	0,09213	0,20998	0,20406
Gender	- Female	7	85,7%(6/7)	7	0%(0/7)	65	[2,239;1887,351]	0,75	[0,432;1,068]	13	[0,87;194,281]	0,0025		
Race	- White	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	16	81,2%(13/16)	15	20%(3/15)	17,333	[2,916;103,021]	0,612	[0,334;0,891]	4,062	[1,437;11,484]	0,00065		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	3	0%(0/3)	4	0%(0/4)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	13	100%(13/13)	11	27,3%(3/11)	65,571	[2,999;1433,821]	0,727	[0,452;1,002]	3,286	[1,371;7,873]	0,00017		
Child-Pugh class	- A	9	77,8%(7/9)	9	22,2%(2/9)	12,25	[1,327;113,06]	0,556	[0,171;0,94]	3,5	[0,982;12,477]	0,01842	0,73351	0,63401
Child-Pugh class	- B	7	85,7%(6/7)	6	16,7%(1/6)	30	[1,471;611,797]	0,69	[0,295;1,086]	5,143	[0,838;31,569]	0,01279		
Invasive procedure	liver-related	15	86,7%(13/15)	15	20%(3/15)	26	[3,686;183,418]	0,667	[0,401;0,932]	4,333	[1,545;12,155]	0,00025	n.d.	n.d.
Invasive procedure	gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	14	78,6%(11/14)	11	18,2%(2/11)	16,5	[2,246;121,228]	0,604	[0,291;0,917]	4,321	[1,198;15,591]	0,0027	0,69614	0,66518
Baseline body weight (kg)	- >= 75	2	100%(2/2)	4	25%(1/4)	11,667	[0,322;422,139]	0,75	[0,168;1,332]	3	[0,812;11,081]	0,08326		
Treatment duration (days)	- < 7	4	75%(3/4)	-	-	2,333	[0,03;182,909]	0,2	[-0,859;1,259]	1,4	[0,182;10,791]	0,69854	0,35128	0,43954
Treatment duration (days)	-7	12	83,3%(10/12)	15	20%(3/15)	20	[2,772;144,31]	0,633	[0,341;0,926]	4,167	[1,468;11,827]	0,00107		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-27: Subgruppenergebnisse für Studie M0626: Vermeidung der Gabe einer Notfalltherapie zur Behandlung einer akuten Blutung

M0626														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	7	100%(7/7)	3	100%(3/3)	-	[NA;NA]	0	[-0,365;0,365]	1	[0,626;1,598]	NaN	1	1
Age (years)	- >=65	9	100%(9/9)	12	100%(12/12)	-	[NA;NA]	0	[-0,171;0,171]	1	[0,829;1,207]	NaN		
Gender	- Male	9	100%(9/9)	8	100%(8/8)	-	[NA;NA]	0	[-0,202;0,202]	1	[0,798;1,253]	NaN	1	1
Gender	- Female	7	100%(7/7)	7	100%(7/7)	-	[NA;NA]	0	[-0,237;0,237]	1	[0,763;1,311]	NaN		
Race	- White	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	16	100%(16/16)	15	100%(15/15)	-	[NA;NA]	0	[-0,117;0,117]	1	[0,883;1,133]	NaN		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	3	100%(3/3)	4	100%(4/4)	-	[NA;NA]	0	[-0,417;0,417]	1	[0,584;1,713]	NaN	1	1
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	13	100%(13/13)	11	100%(11/11)	-	[NA;NA]	0	[-0,149;0,149]	1	[0,851;1,175]	NaN		
Child-Pugh class	- A	9	100%(9/9)	9	100%(9/9)	-	[NA;NA]	0	[-0,191;0,191]	1	[0,809;1,236]	NaN	1	1
Child-Pugh class	- B	7	100%(7/7)	6	100%(6/6)	-	[NA;NA]	0	[-0,254;0,254]	1	[0,746;1,34]	NaN		
Invasive procedure	liver-related	15	100%(15/15)	15	100%(15/15)	-	[NA;NA]	0	[-0,121;0,121]	1	[0,879;1,137]	NaN	n.d.	n.d.
Invasive procedure	gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	14	100%(14/14)	11	100%(11/11)	-	[NA;NA]	0	[-0,145;0,145]	1	[0,855;1,17]	NaN	1	1
Baseline body weight (kg)	- >= 75	2	100%(2/2)	4	100%(4/4)	-	[NA;NA]	0	[-0,497;0,497]	1	[0,496;2,015]	NaN		
Treatment duration (days)	- < 7	4	100%(4/4)	-	-	9	[0,068;1195,397]	0,4	[-0,615;1,415]	1,8	[0,248;13,058]	0,32719	0,56198	0,44401
Treatment duration (days)	-7	12	100%(12/12)	15	100%(15/15)	-	[NA;NA]	0	[-0,135;0,135]	1	[0,865;1,156]	NaN		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-28: Subgruppenergebnisse für Studie M0626: Erfolgreiche Behandlung der schweren Thrombozytopenie

M0626														
		Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)				
Subgroup	Subgroup factor	N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR	p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
Age (years)	- < 65	7	71,4%(5/7)	3	33,3%(1/3)	5	[0,273;91,518]	0,381	[-0,249;1,011]	2,143	[0,404;11,355]	0,2598	0,20888	0,51954
Age (years)	- >=65	9	66,7%(6/9)	12	0%(0/12)	46,429	[2,069;1042,097]	0,612	[0,298;0,925]	16,9	[1,074;265,89]	0,00158		
Gender	- Male	9	55,6%(5/9)	8	12,5%(1/8)	8,75	[0,737;103,824]	0,431	[0,033;0,828]	4,444	[0,649;30,444]	0,06372	0,52616	0,21935
Gender	- Female	7	85,7%(6/7)	7	0%(0/7)	65	[2,239;1887,351]	0,75	[0,432;1,068]	13	[0,87;194,281]	0,0025		
Race	- White	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	16	68,8%(11/16)	15	6,7%(1/15)	30,8	[3,126;303,436]	0,621	[0,361;0,881]	10,313	[1,509;70,489]	0,00039		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	3	0%(0/3)	4	0%(0/4)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	13	84,6%(11/13)	11	9,1%(1/11)	55	[4,3;703,432]	0,755	[0,496;1,015]	9,308	[1,416;61,186]	0,00023		
Child-Pugh class	- A	9	66,7%(6/9)	9	11,1%(1/9)	16	[1,315;194,623]	0,556	[0,185;0,926]	6	[0,893;40,306]	0,01563	0,77985	0,82331
Child-Pugh class	- B	7	71,4%(5/7)	6	0%(0/6)	28,6	[1,118;731,543]	0,616	[0,242;0,99]	9,625	[0,639;144,878]	0,01511		
Invasive procedure	liver-related	15	73,3%(11/15)	15	6,7%(1/15)	38,5	[3,749;395,407]	0,667	[0,41;0,924]	11	[1,616;74,876]	0,00019	n.d.	n.d.
Invasive procedure	gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	14	64,3%(9/14)	11	9,1%(1/11)	18	[1,754;184,679]	0,552	[0,249;0,855]	7,071	[1,048;47,711]	0,00517	0,92204	0,543
Baseline body weight (kg)	- >= 75	2	100%(2/2)	4	0%(0/4)	45	[0,666;3042,572]	0,733	[0,236;1,23]	8,333	[0,573;121,278]	0,03806		
Treatment duration (days)	- < 7	4	75%(3/4)	-	-	2,333	[0,03;182,909]	0,2	[-0,859;1,259]	1,4	[0,182;10,791]	0,69854	0,1708	0,47561
Treatment duration (days)	-7	12	66,7%(8/12)	15	6,7%(1/15)	28	[2,651;295,718]	0,6	[0,305;0,895]	10	[1,444;69,262]	0,00102		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-29: Subgruppenergebnisse für Studie M0626: Unerwünschte Ereignisse

M0626														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	7	100%(7/7)	3	100%(3/3)	-	[NA;NA]	0	[-0,365;0,365]	1	[0,626;1,598]	NaN	1	1
Age (years)	- >=65	9	100%(9/9)	12	100%(12/12)	-	[NA;NA]	0	[-0,171;0,171]	1	[0,829;1,207]	NaN		
Gender	- Male	9	100%(9/9)	8	100%(8/8)	-	[NA;NA]	0	[-0,202;0,202]	1	[0,798;1,253]	NaN	1	1
Gender	- Female	7	100%(7/7)	7	100%(7/7)	-	[NA;NA]	0	[-0,237;0,237]	1	[0,763;1,311]	NaN		
Race	- White	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	16	100%(16/16)	15	100%(15/15)	-	[NA;NA]	0	[-0,117;0,117]	1	[0,883;1,133]	NaN		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	3	100%(3/3)	4	100%(4/4)	-	[NA;NA]	0	[-0,417;0,417]	1	[0,584;1,713]	NaN	1	1
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	13	100%(13/13)	11	100%(11/11)	-	[NA;NA]	0	[-0,149;0,149]	1	[0,851;1,175]	NaN		
Child-Pugh class	- A	9	100%(9/9)	9	100%(9/9)	-	[NA;NA]	0	[-0,191;0,191]	1	[0,809;1,236]	NaN	1	1
Child-Pugh class	- B	7	100%(7/7)	6	100%(6/6)	-	[NA;NA]	0	[-0,254;0,254]	1	[0,746;1,34]	NaN		
Invasive procedure	liver-related	15	100%(15/15)	15	100%(15/15)	-	[NA;NA]	0	[-0,121;0,121]	1	[0,879;1,137]	NaN	n.d.	n.d.
Invasive procedure	gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	14	100%(14/14)	11	100%(11/11)	-	[NA;NA]	0	[-0,145;0,145]	1	[0,855;1,17]	NaN	1	1
Baseline body weight (kg)	- >= 75	2	100%(2/2)	4	100%(4/4)	-	[NA;NA]	0	[-0,497;0,497]	1	[0,496;2,015]	NaN		
Treatment duration (days)	- < 7	4	100%(4/4)	-	-	9	[0,068;1195,397]	0,4	[-0,615;1,415]	1,8	[0,248;13,058]	0,32719	0,56198	0,44401
Treatment duration (days)	-7	12	100%(12/12)	15	100%(15/15)	-	[NA;NA]	0	[-0,135;0,135]	1	[0,865;1,156]	NaN		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-30: Subgruppenergebnisse für Studie M0626: Unerwünschte Ereignisse ohne Morbidität

M0626														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	7	100%(7/7)	3	100%(3/3)	#NV	[NA;NA]	0	[-0,365;0,365]	1	[0,626;1,598]	NaN	1	1
Age (years)	- >=65	9	100%(9/9)	12	100%(12/12)	#NV	[NA;NA]	0	[-0,171;0,171]	1	[0,829;1,207]	NaN		
Gender	- Male	9	100%(9/9)	8	100%(8/8)	#NV	[NA;NA]	0	[-0,202;0,202]	1	[0,798;1,253]	NaN	1	1
Gender	- Female	7	100%(7/7)	7	100%(7/7)	#NV	[NA;NA]	0	[-0,237;0,237]	1	[0,763;1,311]	NaN		
Race	- White	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	16	100%(16/16)	15	100%(15/15)	#NV	[NA;NA]	0	[-0,117;0,117]	1	[0,883;1,133]	NaN		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	3	100%(3/3)	4	100%(4/4)	#NV	[NA;NA]	0	[-0,417;0,417]	1	[0,584;1,713]	NaN	1	1
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	13	100%(13/13)	11	100%(11/11)	#NV	[NA;NA]	0	[-0,149;0,149]	1	[0,851;1,175]	NaN		
Child-Pugh class	- A	9	100%(9/9)	9	100%(9/9)	#NV	[NA;NA]	0	[-0,191;0,191]	1	[0,809;1,236]	NaN	1	1
Child-Pugh class	- B	7	100%(7/7)	6	100%(6/6)	#NV	[NA;NA]	0	[-0,254;0,254]	1	[0,746;1,34]	NaN		
Invasive procedure	liver-related	15	100%(15/15)	15	100%(15/15)	#NV	[NA;NA]	0	[-0,121;0,121]	1	[0,879;1,137]	NaN	n.d.	n.d.
Invasive procedure	gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	14	100%(14/14)	11	100%(11/11)	#NV	[NA;NA]	0	[-0,145;0,145]	1	[0,855;1,17]	NaN	1	1
Baseline body weight (kg)	- >= 75	2	100%(2/2)	4	100%(4/4)	#NV	[NA;NA]	0	[-0,497;0,497]	1	[0,496;2,015]	NaN		
Treatment duration (days)	- < 7	4	100%(4/4)	-	-	9	[0,068;1195,397]	0,4	[-0,615;1,415]	1,8	[0,248;13,058]	0,32719	0,56198	0,44401
Treatment duration (days)	-7	12	100%(12/12)	15	100%(15/15)	#NV	[NA;NA]	0	[-0,135;0,135]	1	[0,865;1,156]	NaN		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-31: Subgruppenergebnisse für Studie M0626: Schwere unerwünschte Ereignisse

M0626														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	7	71,4%(5/7)	3	33,3%(1/3)	5	[0,273;91,518]	0,381	[-0,249;1,011]	2,143	[0,404;11,355]	0,2598	0,2466	0,13277
Age (years)	- >=65	9	55,6%(5/9)	12	75%(9/12)	0,417	[0,065;2,66]	-0,194	[-0,601;0,212]	0,741	[0,379;1,447]	0,34957		
Gender	- Male	9	55,6%(5/9)	8	62,5%(5/8)	0,75	[0,107;5,238]	-0,069	[-0,536;0,397]	0,889	[0,402;1,965]	0,77152	0,82343	0,83858
Gender	- Female	7	71,4%(5/7)	7	71,4%(5/7)	1	[0,098;10,166]	0	[-0,473;0,473]	1	[0,516;1,94]	1		
Race	- White	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	16	62,5%(10/16)	15	66,7%(10/15)	0,833	[0,191;3,644]	-0,042	[-0,378;0,295]	0,938	[0,556;1,579]	0,80854		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	3	100%(3/3)	4	50%(2/4)	7	[0,224;218,945]	0,5	[-0,045;1,045]	1,8	[0,788;4,113]	0,1473	0,09156	0,04176
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	13	53,8%(7/13)	11	72,7%(8/11)	0,438	[0,079;2,437]	-0,189	[-0,567;0,189]	0,74	[0,398;1,376]	0,3411		
Child-Pugh class	- A	9	66,7%(6/9)	9	55,6%(5/9)	1,6	[0,237;10,809]	0,111	[-0,336;0,559]	1,2	[0,57;2,527]	0,62875	0,29478	0,26088
Child-Pugh class	- B	7	57,1%(4/7)	6	83,3%(5/6)	0,267	[0,019;3,653]	-0,262	[-0,734;0,211]	0,686	[0,329;1,429]	0,30774		
Invasive procedure	liver-related	15	60%(9/15)	15	66,7%(10/15)	0,75	[0,169;3,327]	-0,067	[-0,411;0,277]	0,9	[0,521;1,555]	0,70479	n.d.	n.d.
Invasive procedure	gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	14	64,3%(9/14)	11	72,7%(8/11)	0,675	[0,121;3,767]	-0,084	[-0,448;0,279]	0,884	[0,519;1,505]	0,65333	0,89192	0,85853
Baseline body weight (kg)	- >= 75	2	50%(1/2)	4	50%(2/4)	1	[0,034;29,807]	0	[-0,849;0,849]	1	[0,183;5,46]	1		
Treatment duration (days)	- < 7	4	50%(2/4)	-	-	1	[0,014;73,264]	0	[-1,074;1,074]	1	[0,117;8,559]	1	1	1
Treatment duration (days)	-7	12	66,7%(8/12)	15	66,7%(10/15)	1	[0,2;5,004]	0	[-0,358;0,358]	1	[0,585;1,71]	1		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-32: Subgruppenergebnisse für Studie M0626: Schwere unerwünschte Ereignisse unter Ausschluss morbiditätsbedingter Folgekomplikationen

M0626														
		Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)				
Subgroup	Subgroup factor	N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR	p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
Age (years)	- < 65	7	71,4%(5/7)	3	33,3%(1/3)	5	[0,273;91,518]	0,381	[-0,249;1,011]	2,143	[0,404;11,355]	0,2598	0,2466	0,13277
Age (years)	- >=65	9	55,6%(5/9)	12	75%(9/12)	0,417	[0,065;2,66]	-0,194	[-0,601;0,212]	0,741	[0,379;1,447]	0,34957		
Gender	- Male	9	55,6%(5/9)	8	62,5%(5/8)	0,75	[0,107;5,238]	-0,069	[-0,536;0,397]	0,889	[0,402;1,965]	0,77152	0,82343	0,83858
Gender	- Female	7	71,4%(5/7)	7	71,4%(5/7)	1	[0,098;10,166]	0	[-0,473;0,473]	1	[0,516;1,94]	1		
Race	- White	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	16	62,5%(10/16)	15	66,7%(10/15)	0,833	[0,191;3,644]	-0,042	[-0,378;0,295]	0,938	[0,556;1,579]	0,80854		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	3	100%(3/3)	4	50%(2/4)	7	[0,224;218,945]	0,5	[-0,045;1,045]	1,8	[0,788;4,113]	0,1473	0,09156	0,04176
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	13	53,8%(7/13)	11	72,7%(8/11)	0,438	[0,079;2,437]	-0,189	[-0,567;0,189]	0,74	[0,398;1,376]	0,3411		
Child-Pugh class	- A	9	66,7%(6/9)	9	55,6%(5/9)	1,6	[0,237;10,809]	0,111	[-0,336;0,559]	1,2	[0,57;2,527]	0,62875	0,29478	0,26088
Child-Pugh class	- B	7	57,1%(4/7)	6	83,3%(5/6)	0,267	[0,019;3,653]	-0,262	[-0,734;0,211]	0,686	[0,329;1,429]	0,30774		
Invasive procedure	liver-related	15	60%(9/15)	15	66,7%(10/15)	0,75	[0,169;3,327]	-0,067	[-0,411;0,277]	0,9	[0,521;1,555]	0,70479	n.d.	n.d.
Invasive procedure	gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	14	64,3%(9/14)	11	72,7%(8/11)	0,675	[0,121;3,767]	-0,084	[-0,448;0,279]	0,884	[0,519;1,505]	0,65333	0,89192	0,85853
Baseline body weight (kg)	- >= 75	2	50%(1/2)	4	50%(2/4)	1	[0,034;29,807]	0	[-0,849;0,849]	1	[0,183;5,46]	1		
Treatment duration (days)	- < 7	4	50%(2/4)	# N V	NA%(NA/NA)	1	[0,014;73,264]	0	[-1,074;1,074]	1	[0,117;8,559]	1	1	1
Treatment duration (days)	-7	12	66,7%(8/12)	15	66,7%(10/15)	1	[0,2;5,004]	0	[-0,358;0,358]	1	[0,585;1,71]	1		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-33: Subgruppenergebnisse für Studie M0626: Schwerwiegende unerwünschte Ereignisse

M0626														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	7	0%(0/7)	3	0%(0/3)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Age (years)	- >=65	9	11,1%(1/9)	12	8,3%(1/12)	1,375	[0,074;25,433]	0,028	[-0,23;0,286]	1,333	[0,096;18,565]	0,83008		
Gender	- Male	9	11,1%(1/9)	8	12,5%(1/8)	0,875	[0,046;16,744]	-0,014	[-0,322;0,294]	0,889	[0,066;12,004]	0,92931	n.d.	n.d.
Gender	- Female	7	0%(0/7)	7	0%(0/7)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Race	- White	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	16	6,2%(1/16)	15	6,7%(1/15)	0,933	[0,053;16,394]	-0,004	[-0,177;0,169]	0,938	[0,064;13,685]	0,96236		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	3	33,3%(1/3)	4	0%(0/4)	5,4	[0,154;188,831]	0,275	[-0,267;0,817]	3,75	[0,203;69,397]	0,3241	0,23662	0,22083
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	13	0%(0/13)	11	9,1%(1/11)	0,259	[0,01;7,034]	-0,089	[-0,3;0,122]	0,286	[0,013;6,383]	0,39436		
Child-Pugh class	- A	9	11,1%(1/9)	9	11,1%(1/9)	1	[0,053;18,915]	0	[-0,29;0,29]	1	[0,073;13,644]	1	n.d.	n.d.
Child-Pugh class	- B	7	0%(0/7)	6	0%(0/6)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Invasive procedure	liver-related	15	0%(0/15)	15	6,7%(1/15)	0,312	[0,012;8,285]	-0,062	[-0,229;0,104]	0,333	[0,015;7,584]	0,46521	n.d.	n.d.
Invasive procedure	gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	14	7,1%(1/14)	11	0%(0/11)	2,556	[0,095;68,999]	0,058	[-0,131;0,248]	2,4	[0,107;53,772]	0,56522	0,49766	0,54099
Baseline body weight (kg)	- >= 75	2	0%(0/2)	4	25%(1/4)	0,467	[0,013;16,886]	-0,133	[-0,716;0,449]	0,556	[0,032;9,727]	0,67329		
Treatment duration (days)	- < 7	4	25%(1/4)	-	-	0,429	[0,005;33,596]	-0,2	[-1,259;0,859]	0,6	[0,056;6,442]	0,69854	0,84889	0,79111
Treatment duration (days)	-7	12	0%(0/12)	15	6,7%(1/15)	0,387	[0,014;10,367]	-0,055	[-0,232;0,122]	0,41	[0,018;9,252]	0,55899		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-34: Subgruppenergebnisse für Studie M0626: Schwerwiegende unerwünschte Ereignisse unter Ausschluss morbiditätsbedingter Folgekomplikationen

M0626														
		Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)				
Subgroup	Subgroup factor	N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR	p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
Age (years)	- < 65	7	0%(0/7)	3	0%(0/3)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Age (years)	- >=65	9	11,1%(1/9)	12	8,3%(1/12)	1,375	[0,074;25,433]	0,028	[-0,23;0,286]	1,333	[0,096;18,565]	0,83008		
Gender	- Male	9	11,1%(1/9)	8	12,5%(1/8)	0,875	[0,046;16,744]	-0,014	[-0,322;0,294]	0,889	[0,066;12,004]	0,92931	n.d.	n.d.
Gender	- Female	7	0%(0/7)	7	0%(0/7)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Race	- White	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	16	6,2%(1/16)	15	6,7%(1/15)	0,933	[0,053;16,394]	-0,004	[-0,177;0,169]	0,938	[0,064;13,685]	0,96236		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	3	33,3%(1/3)	4	0%(0/4)	5,4	[0,154;188,831]	0,275	[-0,267;0,817]	3,75	[0,203;69,397]	0,3241	0,23662	0,22083
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	13	0%(0/13)	11	9,1%(1/11)	0,259	[0,01;7,034]	-0,089	[-0,3;0,122]	0,286	[0,013;6,383]	0,39436		
Child-Pugh class	- A	9	11,1%(1/9)	9	11,1%(1/9)	1	[0,053;18,915]	0	[-0,29;0,29]	1	[0,073;13,644]	1	n.d.	n.d.
Child-Pugh class	- B	7	0%(0/7)	6	0%(0/6)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Invasive procedure	liver-related	15	0%(0/15)	15	6,7%(1/15)	0,312	[0,012;8,285]	-0,062	[-0,229;0,104]	0,333	[0,015;7,584]	0,46521	n.d.	n.d.
Invasive procedure	gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	14	7,1%(1/14)	11	0%(0/11)	2,556	[0,095;68,999]	0,058	[-0,131;0,248]	2,4	[0,107;53,772]	0,56522	0,49766	0,54099
Baseline body weight (kg)	- >= 75	2	0%(0/2)	4	25%(1/4)	0,467	[0,013;16,886]	-0,133	[-0,716;0,449]	0,556	[0,032;9,727]	0,67329		
Treatment duration (days)	- < 7	4	25%(1/4)	-	-	0,429	[0,005;33,596]	-0,2	[-1,259;0,859]	0,6	[0,056;6,442]	0,69854	0,84889	0,79111
Treatment duration (days)	-7	12	0%(0/12)	15	6,7%(1/15)	0,387	[0,014;10,367]	-0,055	[-0,232;0,122]	0,41	[0,018;9,252]	0,55899		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-35: Subgruppenergebnisse für Studie M0626: Blutungsereignisse

M0626														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	7	0%(0/7)	3	0%(0/3)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Age (years)	- >=65	9	55,6%(5/9)	12	66,7%(8/12)	0,625	[0,105;3,707]	-0,111	[-0,531;0,309]	0,833	[0,41;1,692]	0,60385		
Gender	- Male	9	44,4%(4/9)	8	37,5%(3/8)	1,333	[0,191;9,311]	0,069	[-0,397;0,536]	1,185	[0,373;3,762]	0,77152	0,11324	0,04645
Gender	- Female	7	14,3%(1/7)	7	71,4%(5/7)	0,067	[0,005;0,97]	-0,571	[-0,995;-0,148]	0,2	[0,031;1,303]	0,03075		
Race	- White	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	16	31,2%(5/16)	15	53,3%(8/15)	0,398	[0,092;1,721]	-0,221	[-0,56;0,119]	0,586	[0,246;1,395]	0,21305		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	3	33,3%(1/3)	4	50%(2/4)	0,5	[0,023;11,088]	-0,167	[-0,891;0,558]	0,667	[0,102;4,354]	0,65924	0,87654	0,8655
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	13	30,8%(4/13)	11	54,5%(6/11)	0,37	[0,07;1,971]	-0,238	[-0,624;0,149]	0,564	[0,212;1,5]	0,23911		
Child-Pugh class	- A	9	55,6%(5/9)	9	55,6%(5/9)	1	[0,156;6,42]	0	[-0,459;0,459]	1	[0,438;2,285]	1	0,16047	0,16092
Child-Pugh class	- B	7	0%(0/7)	6	50%(3/6)	0,067	[0,003;1,674]	-0,438	[-0,844;-0,031]	0,125	[0,008;2,023]	0,05593		
Invasive procedure	liver-related	15	26,7%(4/15)	15	53,3%(8/15)	0,318	[0,069;1,468]	-0,267	[-0,604;0,071]	0,5	[0,191;1,31]	0,13604	n.d.	n.d.
Invasive procedure	gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	14	28,6%(4/14)	11	63,6%(7/11)	0,229	[0,042;1,238]	-0,351	[-0,721;0,019]	0,449	[0,175;1,151]	0,07956	0,21954	0,18752
Baseline body weight (kg)	- >= 75	2	50%(1/2)	4	25%(1/4)	3	[0,084;107,447]	0,25	[-0,563;1,063]	2	[0,224;17,894]	0,54029		
Treatment duration (days)	- < 7	4	75%(3/4)	-	-	2,333	[0,03;182,909]	0,2	[-0,859;1,259]	1,4	[0,182;10,791]	0,69854	0,2295	0,31605
Treatment duration (days)	-7	12	16,7%(2/12)	15	53,3%(8/15)	0,175	[0,028;1,086]	-0,367	[-0,696;-0,038]	0,312	[0,081;1,206]	0,04994		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-36: Subgruppenergebnisse für Studie M0626: Thrombose- und Embolieereignisse

M0626														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	7	0%(0/7)	3	0%(0/3)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Age (years)	- >=65	9	0%(0/9)	12	8,3%(1/12)	0,404	[0,015;11,094]	-0,065	[-0,285;0,155]	0,433	[0,02;9,548]	0,58117		
Gender	- Male	9	0%(0/9)	8	12,5%(1/8)	0,263	[0,009;7,431]	-0,117	[-0,395;0,162]	0,3	[0,014;6,471]	0,40802	n.d.	n.d.
Gender	- Female	7	0%(0/7)	7	0%(0/7)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Race	- White	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	16	0%(0/16)	15	6,7%(1/15)	0,293	[0,011;7,765]	-0,064	[-0,228;0,1]	0,314	[0,014;7,154]	0,43885		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	3	0%(0/3)	4	0%(0/4)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	13	0%(0/13)	11	9,1%(1/11)	0,259	[0,01;7,034]	-0,089	[-0,3;0,122]	0,286	[0,013;6,383]	0,39436		
Child-Pugh class	- A	9	0%(0/9)	9	0%(0/9)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Child-Pugh class	- B	7	0%(0/7)	6	16,7%(1/6)	0,244	[0,008;7,212]	-0,152	[-0,499;0,195]	0,292	[0,014;6,071]	0,38828		
Invasive procedure	liver-related	15	0%(0/15)	15	6,7%(1/15)	0,312	[0,012;8,285]	-0,062	[-0,229;0,104]	0,333	[0,015;7,584]	0,46521	n.d.	n.d.
Invasive procedure	gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	14	0%(0/14)	11	9,1%(1/11)	0,241	[0,009;6,529]	-0,092	[-0,3;0,116]	0,267	[0,012;5,975]	0,36613	n.d.	n.d.
Baseline body weight (kg)	- >= 75	2	0%(0/2)	4	0%(0/4)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Treatment duration (days)	- < 7	4	0%(0/4)	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Treatment duration (days)	-7	12	0%(0/12)	15	6,7%(1/15)	0,387	[0,014;10,367]	-0,055	[-0,232;0,122]	0,41	[0,018;9,252]	0,55899		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-37: Subgruppenergebnisse für Studie M0626: PT Aspartataminotransferase erhöht

M0626														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (RR)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	7	42,9% (3/7)	3	0,0% (0/3)	5,444	[0,206;144,102]	0,312	[-0,16;0,785]	3,5	[0,233;52,562]	0,27902	0,93658	0,66867
Age (years)	- >=65	9	77,8%(7/9)	12	25,0%(3/12)	10,5	[1,36;81,053]	0,528	[0,162;0,894]	3,111	[1,099;8,805]	0,01655		
Gender	- Male	9	66,7% (6/9)	8	12,5% (1/8)	14	[1,135;172,642]	0,542	[0,158;0,926]	5,333	[0,805;35,328]	0,02351	0,40636	0,67545
Gender	- Female	7	57,1% (4/7)	7	28,6% (2/7)	3,333	[0,362;30,701]	0,286	[-0,211;0,782]	2	[0,526;7,604]	0,28009		
Race	- White	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	16	62,5% (10/16)	15	20,0% (3/15)	6,667	[1,319;33,693]	0,425	[0,113;0,737]	3,125	[1,06;9,211]	0,01655		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	3	33,3% (1/3)	4	0,0% (0/4)	5,4	[0,154;188,831]	0,275	[-0,267;0,817]	3,75	[0,203;69,397]	0,3241	0,80473	0,57216
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	13	69,2% (9/13)	11	27,3% (3/11)	6	[1,018;35,374]	0,42	[0,056;0,783]	2,538	[0,906;7,116]	0,04052		
Child-Pugh class	- A	9	77,8% (7/9)	9	22,2% (2/9)	12,25	[1,327;113,06]	0,556	[0,171;0,94]	3,5	[0,982;12,477]	0,01842	n.d.	n.d.
Child-Pugh class	- B	7	42,9% (3/7)	6	16,7% (1/6)	3,75	[0,274;51,373]	0,262	[-0,211;0,734]	2,571	[0,354;18,683]	0,30774		
Invasive procedure	liver-related	-	-	-	-	8	[1,522;42,042]	0,467	[0,154;0,78]	3,333	[1,139;9,752]	0,00991	n.d.	n.d.
Invasive procedure	gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Invasive procedure	Non-liver/gi-related	-	-	-	-	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Treatment duration (days)	- < 7	4	75,0%(3/4)			2,333	[0,03;182,909]	0,2	[-0,859;1,259]	1,4	[0,182;10,791]	0,69854	0,53671	0,12771
Treatment duration (days)	-7	12	58,3% (7/12)	15	20,0% (3/15)	5,6	[1,015;30,904]	0,383	[0,039;0,728]	2,917	[0,952;8,934]	0,0404		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Meta-Analyse

Tabelle 4G-38: Subgruppenergebnisse für die Meta-Analyse: Vermeidung von Thrombozytentransfusionen und der Gabe einer Notfalltherapie zur Behandlung einer akuten Blutung

META-ANALYSE														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	106	67,9%(72/106)	110	27,3%(30/110)	5,405	[2,989;9,775]	0,402	[0,281;0,524]	2,258	[1,637;3,114]	4,80E-09	0,25653	0,0491
Age (years)	- >=65	67	71,6%(48/67)	60	16,7%(10/60)	10,631	[4,353;25,964]	0,586	[0,449;0,723]	3,311	[1,857;5,902]	6,49E-10		
Gender	- Male	96	62,5%(60/96)	107	21,5%(23/107)	5,9	[3,147;11,063]	0,421	[0,298;0,543]	2,734	[1,85;4,039]	3,22E-09	0,52645	0,10563
Gender	- Female	77	77,9%(60/77)	63	27%(17/63)	8,598	[3,806;19,422]	0,571	[0,438;0,703]	2,282	[1,528;3,41]	1,03E-09		
Race	- White	85	69,4%(59/85)	86	29,1%(25/86)	n,d,	n,d,	n,d,	n,d,	n,d,	n,d,	n,d,	n,d,	n,d,
Race	- Others	88	69,3%(61/88)	84	17,9%(15/84)	9,454	[4,504;19,845]	0,546	[0,425;0,667]	3,431	[2,106;5,59]	8,84E-12		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	46	41,3%(19/46)	52	13,5%(7/52)	3,92	[1,442;10,659]	0,265	[0,101;0,428]	2,561	[1,217;5,391]	0,001937	0,89092	0,00393
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	126	80,2%(101/126)	117	27,4%(32/117)	10,025	[5,424;18,529]	0,549	[0,445;0,653]	2,709	[2,004;3,663]	9,99E-17		
Child-Pugh class	- A	108	65,7%(71/108)	94	25,5%(24/94)	5,378	[2,892;10,002]	0,421	[0,298;0,544]	2,414	[1,665;3,5]	1,03E-08	0,32203	0,07217
Child-Pugh class	- B	62	77,4%(48/62)	75	21,3%(16/75)	11,719	[5,124;26,799]	0,589	[0,454;0,724]	3,25	[2,059;5,13]	5,74E-11		
Invasive procedure	liver-related	73	74%(54/73)	68	17,6%(12/68)	12,214	[5,254;28,393]	0,595	[0,466;0,724]	3,797	[2,216;6,504]	1,77E-11	0,01356	0,04502
Invasive procedure	gi-related	71	70,4%(50/71)	74	24,3%(18/74)	7,271	[3,474;15,219]	0,46	[0,315;0,605]	2,813	[1,836;4,31]	3,29E-08		
Invasive procedure	Non-liver/gi-related	21	76,2%(16/21)	18	55,6%(10/18)	2,56	[0,652;10,059]	0,206	[-0,087;0,499]	1,371	[0,851;2,211]	0,172954		
Baseline body weight (kg)	- < 75	111	73%(81/111)	99	23,2%(23/99)	8,323	[4,34;15,962]	0,529	[0,417;0,641]	2,649	[1,828;3,838]	4,75E-13	0,8787	0,27709
Baseline body weight (kg)	- >= 75	62	62,9%(39/62)	70	22,9%(16/70)	5,679	[2,635;12,238]	0,424	[0,271;0,576]	2,773	[1,759;4,373]	2,49E-06		
Treatment duration (days)	- < 7	46	84,8%(39/46)	15	53,3%(8/15)	5,444	[1,339;22,129]	0,25	[0,001;0,499]	1,357	[0,873;2,11]	0,013076	0,01296	0,09718
Treatment duration (days)	-7	125	64,8%(81/125)	155	20,6%(32/155)	6,364	[3,658;11,07]	0,477	[0,377;0,578]	2,754	[1,959;3,873]	6,00E-14		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-39: Subgruppenergebnisse für die Meta-Analyse: Vermeidung von Thrombozytentransfusionen vor dem invasiven Eingriff

META-ANALYSE														
		Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)				
Subgroup	Subgroup factor	N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR	p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
Age (years)	- < 65	106	67,9%(72/106)	110	28,2%(31/110)	5,153	[2,858;9,291]	0,394	[0,272;0,516]	2,191	[1,598;3,006]	1,10E-08	0,2065	0,02229
Age (years)	- >=65	67	73,1%(49/67)	60	16,7%(10/60)	11,219	[4,57;27,542]	0,606	[0,471;0,741]	3,35	[1,88;5,97]	2,34E-10		
Gender	- Male	96	62,5%(60/96)	107	22,4%(24/107)	5,545	[2,973;10,342]	0,413	[0,289;0,536]	2,612	[1,782;3,827]	8,01E-09	0,64468	0,05706
Gender	- Female	77	79,2%(61/77)	63	27%(17/63)	8,941	[3,944;20,269]	0,588	[0,457;0,719]	2,293	[1,535;3,426]	4,22E-10		
Race	- White	85	69,4%(59/85)	86	30,2%(26/86)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	88	70,5%(62/88)	84	17,9%(15/84)	9,885	[4,691;20,832]	0,561	[0,442;0,68]	3,472	[2,132;5,655]	3,21E-12		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	46	41,3%(19/46)	52	13,5%(7/52)	3,92	[1,442;10,659]	0,265	[0,101;0,428]	2,561	[1,217;5,391]	0,001937	0,95407	0,00345
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	126	81%(102/126)	117	28,2%(33/117)	9,901	[5,349;18,325]	0,553	[0,45;0,656]	2,622	[1,952;3,523]	1,01E-16		
Child-Pugh class	- A	108	66,7%(72/108)	94	26,6%(25/94)	5,206	[2,805;9,659]	0,426	[0,303;0,549]	2,315	[1,611;3,326]	1,24E-08	0,25362	0,08107
Child-Pugh class	- B	62	77,4%(48/62)	75	21,3%(16/75)	11,719	[5,124;26,799]	0,589	[0,454;0,724]	3,25	[2,059;5,13]	5,74E-11		
Invasive procedure	liver-related	73	74%(54/73)	68	19,1%(13/68)	10,69	[4,648;24,589]	0,588	[0,459;0,718]	3,358	[2,003;5,633]	6,26E-11	0,02321	0,06008
Invasive procedure	gi-related	71	71,8%(51/71)	74	24,3%(18/74)	7,67	[3,642;16,154]	0,485	[0,343;0,627]	2,858	[1,867;4,376]	1,17E-08		
Invasive procedure	Non-liver/gi-related	21	76,2%(16/21)	18	55,6%(10/18)	2,56	[0,652;10,059]	0,206	[-0,087;0,499]	1,371	[0,851;2,211]	0,172954		
Baseline body weight (kg)	- < 75	111	73,9%(82/111)	99	23,2%(23/99)	8,557	[4,454;16,441]	0,542	[0,431;0,653]	2,663	[1,838;3,857]	1,91E-13	0,94346	0,17542
Baseline body weight (kg)	- >= 75	62	62,9%(39/62)	70	24,3%(17/70)	5,196	[2,434;11,092]	0,41	[0,256;0,564]	2,608	[1,677;4,056]	6,17E-06		
Treatment duration (days)	- < 7	46	84,8%(39/46)	15	53,3%(8/15)	5,444	[1,339;22,129]	0,25	[0,001;0,499]	1,357	[0,873;2,11]	0,013076	0,01714	0,08463
Treatment duration (days)	-7	125	65,6%(82/125)	155	21,3%(33/155)	6,211	[3,575;10,79]	0,486	[0,386;0,586]	2,666	[1,906;3,729]	5,96E-14		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-40: Subgruppenergebnisse für die Meta-Analyse: Vermeidung der Gabe einer Notfalltherapie zur Behandlung einer akuten Blutung

META-ANALYSE														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	106	100%(106/106)	110	98,2%(108/110)	2,702	[0,273;26,753]	0,013	[-0,017;0,044]	1,013	[0,991;1,036]	0,183172	0,20478	0,41496
Age (years)	- >=65	67	98,5%(66/67)	60	100%(60/60)	0,379	[0,015;9,652]	-0,014	[-0,07;0,042]	0,98	[0,935;1,028]	0,351871		
Gender	- Male	96	100%(96/96)	107	99,1%(106/107)	2,288	[0,089;58,852]	0,003	[-0,025;0,03]	1,005	[0,979;1,032]	0,387201	1	0,87661
Gender	- Female	77	98,7%(76/77)	63	98,4%(62/63)	1,299	[0,131;12,864]	0,008	[-0,048;0,065]	1,005	[0,964;1,048]	0,850281		
Race	- White	85	100%(85/85)	86	100%(86/86)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	88	98,9%(87/88)	84	97,6%(82/84)	1,712	[0,205;14,305]	0,008	[-0,039;0,054]	1,012	[0,967;1,059]	0,533677		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	46	100%(46/46)	52	98,1%(51/52)	2,92	[0,115;74,03]	0,023	[-0,043;0,089]	1,025	[0,975;1,078]	0,3271	0,39015	0,52748
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	126	99,2%(125/126)	117	99,1%(116/117)	1,108	[0,067;18,354]	0	[-0,025;0,026]	1	[0,975;1,026]	0,94284		
Child-Pugh class	- A	108	99,1%(107/108)	94	100%(94/94)	0,393	[0,015;10,121]	-0,003	[-0,03;0,025]	0,995	[0,969;1,022]	0,361755	0,19078	0,35425
Child-Pugh class	- B	62	100%(62/62)	75	97,3%(73/75)	2,501	[0,253;24,749]	0,026	[-0,029;0,082]	1,027	[0,988;1,068]	0,200223		
Invasive procedure	liver-related	73	100%(73/73)	68	100%(68/68)	#NV	[NA,NA]	0	[-0,043;0,043]	1	[0,956;1,046]	#NV	0,61502	0,72806
Invasive procedure	gi-related	71	98,6%(70/71)	74	98,6%(73/74)	0,692	[0,038;12,572]	-0,001	[-0,032;0,031]	0,999	[0,968;1,032]	0,80283		
Invasive procedure	Non-liver/gi-related	21	100%(21/21)	18	94,4%(17/18)	3,686	[0,141;96,224]	0,056	[-0,081;0,192]	1,057	[0,948;1,179]	0,27384		
Baseline body weight (kg)	- < 75	111	99,1%(110/111)	99	98%(97/99)	1,809	[0,218;15,02]	0,013	[-0,027;0,053]	1,015	[0,982;1,05]	0,492279	0,54412	0,62042
Baseline body weight (kg)	- >= 75	62	100%(62/62)	70	100%(70/70)	-	[NA;NA]	0	[-0,034;0,034]	1	[0,966;1,035]	NaN		
Treatment duration (days)	- < 7	46	100%(46/46)	15	100%(15/15)	-	[NA;NA]	0	[-0,102;0,102]	1	[0,895;1,117]	NaN	0,87564	0,8819
Treatment duration (days)	-7	125	99,2%(124/125)	155	98,7%(153/155)	1,336	[0,161;11,057]	0,008	[-0,02;0,035]	1,009	[0,99;1,029]	0,667346		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-41: Subgruppenergebnisse für die Meta-Analyse: Erfolgreiche Behandlung der schweren Thrombozytopenie

META-ANALYSE														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	106	67%(71/106)	11 0	11,8%(13/110)	14,181	[6,952;28,929]	0,555	[0,447;0,663]	5,154	[3,056;8,692]	1,55E-16	0,63788	0,37011
Age (years)	- >=65	67	70,1%(47/67)	60	8,3%(5/60)	20,237	[7,17;57,12]	0,632	[0,503;0,761]	6,494	[2,895;14,566]	1,93E-12		
Gender	- Male	96	58,3%(56/96)	10 7	9,3%(10/107)	13,185	[6,099;28,505]	0,502	[0,39;0,613]	6,035	[3,264;11,158]	7,80E-14	0,77181	0,01907
Gender	- Female	77	80,5%(62/77)	63	12,7%(8/63)	26,413	[10,111;68,997]	0,696	[0,579;0,814]	5,3	[2,832;9,918]	1,07E-15		
Race	- White	85	69,4%(59/85)	86	15,1%(13/86)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	88	67%(59/88)	84	6%(5/84)	34,775	[12,548;96,374]	0,62	[0,513;0,727]	11,29 3	[4,771;26,731]	5,68E-17		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	46	41,3%(19/46)	52	5,8%(3/52)	9,995	[2,882;34,66]	0,333	[0,181;0,485]	6,002	[2,071;17,397]	2,41E-05	0,94211	0,00026
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	126	78,6%(99/126)	11 7	12,8%(15/117)	24,191	[12,027;48,659]	0,666	[0,574;0,758]	5,748	[3,559;9,282]	9,75E-25		
Child-Pugh class	- A	108	65,7%(71/108)	94	11,7%(11/94)	14,239	[6,755;30,018]	0,544	[0,433;0,654]	5,527	[3,119;9,794]	6,28E-15	0,77812	0,10612
Child-Pugh class	- B	62	74,2%(46/62)	75	9,3%(7/75)	22,037	[8,346;58,188]	0,679	[0,557;0,801]	6,291	[3,138;12,611]	7,80E-15		
Invasive procedure	liver-related	73	72,6%(53/73)	68	7,4%(5/68)	34,122	[11,871;98,077]	0,651	[0,532;0,771]	9,639	[4,108;22,616]	3,55E-15	0,00011	0,03111
Invasive procedure	gi-related	71	70,4%(50/71)	74	6,8%(5/74)	28,058	[10,24;76,882]	0,646	[0,525;0,767]	9,067	[4,005;20,525]	3,07E-15		
Invasive procedure	Non-liver/gi-related	21	66,7%(14/21)	18	44,4%(8/18)	2,5	[0,682;9,164]	0,222	[-0,083;0,528]	1,5	[0,824;2,729]	0,162961		
Baseline body weight (kg)	- < 75	111	72,1%(80/111)	99	11,1%(11/99)	19,288	[8,88;41,893]	0,624	[0,522;0,725]	5,696	[3,237;10,024]	4,61E-19	0,68755	0,41783
Baseline body weight (kg)	- >= 75	62	61,3%(38/62)	70	8,6%(6/70)	16,645	[6,276;44,149]	0,554	[0,419;0,689]	6,912	[3,249;14,708]	1,06E-10		
Treatment duration (days)	- < 7	46	91,3%(42/46)	15	60%(9/15)	8,857	[1,77;44,329]	0,264	[0,023;0,506]	1,379	[0,923;2,059]	0,003620825	0	0,02062
Treatment duration (days)	-7	125	60,8%(76/125)	15 5	5,8%(9/155)	20,535	[9,427;44,73]	0,568	[0,478;0,659]	8,862	[4,607;17,048]	2,55E-23		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-42: Subgruppenergebnisse für die Meta-Analyse: Unerwünschte Ereignisse

META-ANALYSE														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	104	56,7%(59/104)	11 0	60,9%(67/110)	0,83	[0,46;1,495]	-0,063	[-0,177;0,051]	0,899	[0,766;1,055]	0,470411315	0,34606	0,50041
Age (years)	- >=65	67	79,1%(53/67)	60	80%(48/60)	1,224	[0,388;3,868]	-0,017	[-0,089;0,054]	0,975	[0,923;1,03]	0,76921726		
Gender	- Male	94	61,7%(58/94)	10 7	64,5%(69/107)	0,953	[0,488;1,86]	-0,026	[-0,112;0,06]	0,963	[0,885;1,047]	0,874216962	0,6621	0,67763
Gender	- Female	77	70,1%(54/77)	63	73%(46/63)	0,78	[0,336;1,812]	-0,054	[-0,154;0,046]	0,936	[0,851;1,029]	0,487105512		
Race	- White	84	47,6%(40/84)	86	47,7%(41/86)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	87	82,8%(72/87)	84	88,1%(74/84)	0,65	[0,216;1,956]	-0,044	[-0,107;0,019]	0,953	[0,895;1,014]	0,283037855		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	46	65,2%(30/46)	52	61,5%(32/52)	1,389	[0,556;3,469]	0,033	[-0,111;0,177]	1,031	[0,849;1,251]	0,481255966	0,38216	0,27963
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	125	65,6%(82/125)	11 7	70,9%(83/117)	0,715	[0,373;1,373]	-0,055	[-0,125;0,015]	0,94	[0,873;1,012]	0,233749475		
Child-Pugh class	- A	106	57,5%(61/106)	94	59,6%(56/94)	0,92	[0,468;1,811]	-0,039	[-0,128;0,049]	0,942	[0,858;1,036]	0,731261398	0,76645	0,95152
Child-Pugh class	- B	62	77,4%(48/62)	75	78,7%(59/75)	0,831	[0,339;2,037]	-0,035	[-0,129;0,058]	0,96	[0,883;1,043]	0,659651088		
Invasive procedure	liver-related	73	83,6%(61/73)	68	77,9%(53/68)	1,974	[0,578;6,736]	-0,019	[-0,087;0,05]	0,964	[0,905;1,028]	0,350318204	0,59074	0,59468
Invasive procedure	gi-related	71	56,3%(40/71)	74	66,2%(49/74)	0,699	[0,346,1,409]	-0,085	[-0,223;0,054]	0,896	[0,757,1,06]	0,304376625		
Invasive procedure	Non-liver/gi-related	21	42,9%(9/21)	18	55,6%(10/18)	0,6	[0,169,2,135]	-0,127	[-0,439,0,185]	0,771	[0,405,1,469]	0,428987185		
Baseline body weight (kg)	- < 75	111	70,3%(78/111)	99	76,8%(76/99)	0,596	[0,281;1,265]	-0,058	[-0,127;0,011]	0,941	[0,878;1,009]	0,123389042	0,30142	0,16564
Baseline body weight (kg)	- >= 75	60	56,7%(34/60)	70	54,3%(38/70)	1,436	[0,677;3,045]	0,058	[-0,091;0,207]	1,077	[0,841;1,378]	0,344851193		
Treatment duration (days)	- < 7	46	58,7%(27/46)	15	66,7%(10/15)	0,599	[0,169;2,115]	-0,086	[-0,335;0,162]	0,86	[0,566;1,306]	0,405947661	0,64607	0,70937
Treatment duration (days)	-7	125	68%(85/125)	15 5	67,7%(105/155)	1,01	[0,554;1,839]	-0,037	[-0,104;0,031]	0,95	[0,884;1,022]	0,862273083		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-43: Subgruppenergebnisse für die Meta-Analyse: Unerwünschte Ereignisse unter Ausschluss morbiditätsbedingter Folgekomplikationen

META-ANALYSE														
		Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)				
Subgroup	Subgroup factor	N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR	p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
Age (years)	- < 65	104	54,8%(57/104)	110	60%(66/110)	0,789	[0,438;1,424]	-0,071	[-0,185;0,043]	0,892	[0,759;1,048]	0,3759	0,31208	0,455
Age (years)	- >=65	67	77,6%(52/67)	60	80%(48/60)	1,055	[0,332;3,347]	-0,02	[-0,091;0,051]	0,974	[0,922;1,029]	0,975448		
Gender	- Male	94	58,5%(55/94)	107	64,5%(69/107)	0,792	[0,404;1,554]	-0,038	[-0,123;0,048]	0,958	[0,88;1,042]	0,485703	0,74578	0,88198
Gender	- Female	77	70,1%(54/77)	63	71,4%(45/63)	0,861	[0,371;1,996]	-0,048	[-0,148;0,052]	0,938	[0,853;1,032]	0,640016		
Race	- White	84	44%(37/84)	86	46,5%(40/86)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	87	82,8%(72/87)	84	88,1%(74/84)	0,65	[0,216;1,956]	-0,044	[-0,107;0,019]	0,953	[0,895;1,014]	0,283038		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	46	65,2%(30/46)	52	61,5%(32/52)	1,389	[0,556;3,469]	0,033	[-0,111;0,177]	1,031	[0,849;1,251]	0,481256	0,37129	0,25321
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	125	63,2%(79/125)	117	70,1%(82/117)	0,64	[0,332;1,235]	-0,06	[-0,13;0,01]	0,938	[0,871;1,009]	0,130804		
Child-Pugh class	- A	106	57,5%(61/106)	94	58,5%(55/94)	0,98	[0,497;1,934]	-0,035	[-0,123;0,053]	0,944	[0,859;1,038]	0,871494	0,88163	0,80787
Child-Pugh class	- B	62	72,6%(45/62)	75	78,7%(59/75)	0,591	[0,244;1,434]	-0,051	[-0,145;0,043]	0,953	[0,877;1,036]	0,226721		
Invasive procedure	liver-related	73	83,6%(61/73)	68	77,9%(53/68)	1,974	[0,578;6,736]	-0,019	[-0,087;0,05]	0,964	[0,905;1,028]	0,350318204	0,43438	0,42967
Invasive procedure	gi-related	71	53,5%(38/71)	74	64,9%(48/74)	0,658	[0,327;1,325]	-0,095	[-0,233;0,044]	0,888	[0,749;1,053]	0,230680567		
Invasive procedure	Non-liver/gi-related	21	38,1%(8/21)	18	55,6%(10/18)	0,492	[0,137;1,772]	-0,175	[-0,484;0,135]	0,686	[0,346;1,359]	0,275538534		
Baseline body weight (kg)	- < 75	111	69,4%(77/111)	99	75,8%(75/99)	0,598	[0,281;1,27]	-0,058	[-0,126;0,011]	0,941	[0,878;1,009]	0,125421	0,43248	0,27154
Baseline body weight (kg)	- >= 75	60	53,3%(32/60)	70	54,3%(38/70)	1,238	[0,584;2,626]	0,034	[-0,115;0,183]	1,044	[0,813;1,341]	0,577431		
Treatment duration (days)	- < 7	46	56,5%(26/46)	15	66,7%(10/15)	0,536	[0,151;1,898]	-0,105	[-0,353;0,143]	0,834	[0,546;1,274]	0,313006	0,55874	0,62102
Treatment duration (days)	-7	125	66,4%(83/125)	155	67,1%(104/155)	0,947	[0,519;1,726]	-0,04	[-0,107;0,027]	0,948	[0,882;1,02]	0,702374		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-44: Subgruppenergebnisse für die Meta-Analyse: Schwere unerwünschte Ereignisse

META-ANALYSE														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	104	13,5%(14/104)	11 0	10,9%(12/110)	1,197	[0,461;3,106]	0,006	[-0,056;0,068]	1,137	[0,57;2,269]	0,689478147	0,38365	0,23867
Age (years)	- >=65	67	31,3%(21/67)	60	43,3%(26/60)	0,6	[0,257;1,398]	-0,07	[-0,18;0,039]	0,799	[0,541;1,179]	0,22038723		
Gender	- Male	94	14,9%(14/94)	10 7	20,6%(22/107)	0,634	[0,265;1,518]	-0,02	[-0,082;0,042]	0,782	[0,47;1,3]	0,304225242	0,44513	0,772
Gender	- Female	77	27,3%(21/77)	63	25,4%(16/63)	1,018	[0,398;2,601]	-0,004	[-0,093;0,085]	1,013	[0,66;1,555]	0,970757881		
Race	- White	84	4,8%(4/84)	86	5,8%(5/86)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	87	35,6%(31/87)	84	39,3%(33/84)	0,843	[0,416;1,707]	-0,008	[-0,084;0,068]	0,923	[0,661;1,29]	0,634303618		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	46	13%(6/46)	52	13,5%(7/52)	1,125	[0,251;5,042]	0,007	[-0,065;0,08]	1,39	[0,698;2,766]	0,75632441	0,21079	0,54275
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	125	23,2%(29/125)	11 7	26,5%(31/117)	0,74	[0,368;1,489]	-0,024	[-0,092;0,044]	0,847	[0,593;1,211]	0,391249413		
Child-Pugh class	- A	106	16%(17/106)	94	17%(16/94)	0,925	[0,362;2,367]	-0,016	[-0,057;0,025]	1,008	[0,623;1,629]	0,837833455	0,48772	0,61035
Child-Pugh class	- B	62	25,8%(16/62)	75	29,3%(22/75)	0,677	[0,276;1,663]	-0,046	[-0,153;0,061]	0,799	[0,512;1,249]	0,373697515		
Invasive procedure	liver-related	73	41,1%(30/73)	68	42,6%(29/68)	0,862	[0,399;1,866]	0,016	[-0,09;0,123]	0,921	[0,661;1,283]	0,733740041	0,68558	0,80604
Invasive procedure	gi-related	71	4,2%(3/71)	74	9,5%(7/74)	0,471	[0,111;1,999]	-0,026	[-0,095;0,043]	0,502	[0,133;1,895]	0,275145721		
Invasive procedure	Non-liver/gi-related	21	4,8%(1/21)	18	5,6%(1/18)	0,85	[0,049;14,639]	-0,008	[-0,148;0,132]	0,857	[0,058;12,746]	0,91080832		
Baseline body weight (kg)	- < 75	111	25,2%(28/111)	99	30,3%(30/99)	0,615	[0,293;1,293]	-0,031	[-0,093;0,031]	0,812	[0,574;1,149]	0,196093058	0,11695	0,40116
Baseline body weight (kg)	- >= 75	60	11,7%(7/60)	70	11,4%(8/70)	1,633	[0,449;5,939]	0,014	[-0,069;0,097]	1,625	[0,734;3,599]	0,39192661		
Treatment duration (days)	- < 7	46	13%(6/46)	15	13,3%(2/15)	0,531	[0,08;3,516]	-0,05	[-0,201;0,101]	0,719	[0,222;2,334]	0,512541518	0,63761	0,56953
Treatment duration (days)	-7	125	23,2%(29/125)	15 5	23,2%(36/155)	0,924	[0,471;1,815]	-0,003	[-0,061;0,055]	0,965	[0,688;1,354]	0,819221785		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-45: Subgruppenergebnisse für die Meta-Analyse: Schwere unerwünschte Ereignisse unter Ausschluss morbiditätsbedingter Folgekomplikationen

META-ANALYSE														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	104	13,5%(14/104)	11 0	9,1%(10/110)	1,53	[0,567;4,126]	0,018	[-0,04;0,077]	1,348	[0,652;2,787]	0,383825	0,17963	0,13897
Age (years)	- >=65	67	29,9%(20/67)	60	43,3%(26/60)	0,55	[0,236;1,284]	-0,076	[-0,185;0,033]	0,765	[0,514;1,138]	0,155227		
Gender	- Male	94	14,9%(14/94)	10 7	18,7%(20/107)	0,744	[0,305;1,813]	-0,003	[-0,06;0,053]	0,838	[0,499;1,406]	0,512884	0,66297	0,94044
Gender	- Female	77	26%(20/77)	63	25,4%(16/63)	0,929	[0,363;2,373]	-0,007	[-0,096;0,082]	0,974	[0,631;1,506]	0,876893		
Race	- White	84	4,8%(4/84)	86	4,7%(4/86)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	87	34,5%(30/87)	84	38,1%(32/84)	0,842	[0,415;1,709]	-0,008	[-0,084;0,068]	0,921	[0,654;1,298]	0,633157		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	46	13%(6/46)	52	13,5%(7/52)	1,125	[0,251;5,042]	0,007	[-0,065;0,08]	1,39	[0,698;2,766]	0,756324	0,22542	0,73168
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	125	22,4%(28/125)	11 7	24,8%(29/117)	0,787	[0,387;1,601]	-0,01	[-0,074;0,054]	0,857	[0,592;1,241]	0,500252		
Child-Pugh class	- A	106	16%(17/106)	94	16%(15/94)	1,031	[0,386;2,75]	0	[-0,029;0,029]	1,037	[0,638;1,686]	0,950177	0,40512	0,40168
Child-Pugh class	- B	62	24,2%(15/62)	75	28%(21/75)	0,663	[0,269;1,635]	-0,047	[-0,154;0,06]	0,779	[0,488;1,243]	0,352057		
Invasive procedure	liver-related	73	39,7%(29/73)	68	42,6%(29/68)	0,803	[0,371,1,737]	0,011	[-0,096,0,117]	0,893	[0,637,1,251]	0,602802	0,94861	0,96057
Invasive procedure	gi-related	71	4,2%(3/71)	74	6,8%(5/74)	0,69	[0,148,3,219]	-0,006	[-0,068,0,056]	0,701	[0,169,2,911]	0,608301	#NV	#NV
Invasive procedure	Non-liver/gi-related	21	4,8%(1/21)	18	5,6%(1/18)	0,85	[0,049,14,639]	-0,008	[-0,148,0,132]	0,857	[0,058,12,746]	0,910808	#NV	#NV
Baseline body weight (kg)	- < 75	111	24,3%(27/111)	99	29,3%(29/99)	0,62	[0,294;1,305]	-0,031	[-0,092;0,031]	0,812	[0,568;1,159]	0,204192	0,07579	0,2343
Baseline body weight (kg)	- >= 75	60	11,7%(7/60)	70	10%(7/70)	2,203	[0,557;8,709]	0,029	[-0,047;0,106]	1,822	[0,804;4,128]	0,219676		
Treatment duration (days)	- < 7	46	13%(6/46)	15	13,3%(2/15)	0,531	[0,08;3,516]	-0,05	[-0,201;0,101]	0,719	[0,222;2,334]	0,512542	0,62678	0,4943
Treatment duration (days)	-7	125	22,4%(28/125)	15 5	21,9%(34/155)	0,965	[0,486;1,913]	0,006	[-0,049;0,061]	0,975	[0,688;1,381]	0,917252		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-46: Subgruppenergebnisse für die Meta-Analyse: Schwerwiegende unerwünschte Ereignisse

META-ANALYSE														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	104	5,8%(6/104)	110	5,5%(6/110)	1,128	[0,358;3,558]	0,004	[-0,061;0,069]	1,123	[0,382;3,301]	0,861567349	0,34358	0,28032
Age (years)	- >=65	67	4,5%(3/67)	60	10%(6/60)	0,449	[0,104;1,945]	-0,058	[-0,149;0,034]	0,484	[0,123;1,9]	0,239151213		
Gender	- Male	94	5,3%(5/94)	107	8,4%(9/107)	0,686	[0,219;2,154]	-0,034	[-0,103;0,035]	0,714	[0,247;2,067]	0,402785857	0,64983	0,48014
Gender	- Female	77	5,2%(4/77)	63	4,8%(3/63)	1,088	[0,232;5,112]	0,003	[-0,074;0,079]	1,085	[0,252;4,676]	0,909072551		
Race	- White	84	7,1%(6/84)	86	7%(6/86)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	87	3,4%(3/87)	84	7,1%(6/84)	0,497	[0,111;2,218]	-0,037	[-0,103;0,029]	0,521	[0,125;2,171]	0,279506973		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	46	6,5%(3/46)	52	7,7%(4/52)	1,004	[0,216;4,668]	-0,006	[-0,102;0,09]	1,032	[0,255;4,177]	0,943985913	0,70398	0,79403
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	125	4,8%(6/125)	117	6,8%(8/117)	0,718	[0,245;2,107]	-0,021	[-0,08;0,037]	0,739	[0,27;2,024]	0,506737697		
Child-Pugh class	- A	106	0,9%(1/106)	94	3,2%(3/94)	0,453	[0,075;2,757]	-0,02	[-0,059;0,019]	0,49	[0,089;2,683]	0,337923537	0,55419	0,89832
Child-Pugh class	- B	62	9,7%(6/62)	75	12%(9/75)	0,853	[0,277;2,629]	-0,027	[-0,127;0,074]	0,886	[0,332;2,363]	0,734110948		
Invasive procedure	liver-related	73	2,7%(2/73)	68	5,9%(4/68)	0,52	[0,101;2,668]	-0,026	[-0,101;0,049]	0,536	[0,112;2,568]	0,405871878	0,923	0,99547
Invasive procedure	gi-related	71	5,6%(4/71)	74	8,1%(6/74)	0,708	[0,2,2.502]	-0,025	[-0,109;0,06]	0,728	[0,225;2,349]	0,57888659		
Invasive procedure	Non-liver/gi-related	21	9,5%(2/21)	18	11,1%(2/18)	0,842	[0,106;6,672]	-0,016	[-0,208;0,176]	0,857	[0,134;5,485]	0,870611183		
Baseline body weight (kg)	- < 75	111	3,6%(4/111)	99	5,1%(5/99)	0,72	[0,182;2,844]	-0,015	[-0,072;0,041]	0,735	[0,197;2,742]	0,5957235	0,79319	0,85127
Baseline body weight (kg)	- >= 75	60	8,3%(5/60)	70	10%(7/70)	0,916	[0,29;2,894]	-0,004	[-0,105;0,096]	0,919	[0,329;2,568]	0,869704991		
Treatment duration (days)	- < 7	46	6,5%(3/46)	15	13,3%(2/15)	0,358	[0,055;2,334]	-0,082	[-0,27;0,107]	0,453	[0,105;1,954]	0,268307532	0,49997	0,52217
Treatment duration (days)	-7	125	4,8%(6/125)	155	6,5%(10/155)	0,814	[0,284;2,33]	-0,018	[-0,073;0,037]	0,832	[0,308;2,248]	0,58199394		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-47: Subgruppenergebnisse für die Meta-Analyse: Schwerwiegende unerwünschte Ereignisse unter Ausschluss morbiditätsbedingter Folgekomplikationen

META-ANALYSE														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	104	4,8%(5/104)	110	4,5%(5/110)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Age (years)	- >=65	67	1,5%(1/67)	60	10%(6/60)	0,291	[0,051;1,651]	-0,088	[-0,177;0,002]	0,333	[0,065;1,71]	0,062566		
Gender	- Male	94	3,2%(3/94)	107	7,5%(8/107)	0,442	[0,118;1,653]	-0,045	[-0,106;0,016]	0,472	[0,136;1,636]	0,192764	0,53539	0,50772
Gender	- Female	77	3,9%(3/77)	63	4,8%(3/63)	0,861	[0,173;4,287]	-0,012	[-0,089;0,065]	0,878	[0,192;4,011]	0,78647		
Race	- White	84	4,8%(4/84)	86	7%(6/86)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	87	2,3%(2/87)	84	6%(5/84)	0,504	[0,095;2,684]	-0,04	[-0,101;0,021]	0,532	[0,108;2,631]	0,252718		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	46	6,5%(3/46)	52	7,7%(4/52)	1,004	[0,216;4,668]	-0,006	[-0,102;0,09]	1,032	[0,255;4,177]	0,943986	0,40807	0,63927
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	125	2,4%(3/125)	117	6%(7/117)	0,456	[0,132;1,577]	-0,032	[-0,082;0,018]	0,477	[0,147;1,551]	0,190879		
Child-Pugh class	- A	106	0,9%(1/106)	94	3,2%(3/94)	0,453	[0,075;2,757]	-0,02	[-0,059;0,019]	0,49	[0,089;2,683]	0,337924	0,90929	0,48992
Child-Pugh class	- B	62	4,8%(3/62)	75	10,7%(8/75)	0,509	[0,135;1,916]	-0,054	[-0,142;0,034]	0,553	[0,167;1,833]	0,272048		
Invasive procedure	liver-related	73	1,4%(1/73)	68	5,9%(4/68)	0,444	[0,071;2,771]	-0,039	[-0,113;0,035]	0,466	[0,08;2,729]	0,233228	n.d.	n.d.
Invasive procedure	gi-related	71	4,2%(3/71)	74	6,8%(5/74)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Invasive procedure	Non-liver/gi-related	21	4,8%(1/21)	18	11,1%(2/18)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	111	1,8%(2/111)	99	4%(4/99)	0,525	[0,101;2,736]	-0,027	[-0,077;0,022]	0,546	[0,111;2,696]	0,360468	0,72449	0,89874
Baseline body weight (kg)	- >= 75	60	6,7%(4/60)	70	10%(7/70)	0,753	[0,227;2,495]	-0,02	[-0,117;0,076]	0,772	[0,263;2,267]	0,63505		
Treatment duration (days)	- < 7	46	4,3%(2/46)	15	13,3%(2/15)	0,21	[0,024;1,835]	-0,106	[-0,289;0,077]	0,334	[0,064;1,75]	0,121949	0,45615	0,4133
Treatment duration (days)	-7	125	3,2%(4/125)	155	5,8%(9/155)	0,689	[0,217;2,184]	-0,027	[-0,078;0,023]	0,711	[0,237;2,129]	0,365512		

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-48: Subgruppenergebnisse für die Meta-Analyse: Blutungsereignisse

META-ANALYSE														
Subgroup	Subgroup factor	Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)		p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
		N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR			
Age (years)	- < 65	104	6,7%(7/104)	110	7,3%(8/110)	1,054	[0,348;3,191]	-0,014	[-0,074;0,047]	1,103	[0,421;2,89]	0,934915523	0,28486	0,10339
Age (years)	- >=65	67	11,9%(8/67)	60	31,7%(19/60)	0,29	[0,102;0,826]	-0,114	[-0,218;-0,01]	0,594	[0,327;1,08]	0,011660816		
Gender	- Male	94	9,6%(9/94)	107	10,3%(11/107)	0,926	[0,324;2,646]	0,006	[-0,055;0,067]	0,97	[0,431;2,183]	0,836297543	0,08743	0,0118
Gender	- Female	77	7,8%(6/77)	63	25,4%(16/63)	0,218	[0,071;0,668]	-0,14	[-0,236;-0,045]	0,352	[0,153;0,809]	0,001800486		
Race	- White	84	3,6%(3/84)	86	3,5%(3/86)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	87	13,8%(12/87)	84	28,6%(24/84)	0,398	[0,177;0,893]	-0,141	[-0,249;-0,032]	0,528	[0,294;0,95]	0,015404915		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	46	4,3%(2/46)	52	17,3%(9/52)	0,255	[0,05;1,29]	-0,088	[-0,181;0,006]	0,401	[0,117;1,375]	0,061039523	0,50931	0,23167
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	125	10,4%(13/125)	117	15,4%(18/117)	0,576	[0,254;1,304]	-0,019	[-0,082;0,043]	0,638	[0,343;1,186]	0,179330107		
Child-Pugh class	- A	106	9,4%(10/106)	94	14,9%(14/94)	0,542	[0,197;1,491]	-0,038	[-0,095;0,019]	0,754	[0,398;1,429]	0,207222926	0,49236	0,73861
Child-Pugh class	- B	62	8,1%(5/62)	75	17,3%(13/75)	0,441	[0,148;1,317]	-0,057	[-0,154;0,04]	0,506	[0,197;1,299]	0,083969604		
Invasive procedure	liver-related	73	12,3%(9/73)	68	23,5%(16/68)	0,405	[0,155;1,057]	-0,036	[-0,116;0,043]	0,52	[0,258;1,046]	0,060396134	0,92568	0,8334
Invasive procedure	gi-related	71	5,6%(4/71)	74	13,5%(10/74)	0,405	[0,115;1,425]	-0,056	[-0,137;0,025]	0,479	[0,165;1,389]	0,147706703		
Invasive procedure	Non-liver/gi-related	21	4,8%(1/21)	18	5,6%(1/18)	0,85	[0,049;14,639]	-0,008	[-0,148;0,132]	0,857	[0,058;12,746]	0,91080832		
Baseline body weight (kg)	- < 75	111	9,9%(11/111)	99	23,2%(23/99)	0,312	[0,132;0,736]	-0,102	[-0,175;-0,029]	0,448	[0,244;0,822]	0,003176544	0,09005	0,0244
Baseline body weight (kg)	- >= 75	60	6,7%(4/60)	70	5,7%(4/70)	1,518	[0,349;6,59]	0,019	[-0,057;0,095]	1,485	[0,427;5,16]	0,580980015		
Treatment duration (days)	- < 7	46	8,7%(4/46)	15	6,7%(1/15)	0,509	[0,063;4,14]	-0,077	[-0,233;0,079]	0,763	[0,174;3,344]	0,419098772	0,62287	0,64806
Treatment duration (days)	-7	125	8,8%(11/125)	155	16,8%(26/155)	0,439	[0,2;0,962]	-0,038	[-0,097;0,021]	0,509	[0,266;0,974]	0,030237144		

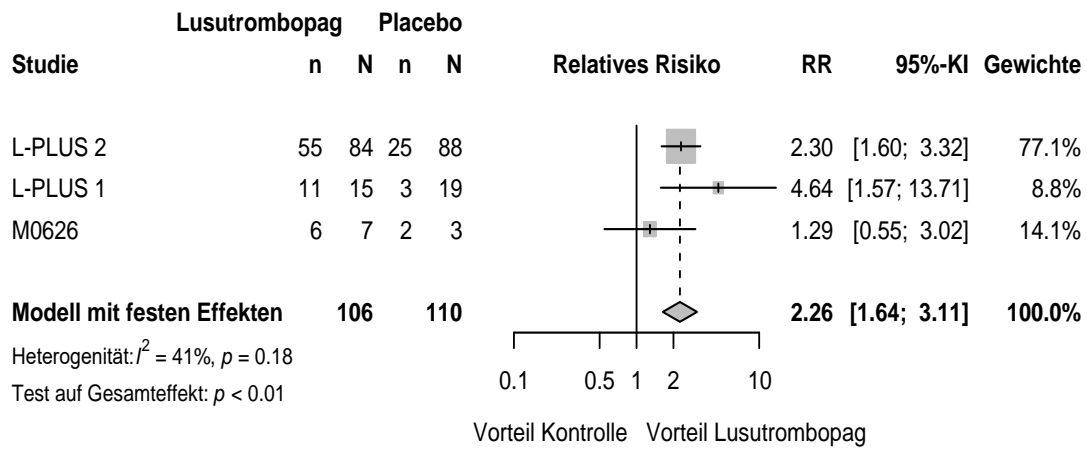
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Tabelle 4G-49: Subgruppenergebnisse für die Meta-Analyse: Thrombose- und Embolieereignisse

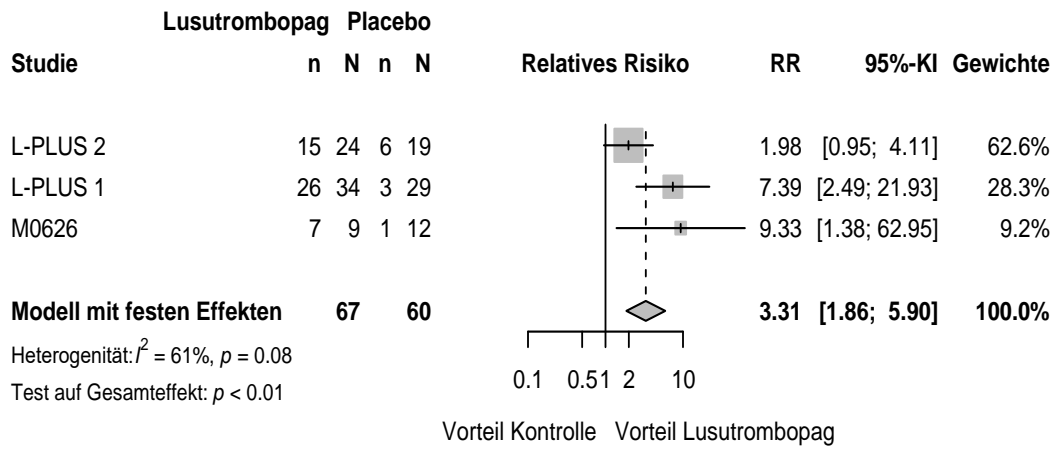
META-ANALYSE														
		Lusutrombopag		Kontrolle		Odds Ratio (OR)		Risikodifferenz (RD)		Risk Ratio (RR)				
Subgroup	Subgroup factor	N	% (n/N)	N	% (n/N)	OR	95%-CI OR	RD	95%-CI RD	RR	95%-CI RR	p-Value (CMH)	inter-action p-value RR	inter-action p-value RD
Age (years)	- < 65	104	1%(1/104)	110	1,8%(2/110)	0,722	[0,086;6,034]	-0,001	[-0,033;0,03]	0,725	[0,092;5,738]	0,737289194	0,8564	0,80614
Age (years)	- >=65	67	3%(2/67)	60	3,3%(2/60)	0,936	[0,156;5,635]	0,008	[-0,057;0,074]	0,929	[0,168;5,15]	0,957705664		
Gender	- Male	94	2,1%(2/94)	107	2,8%(3/107)	0,844	[0,157;4,527]	0,004	[-0,04;0,049]	0,839	[0,167;4,214]	0,799126918	0,95937	0,68529
Gender	- Female	77	1,3%(1/77)	63	1,6%(1/63)	0,77	[0,078;7,625]	-0,011	[-0,068;0,045]	0,781	[0,084;7,295]	0,795920143		
Race	- White	84	2,4%(2/84)	86	1,2%(1/86)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Race	- Others	87	1,1%(1/87)	84	3,6%(3/84)	0,48	[0,081;2,854]	-0,014	[-0,063;0,035]	0,492	[0,088;2,763]	0,370253327		
Baseline platelet count (*10 ⁴ /uL)	- < 3.5	46	0%(0/46)	52	0%(0/52)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Baseline platelet count (*10 ⁴ /uL)	- >= 3.5	125	2,4%(3/125)	117	3,4%(4/117)	0,735	[0,171;3,154]	-0,005	[-0,048;0,037]	0,741	[0,181;3,025]	0,634512742		
Child-Pugh class	- A	106	0%(0/106)	94	2,1%(2/94)	0,281	[0,029;2,765]	-0,019	[-0,058;0,019]	0,29	[0,031;2,723]	0,247038943	0,23661	0,20671
Child-Pugh class	- B	62	4,8%(3/62)	75	2,7%(2/75)	1,616	[0,297;8,775]	0,033	[-0,037;0,104]	1,53	[0,308;7,599]	0,576143936		
Invasive procedure	liver-related	73	1,4%(1/73)	68	4,4%(3/68)	0,473	[0,079;2,821]	-0,022	[-0,084;0,039]	0,487	[0,087;2,725]	0,370456275	n.d.	n.d.
Invasive procedure	gi-related	71	1,4%(1/71)	74	0%(0/74)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Invasive procedure	Non-liver/gi-related	21	4,8%(1/21)	18	5,6%(1/18)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Baseline body weight (kg)	- < 75	111	1,8%(2/111)	99	2%(2/99)	0,859	[0,145;5,102]	0,006	[-0,034;0,046]	0,854	[0,152;4,793]	0,858848284	n.d.	n.d.
Baseline body weight (kg)	- >= 75	60	1,7%(1/60)	70	2,9%(2/70)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.		
Treatment duration (days)	- < 7	46	2,2%(1/46)	15	6,7%(1/15)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Treatment duration (days)	-7	125	1,6%(2/125)	155	1,9%(3/155)	0,9	[0,165;4,9]	0,001	[-0,028;0,031]	0,897	[0,173;4,665]	0,86661925		

Forest Plots der Subgruppen (Morbidity)

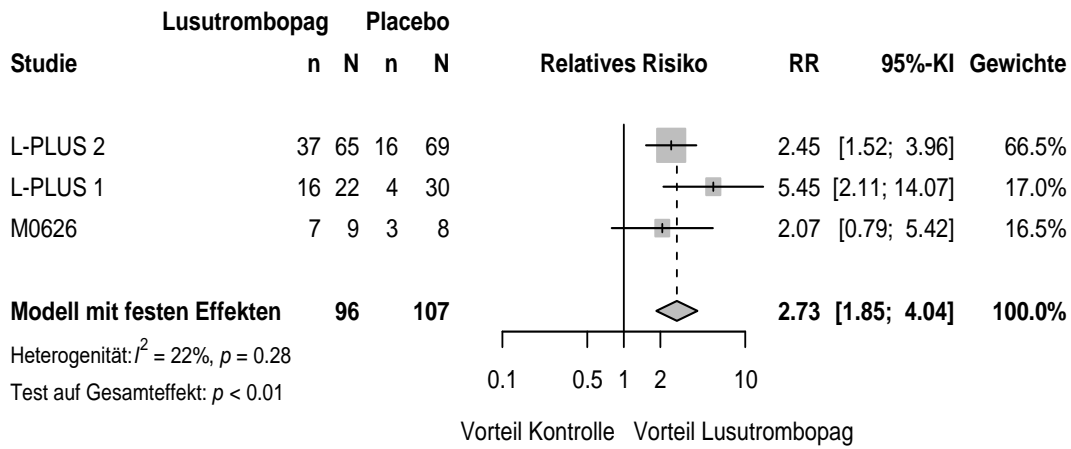
1. Vermeidung_TK-Transfusion+Notfalltherapie_RR Age (years) - < 65



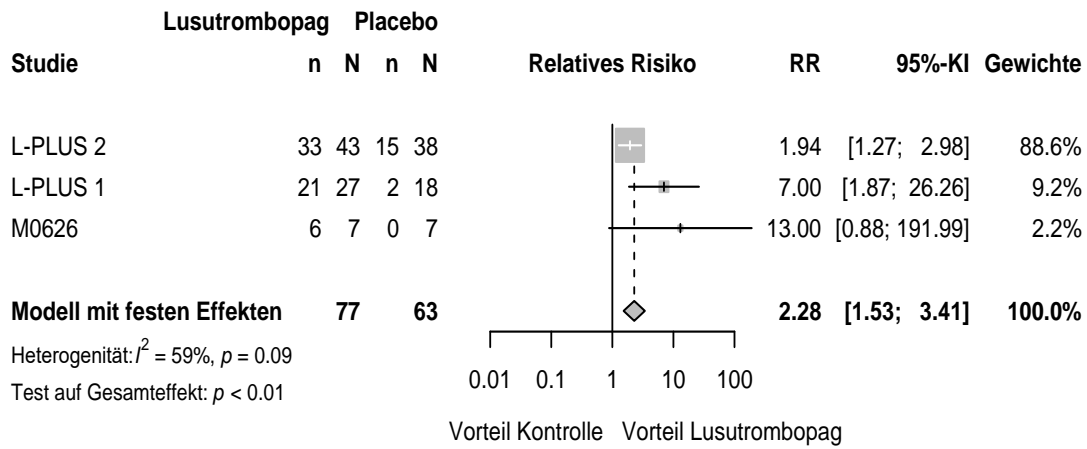
2 Vermeidung_TK-Transfusion+Notfalltherapie_RR Age (years) - >=65



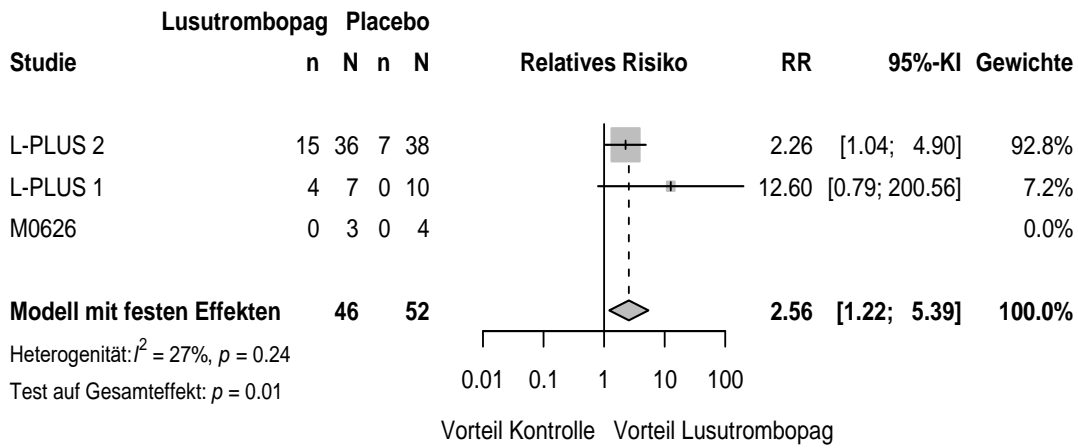
3 Vermeidung_TK-Transfusion+Notfalltherapie_RR Gender - Male



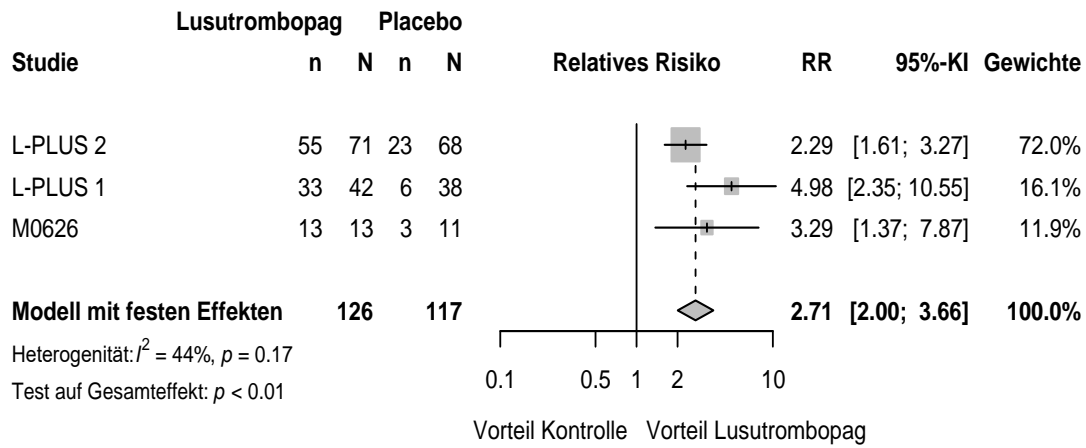
4 Vermeidung_TK-Transfusion+Notfalltherapie_RR Gender - Female



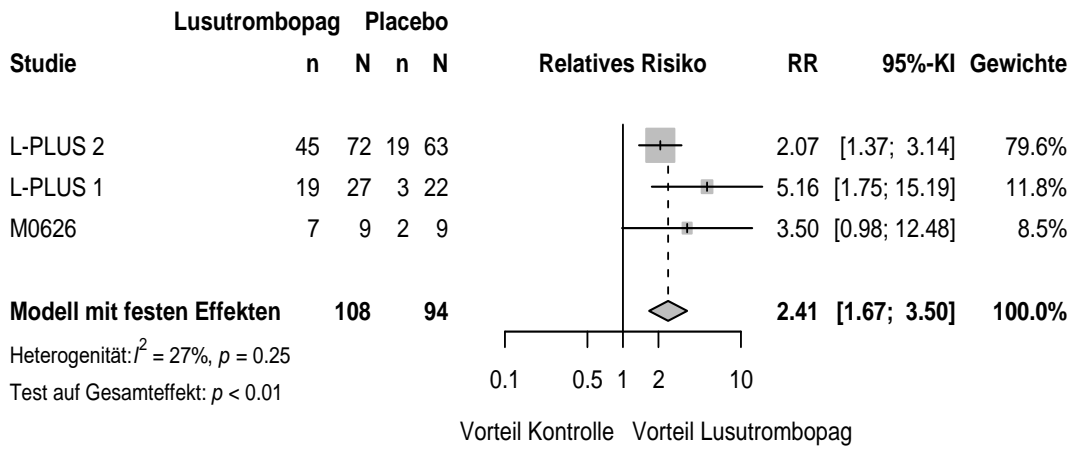
5 Vermeidung_TK-Transfusion+Notfalltherapie_RR Baseline platelet count (*10⁴/uL) - < 3.5



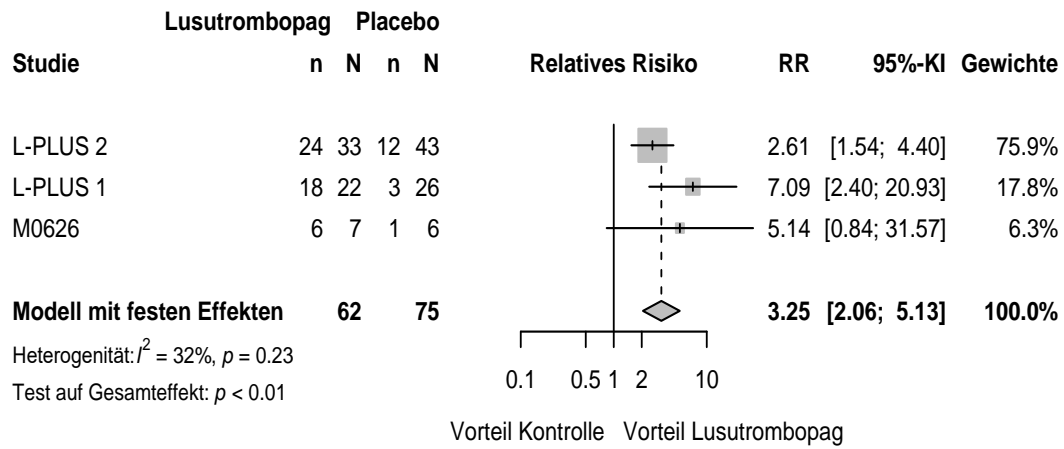
6 Vermeidung_TK-Transfusion+Notfalltherapie_RR Baseline platelet count (*10⁴/uL) - >= 3.5



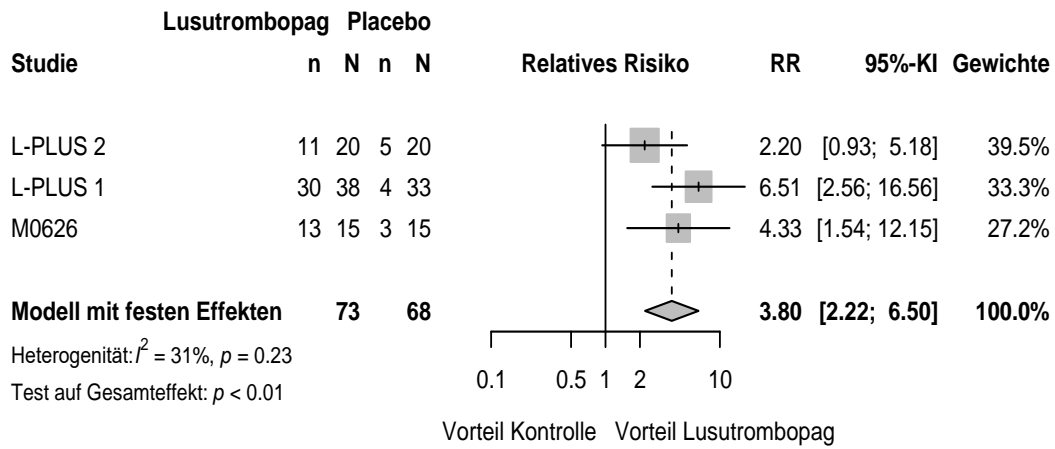
7 Vermeidung_TK-Transfusion+Notfalltherapie_RR Child-Pugh class - A



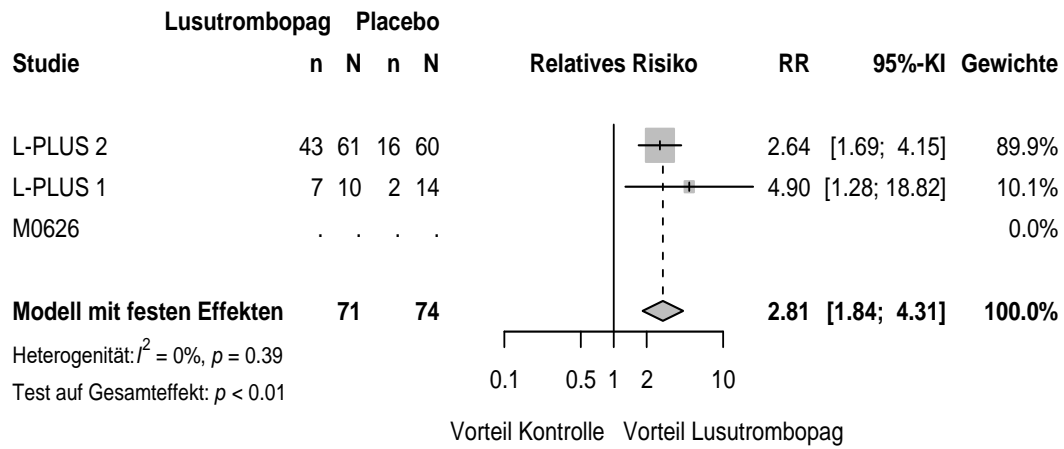
8 Vermeidung_TK-Transfusion+Notfalltherapie_RR Child-Pugh class - B



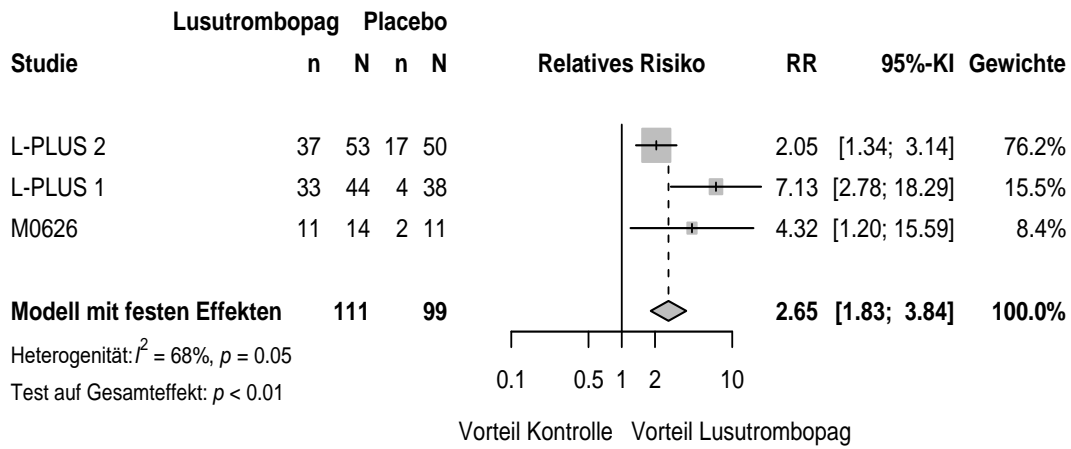
9 Vermeidung_TK-Transfusion+Notfalltherapie_RR Invasive procedure liver-related



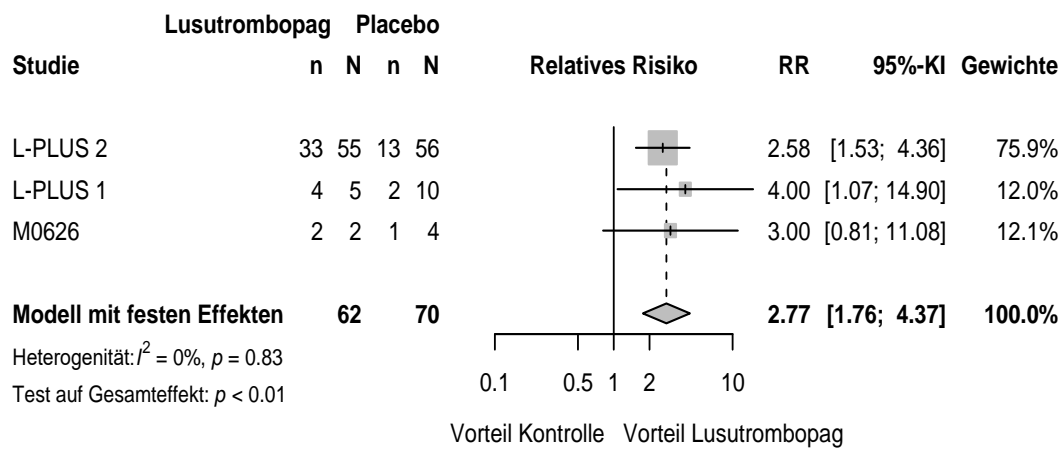
10 Vermeidung_TK-Transfusion+Notfalltherapie_RR Invasive procedure gi-related



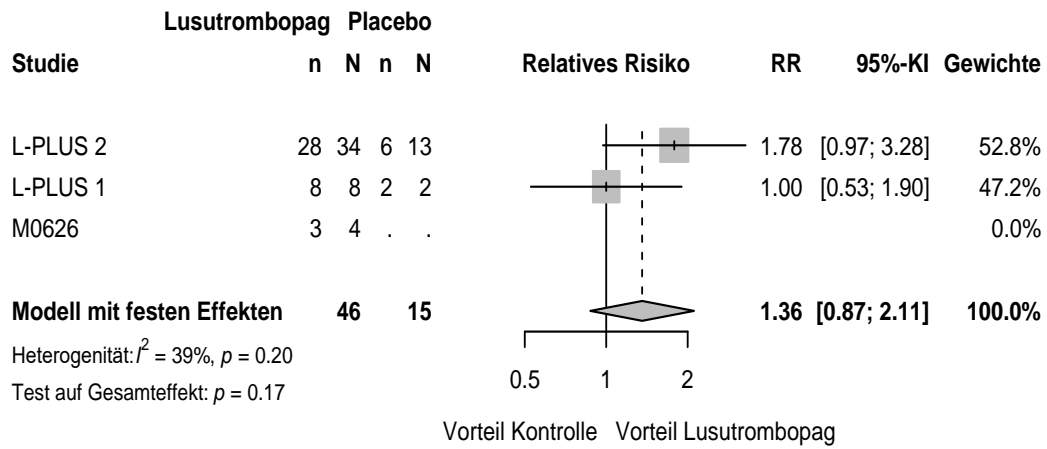
11 Vermeidung_TK-Transfusion+Notfalltherapie_RR Baseline body weight (kg) - < 75



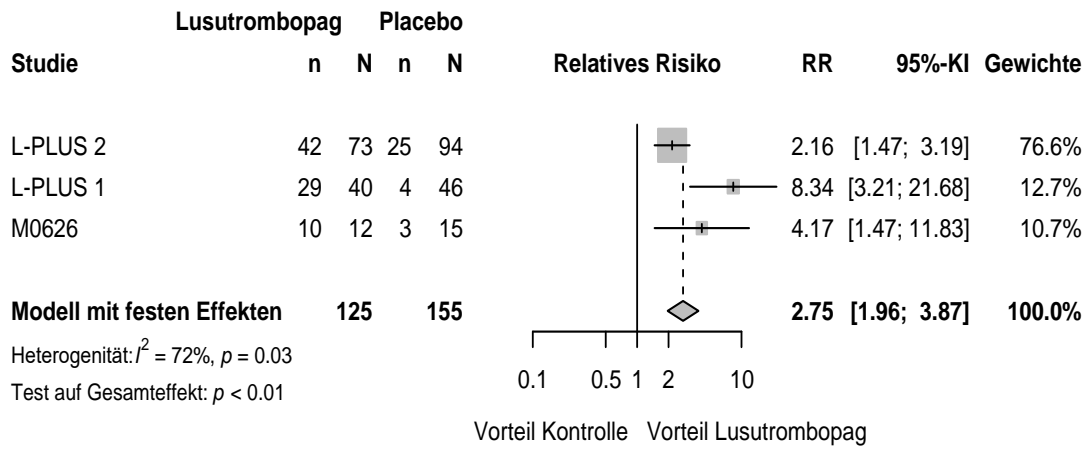
12 Vermeidung_TK-Transfusion+Notfalltherapie_RR Baseline body weight (kg) - >= 75



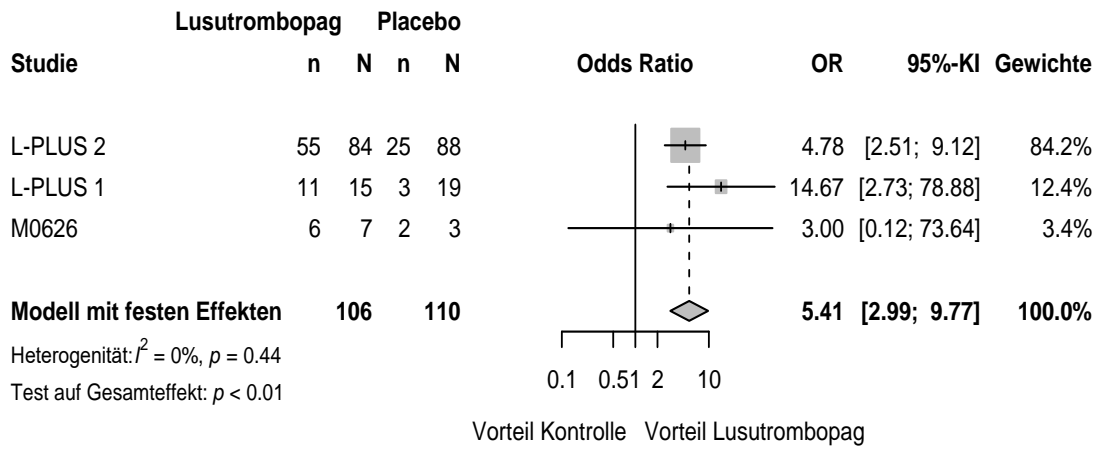
13 Vermeidung_TK-Transfusion+Notfalltherapie_RR Treatment duration (days) - < 7



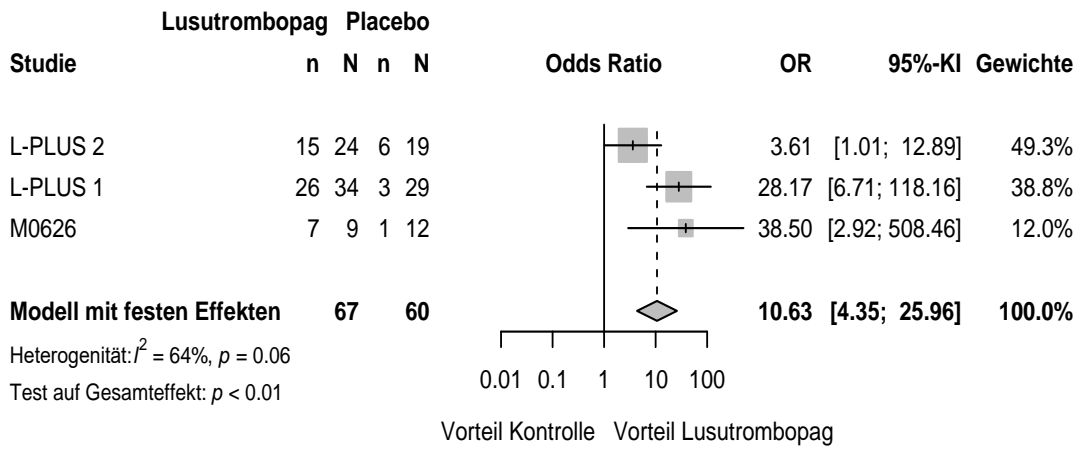
14 Vermeidung_TK-Transfusion+Notfalltherapie_RR Treatment duration (days) -7



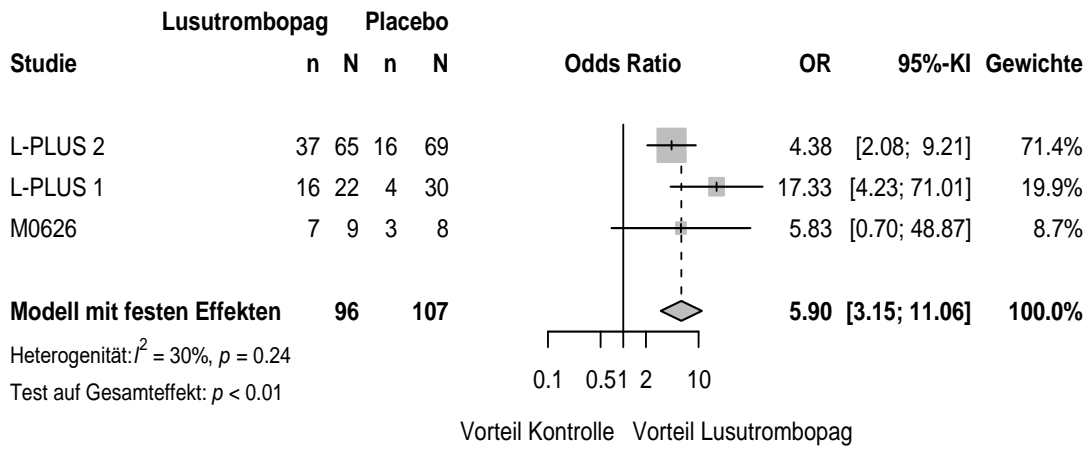
15 Vermeidung_TK-Transfusion+Notfalltherapie_OR Age (years) - < 65



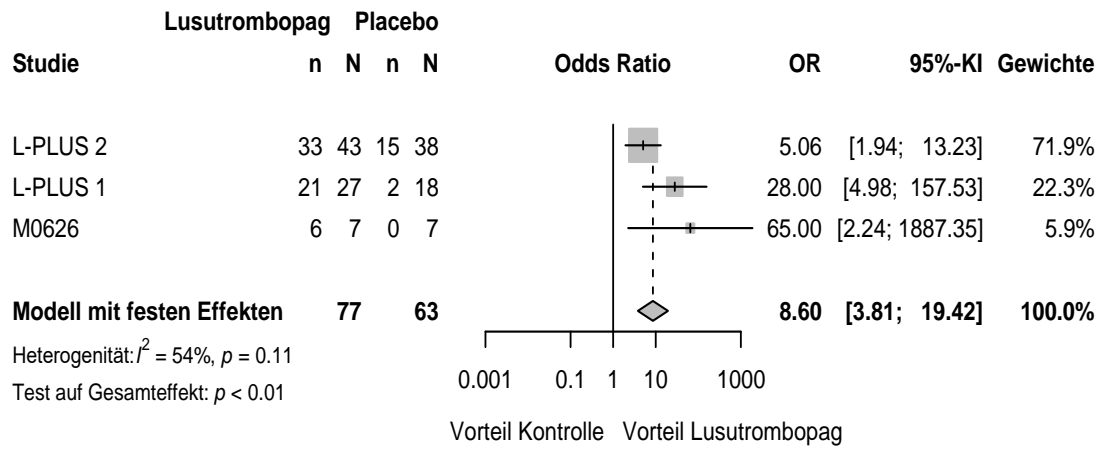
16 Vermeidung_TK-Transfusion+Notfalltherapie_OR Age (years) - >=65



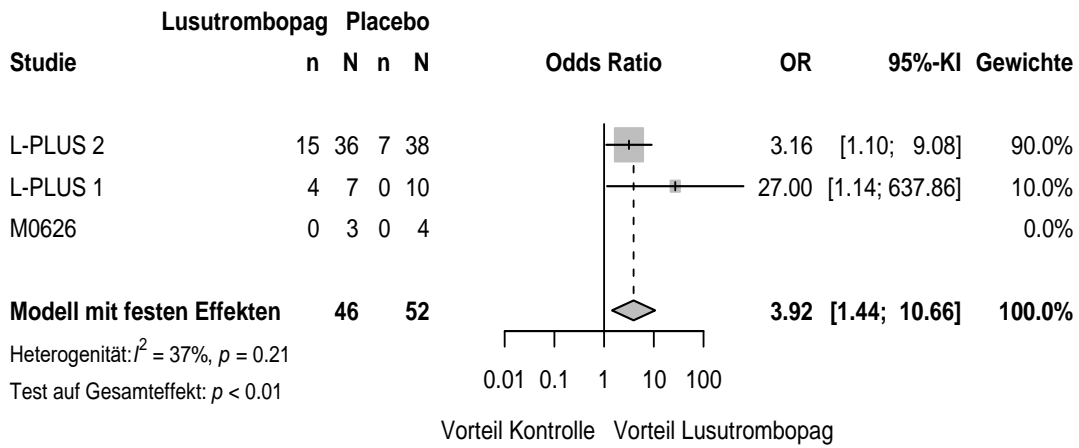
17 Vermeidung_TK-Transfusion+Notfalltherapie_OR Gender - Male



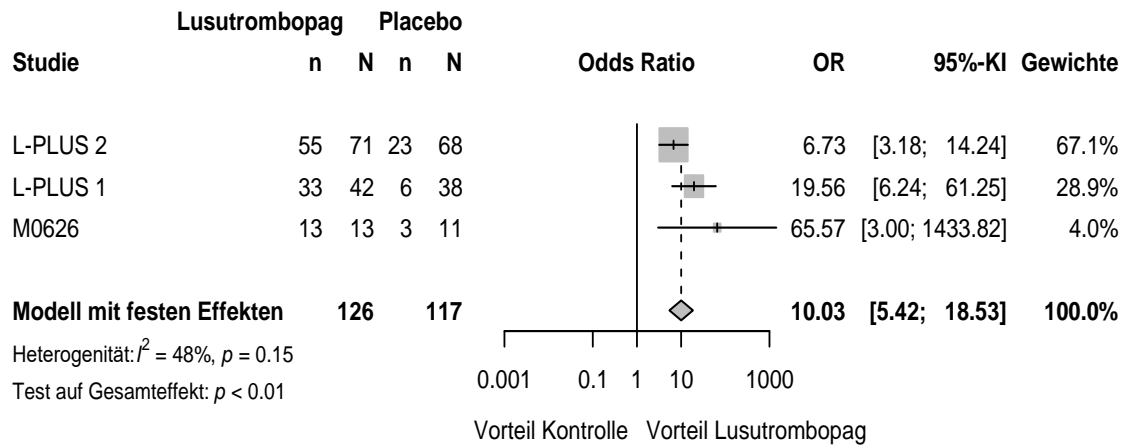
18 Vermeidung_TK-Transfusion+Notfalltherapie_OR Gender - Female



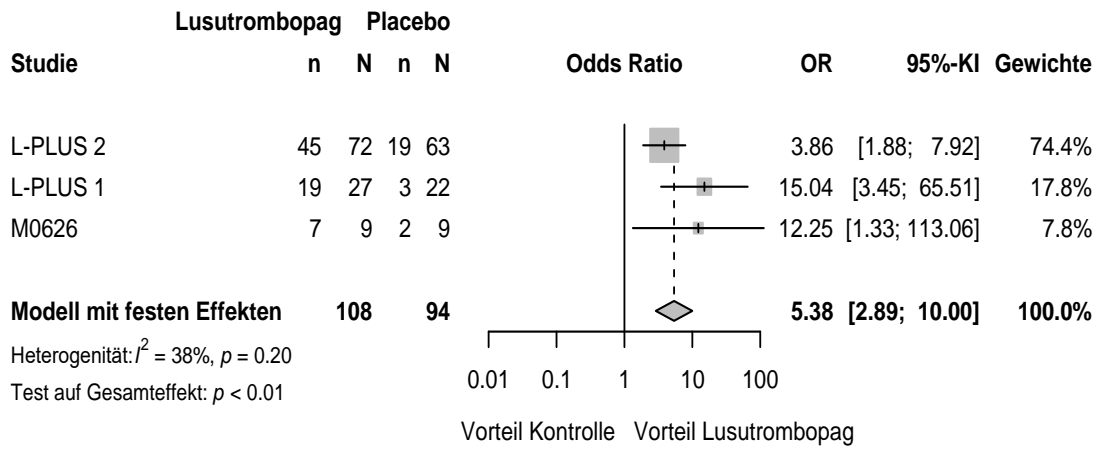
19 Vermeidung_TK-Transfusion+Notfalltherapie_OR Baseline platelet count (*10⁴/uL) - < 3.5



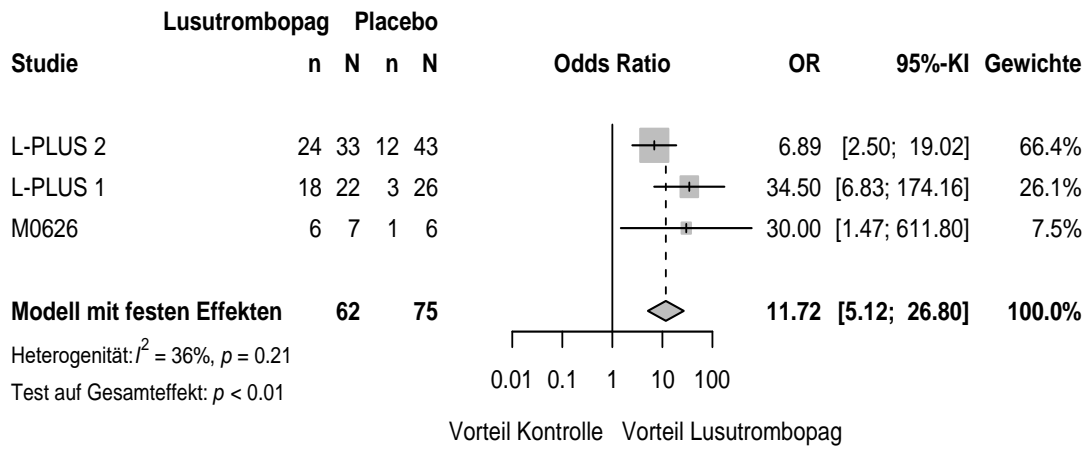
**20 Vermeidung_TK-Transfusion+Notfalltherapie_OR Baseline platelet count
(*10⁴/uL) - >= 3.5**



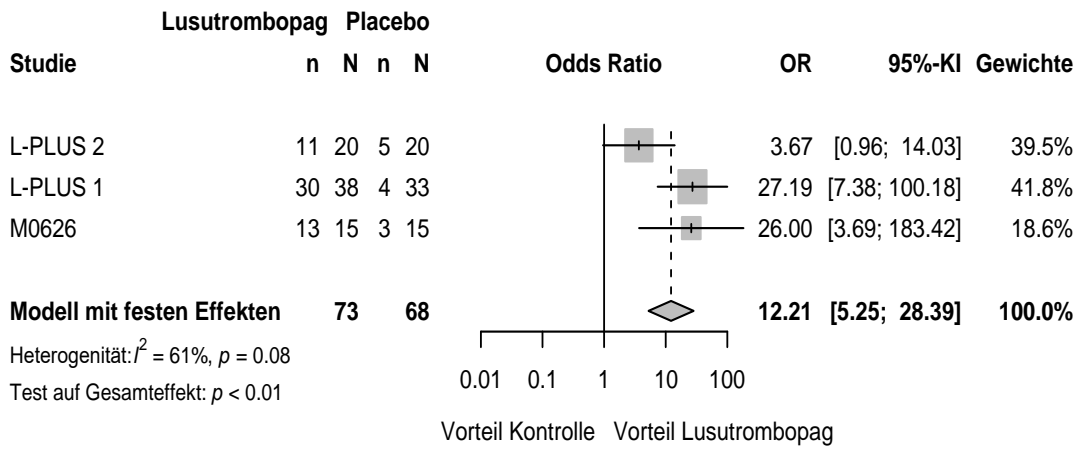
21 Vermeidung_TK-Transfusion+Notfalltherapie_OR Child-Pugh class - A



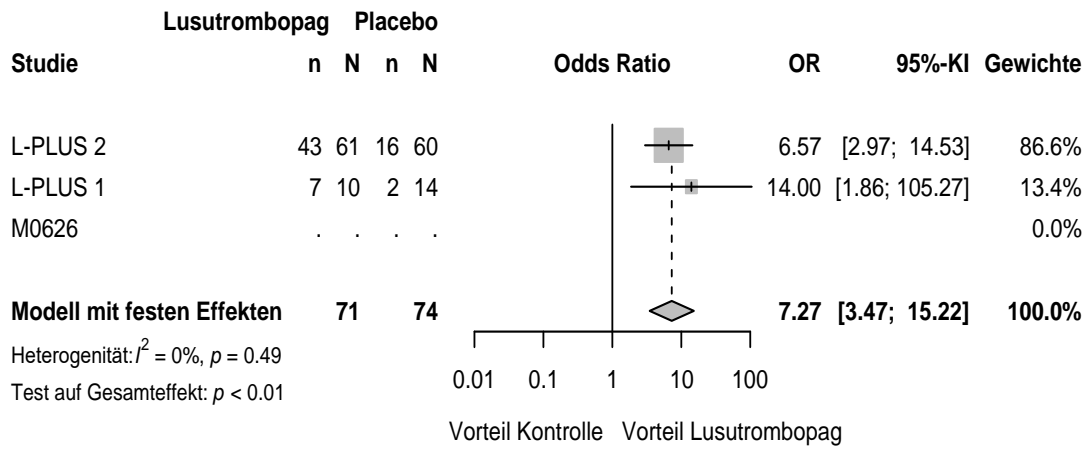
22 Vermeidung_TK-Transfusion+Notfalltherapie_OR Child-Pugh class - B



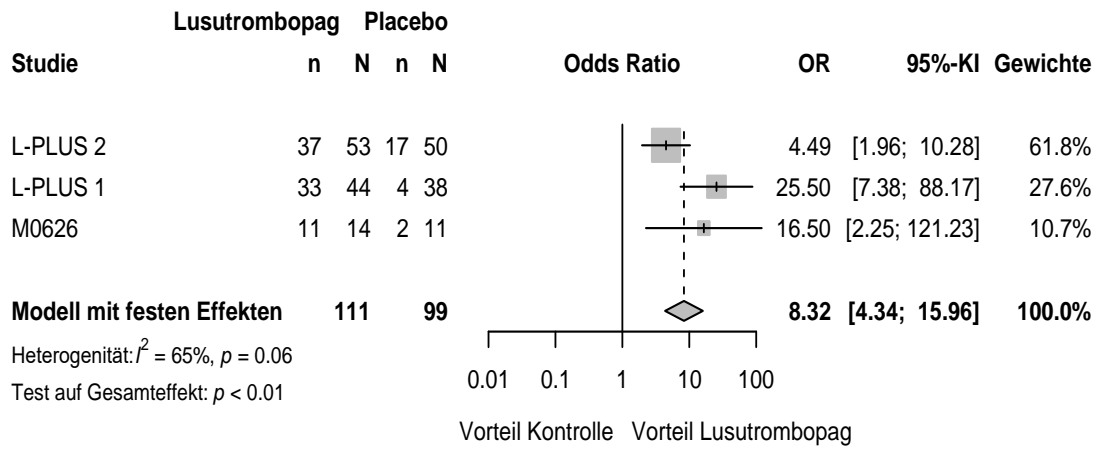
23 Vermeidung_TK-Transfusion+Notfalltherapie_OR Invasive procedure liver-related



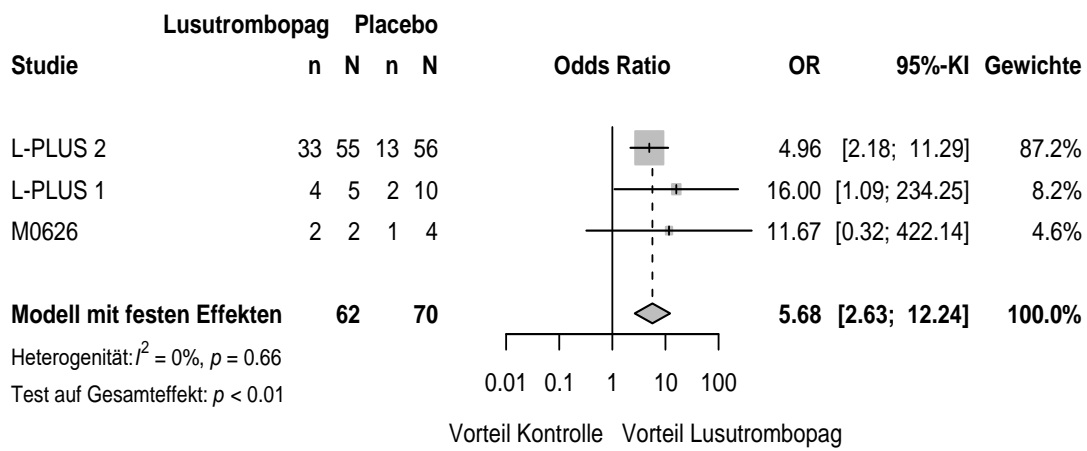
24 Vermeidung_TK-Transfusion+Notfalltherapie_OR Invasive procedure gi-related



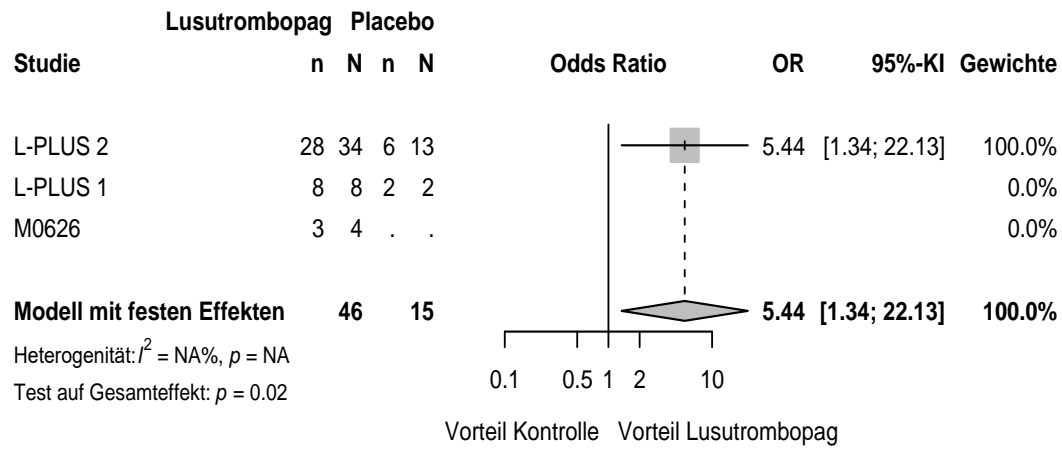
25 Vermeidung_TK-Transfusion+Notfalltherapie_OR Baseline body weight (kg) - < 75



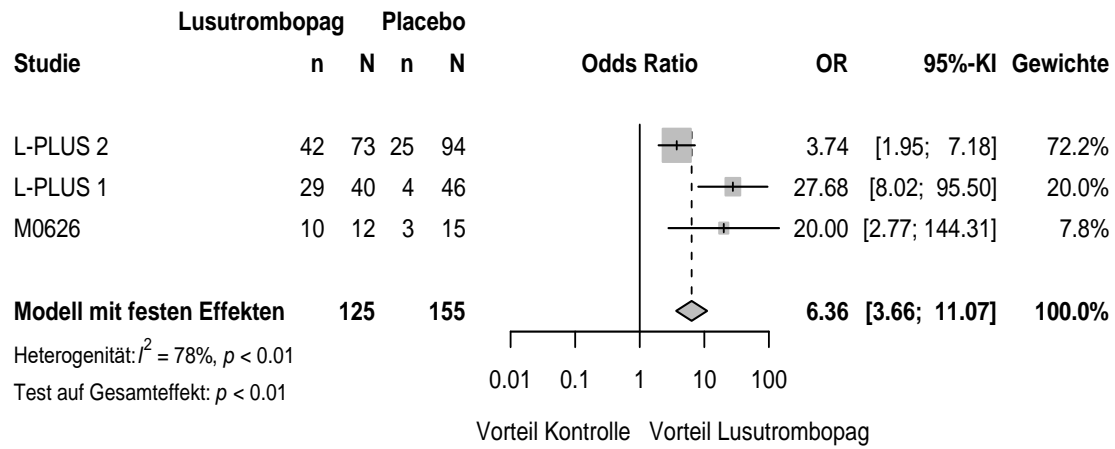
26 Vermeidung_TK-Transfusion+Notfalltherapie_OR Baseline body weight (kg) - >= 75



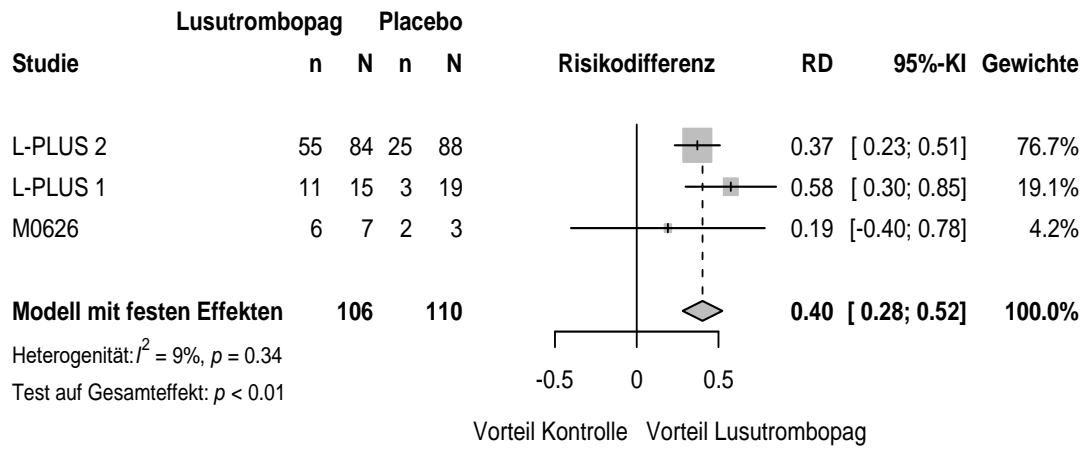
27 Vermeidung_TK-Transfusion+Notfalltherapie_OR Treatment duration (days) - < 7



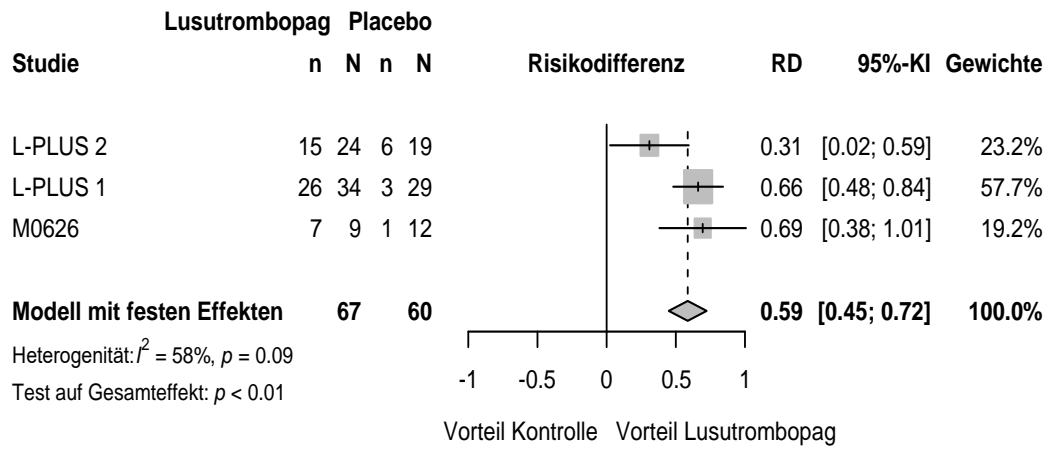
28 Vermeidung_TK-Transfusion+Notfalltherapie_OR Treatment duration (days) -7



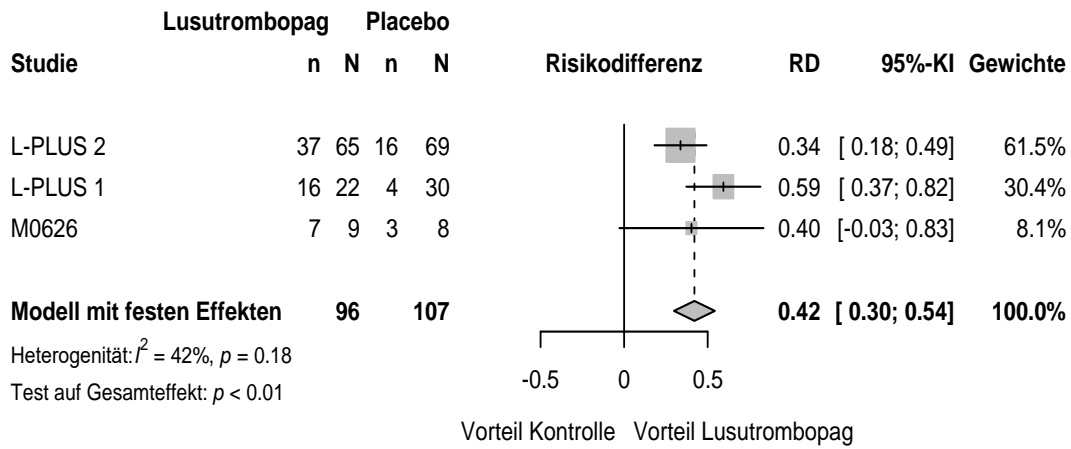
29 Vermeidung_TK-Transfusion+Notfalltherapie_RD Age (years) - < 65



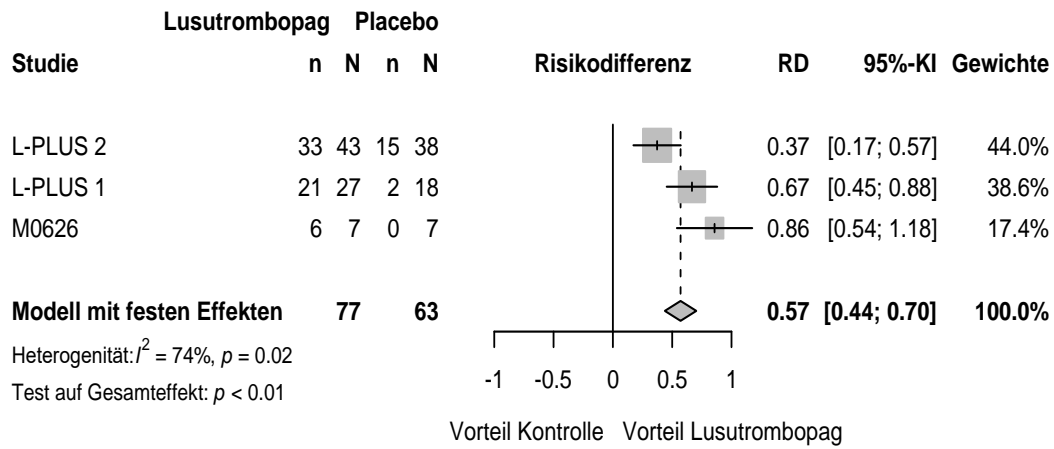
30 Vermeidung_TK-Transfusion+Notfalltherapie_RD Age (years) - >=65



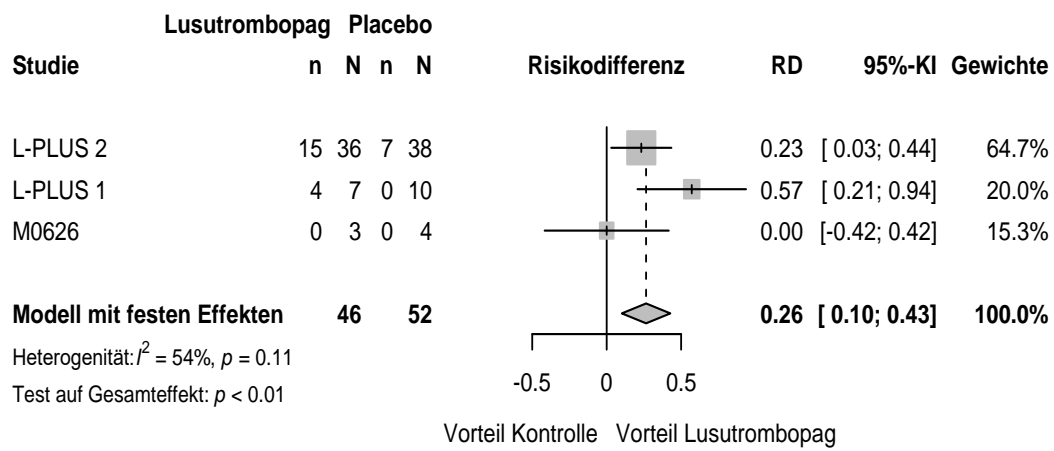
31 Vermeidung_TK-Transfusion+Notfalltherapie_RD Gender - Male



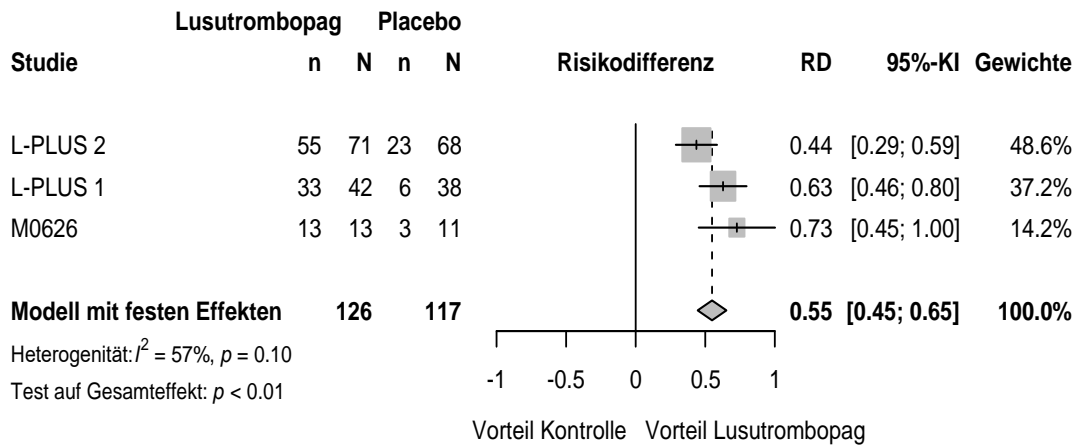
32 Vermeidung_TK-Transfusion+Notfalltherapie_RD Gender - Female



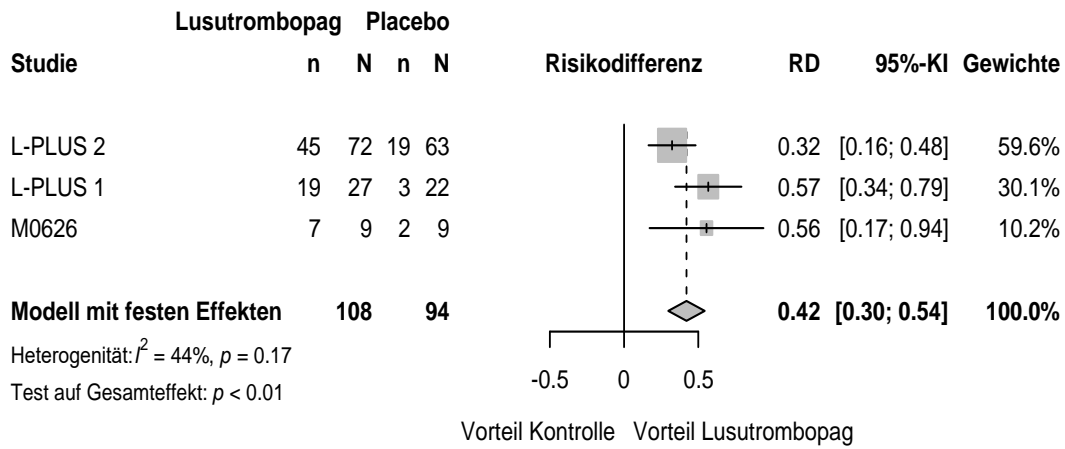
33 Vermeidung_TK-Transfusion+Notfalltherapie_RD Baseline platelet count (*10⁴/uL) - < 3.5



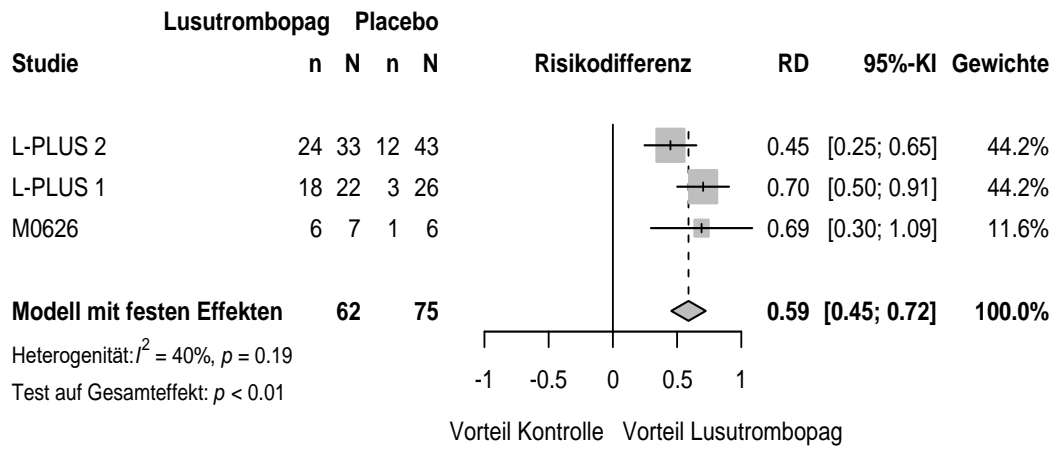
34 Vermeidung_TK-Transfusion+Notfalltherapie_RD Baseline platelet count (*10⁴/uL) - >= 3.5



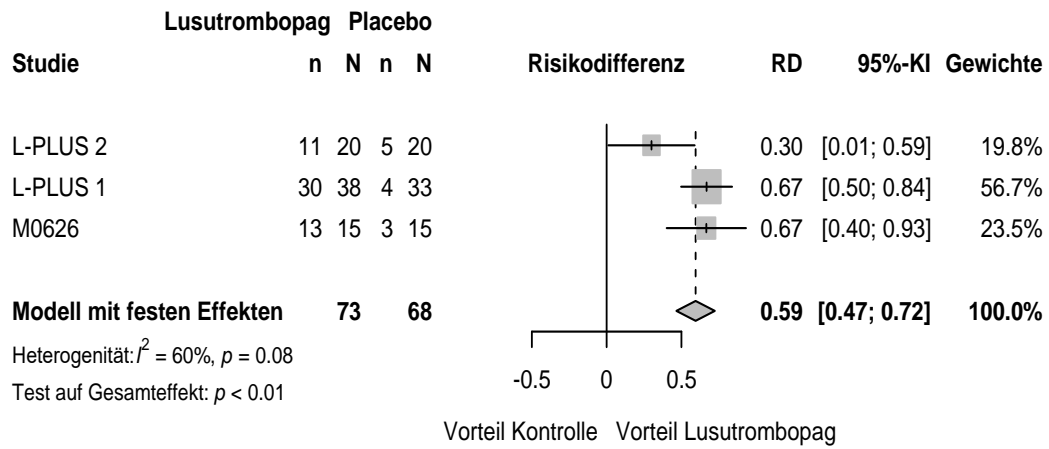
35 Vermeidung_TK-Transfusion+Notfalltherapie_RD Child-Pugh class - A



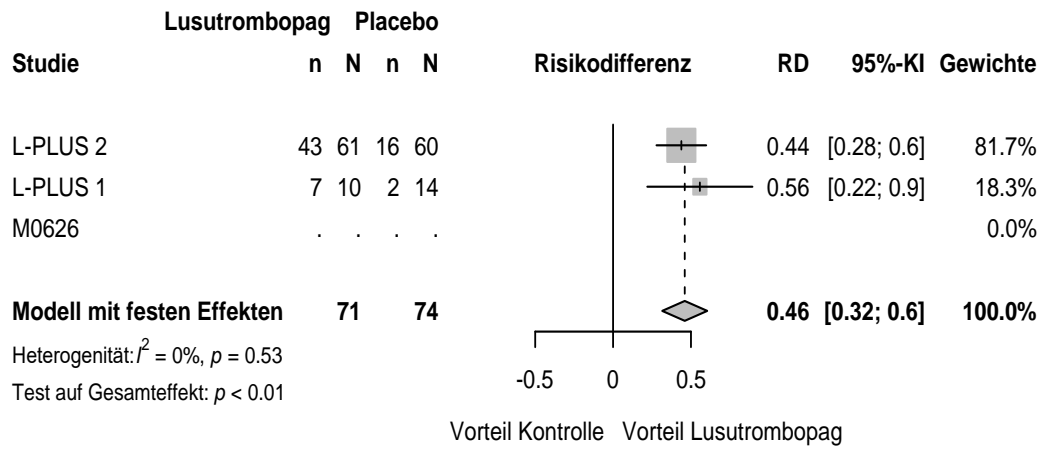
36 Vermeidung_TK-Transfusion+Notfalltherapie_RD Child-Pugh class - B



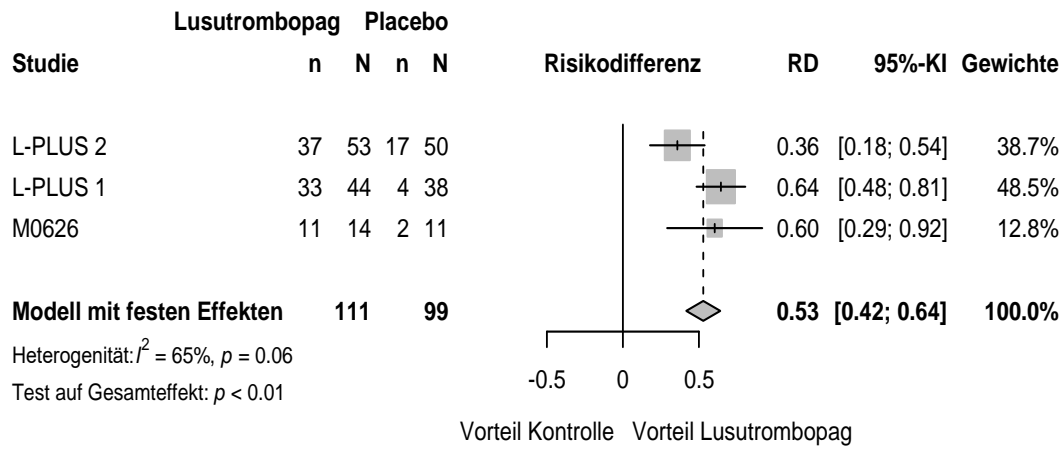
37 Vermeidung_TK-Transfusion+Notfalltherapie_RD Invasive procedure liver-related



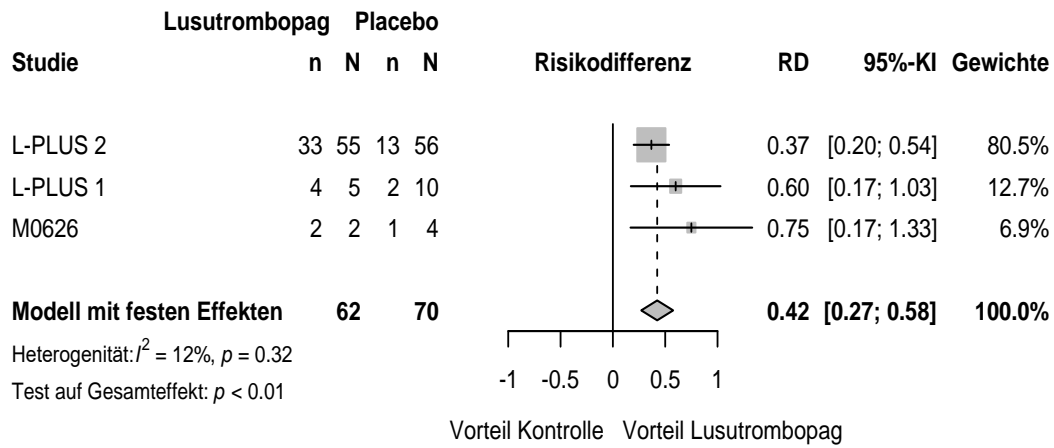
38 Vermeidung_TK-Transfusion+Notfalltherapie_RD Invasive procedure gi-related



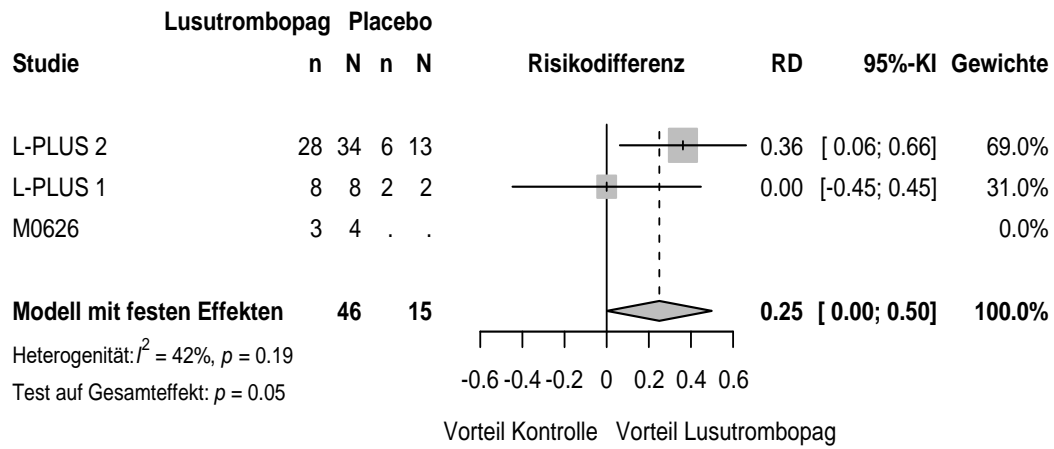
39 Vermeidung_TK-Transfusion+Notfalltherapie_RD Baseline body weight (kg) - < 75



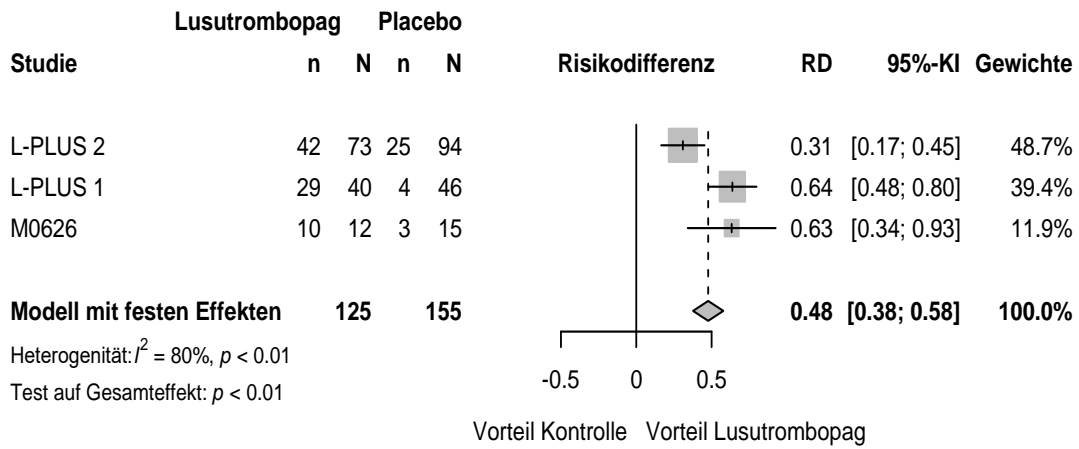
40 Vermeidung_TK-Transfusion+Notfalltherapie_RD Baseline body weight (kg) - >= 75



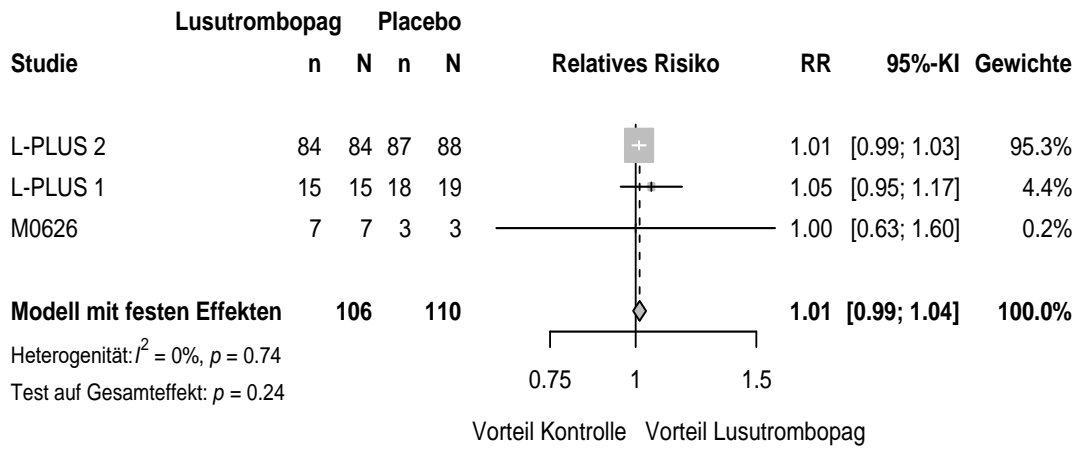
41 Vermeidung_TK-Transfusion+Notfalltherapie_RD Treatment duration (days) - < 7



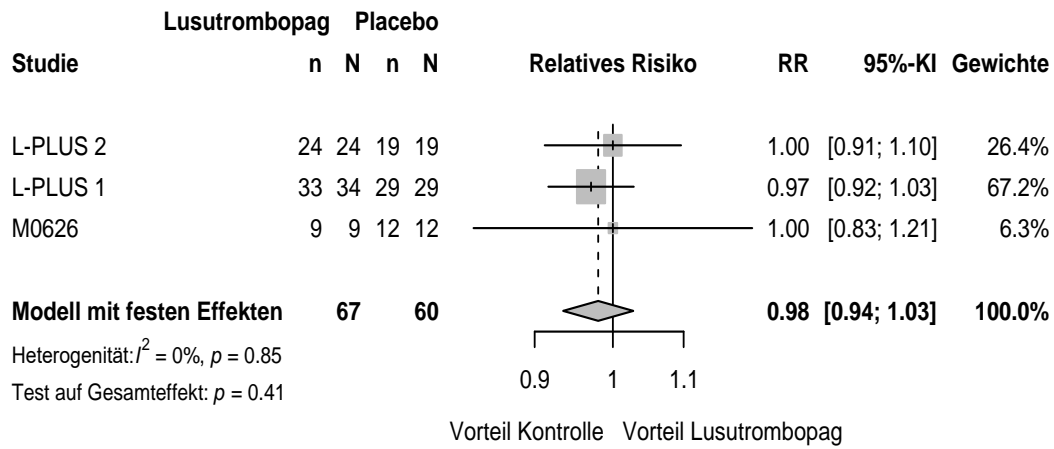
42 Vermeidung_TK-Transfusion+Notfalltherapie_RD Treatment duration (days) -7



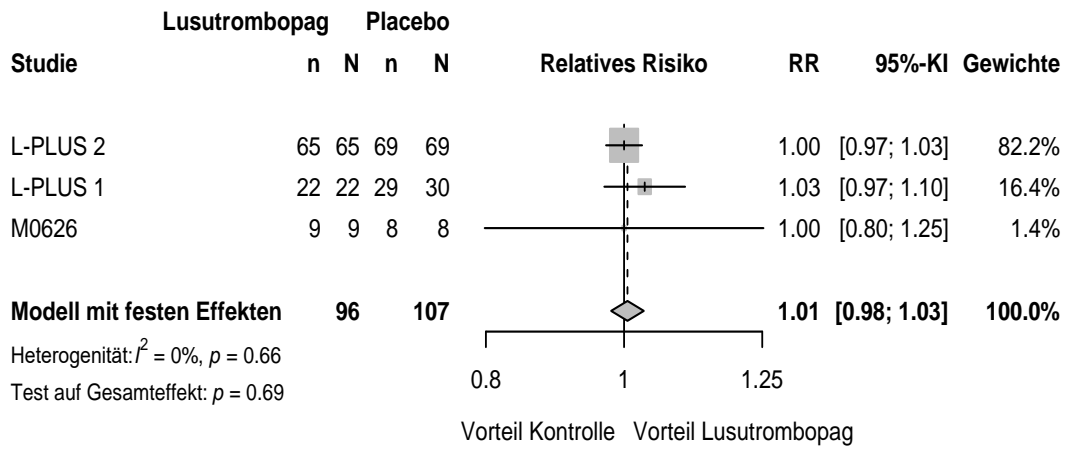
43 Vermeidung_Notfalltherapie_RR Age (years) - < 65



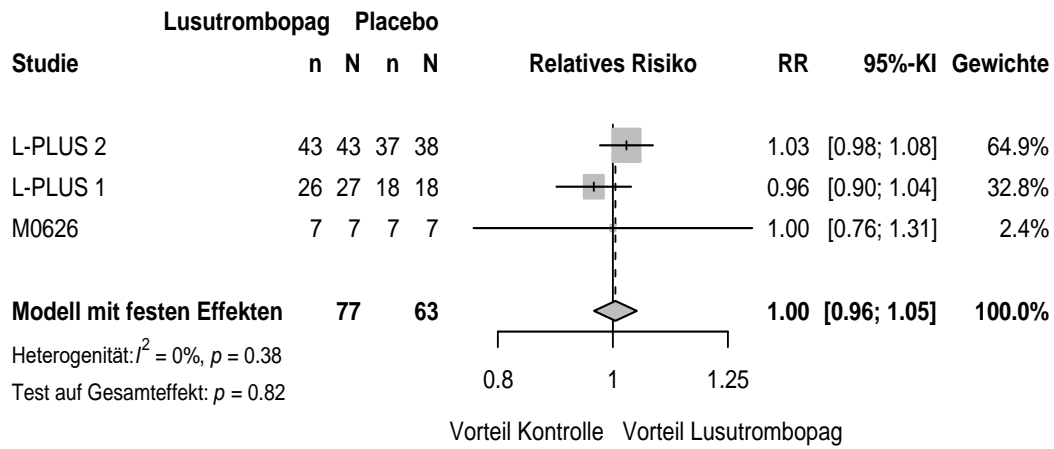
44 Vermeidung_Notfalltherapie_RR Age (years) - >=65



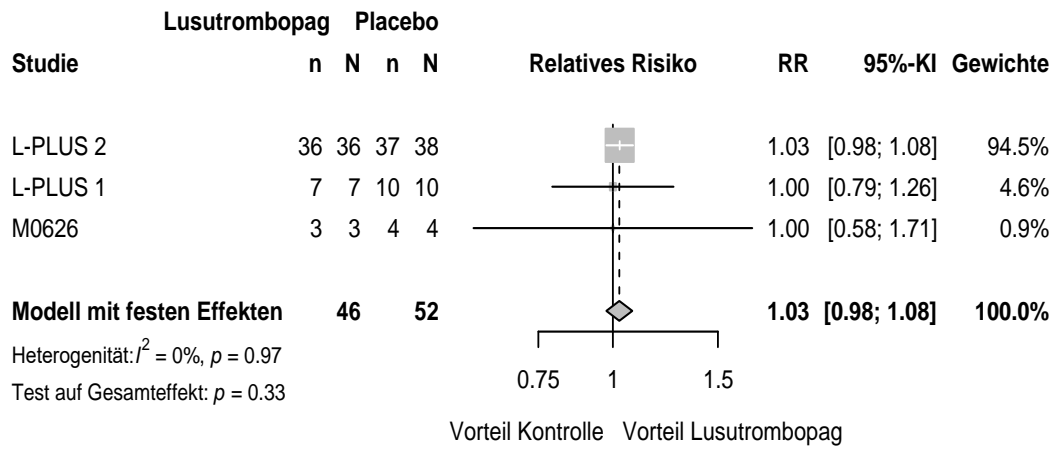
45 Vermeidung_Notfalltherapie_RR Gender - Male



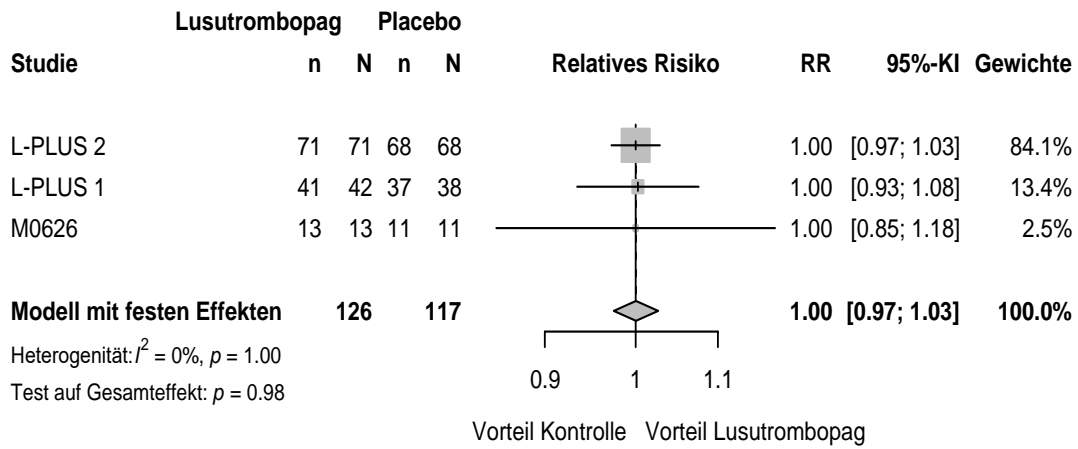
46 Vermeidung_Notfalltherapie_RR Gender - Female



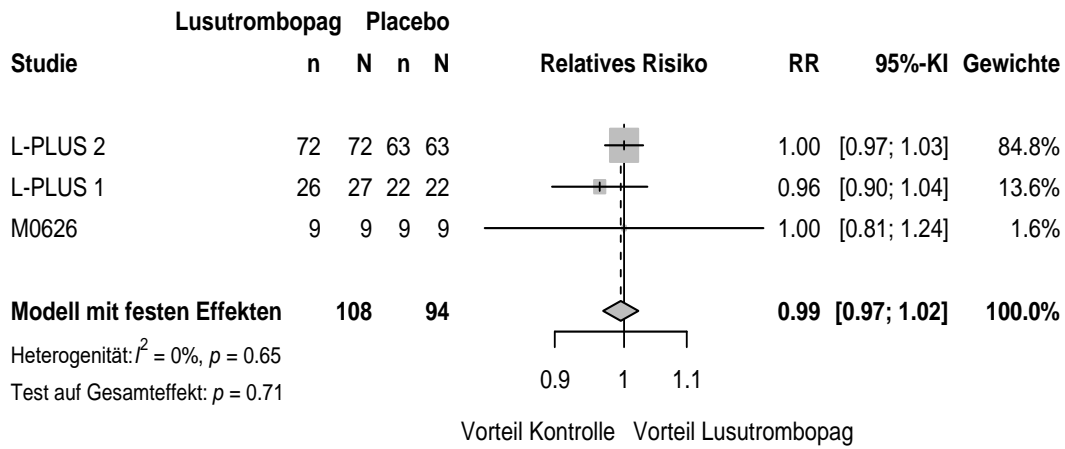
47 Vermeidung_Notfalltherapie_RR Baseline platelet count (*10⁴/uL) - < 3.5



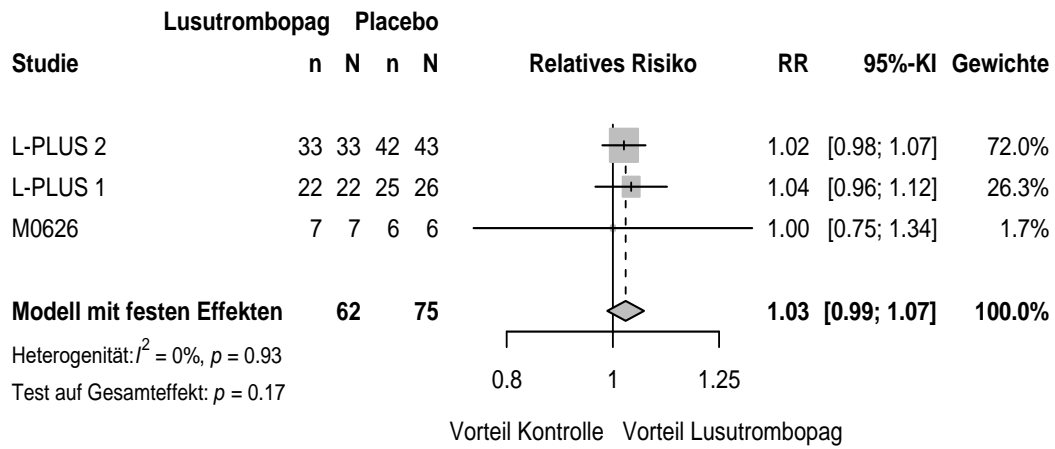
48 Vermeidung_Notfalltherapie_RR Baseline platelet count ($\cdot 10^4/uL$) - ≥ 3.5



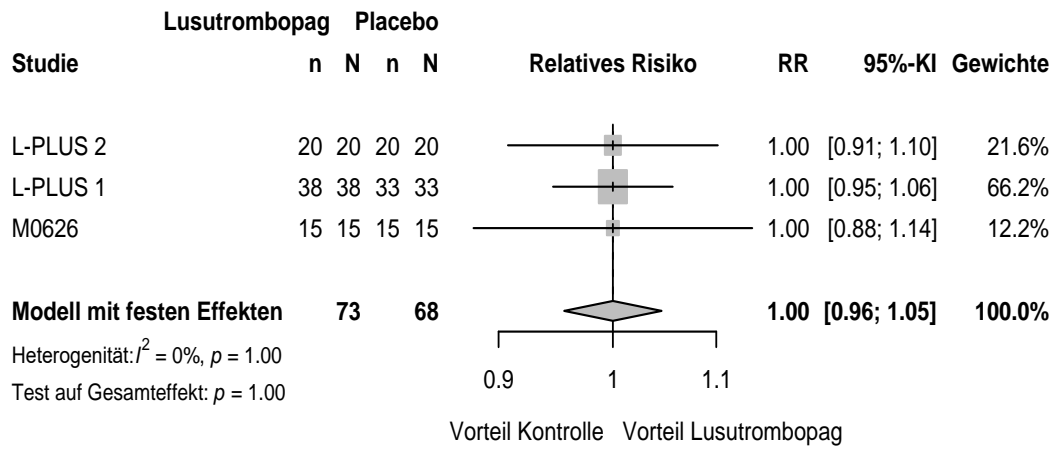
49 Vermeidung_Notfalltherapie_RR Child-Pugh class - A



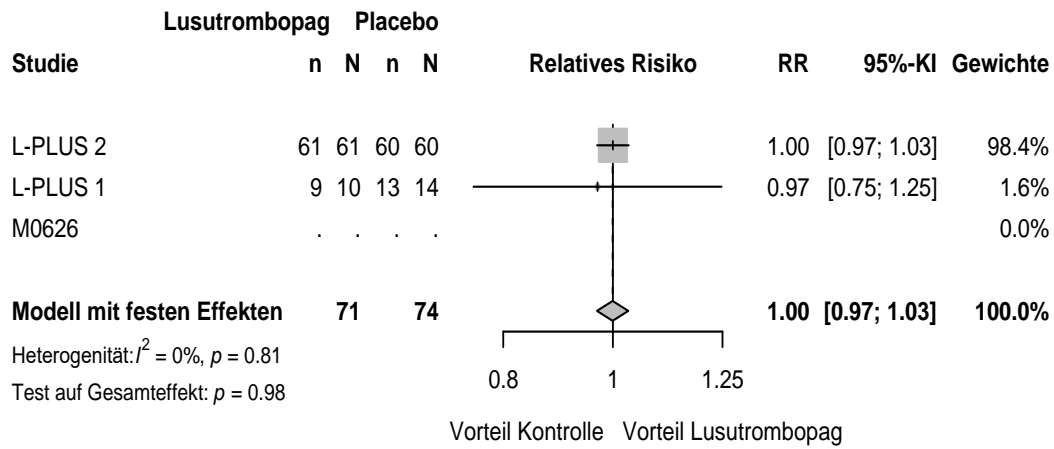
50 Vermeidung_Notfalltherapie_RR Child-Pugh class - B



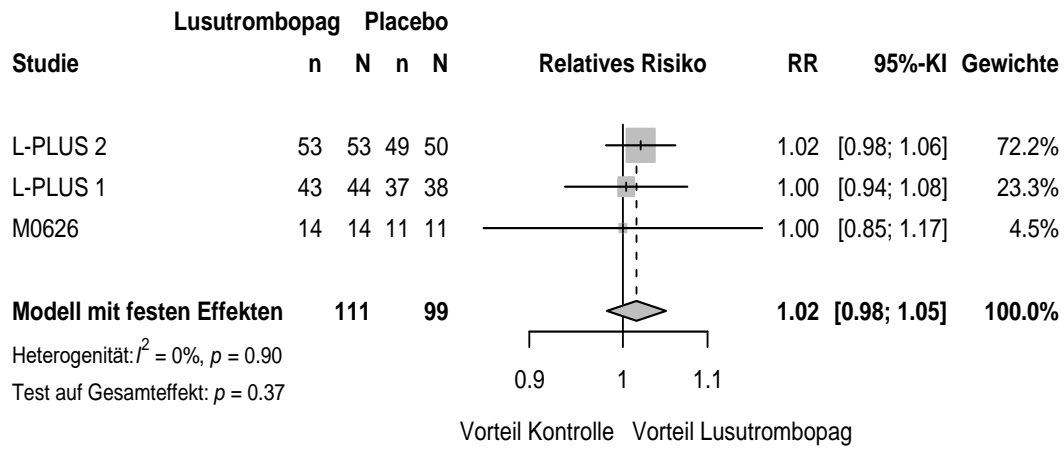
51 Vermeidung_Notfalltherapie_RR Invasive procedure liver-related



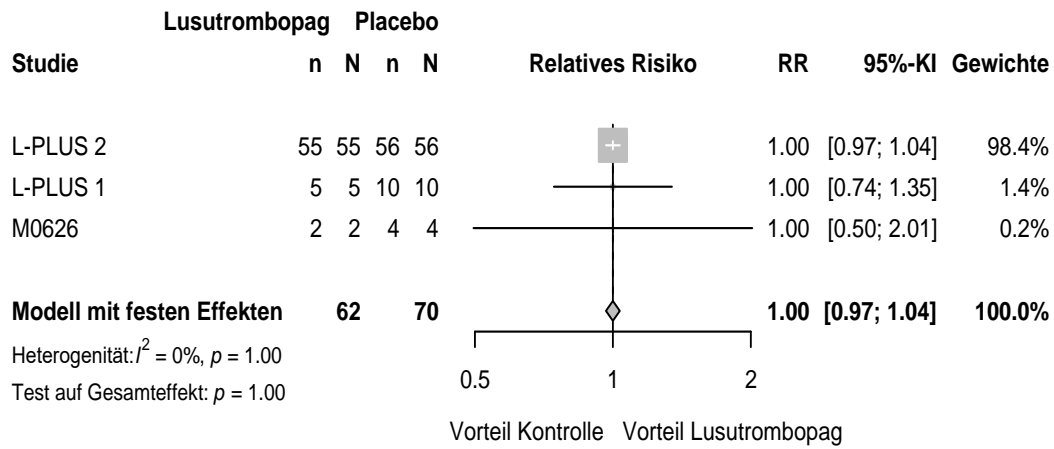
52 Vermeidung_Notfalltherapie_RR Invasive procedure gi-related



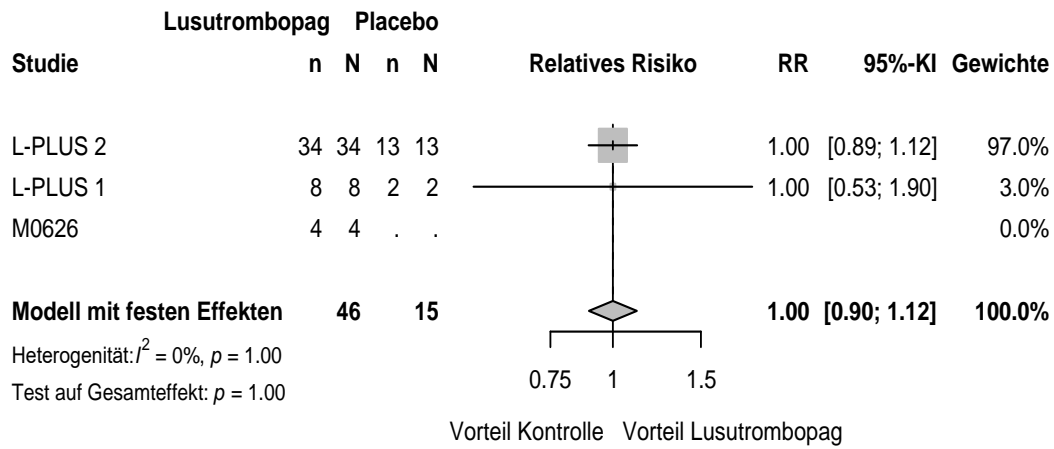
53 Vermeidung_Notfalltherapie_RR Baseline body weight (kg) - < 75



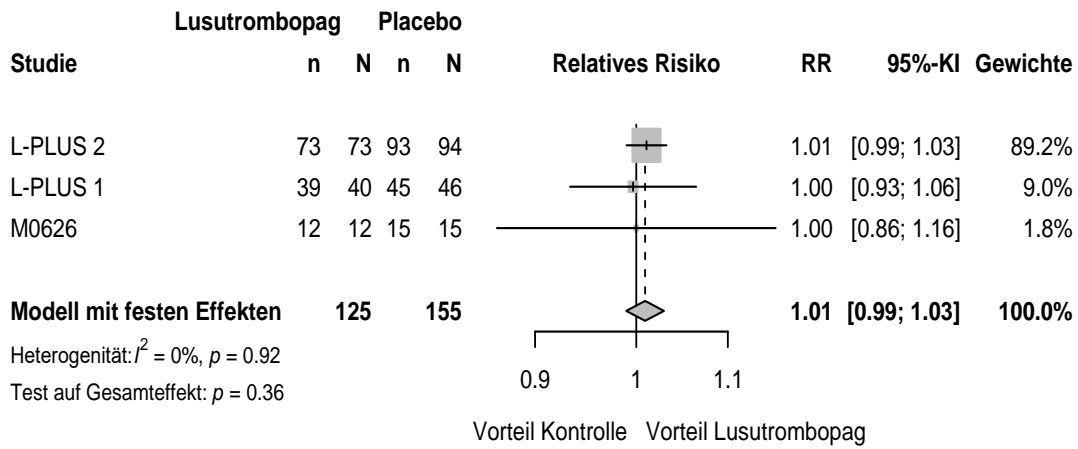
54 Vermeidung_Notfalltherapie_RR Baseline body weight (kg) - >= 75



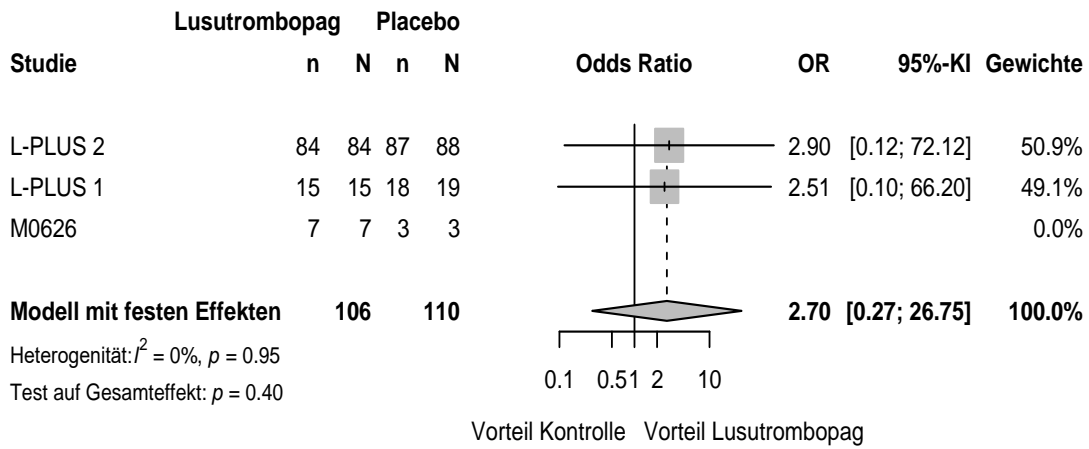
55 Vermeidung_Notfalltherapie_RR Treatment duration (days) - < 7



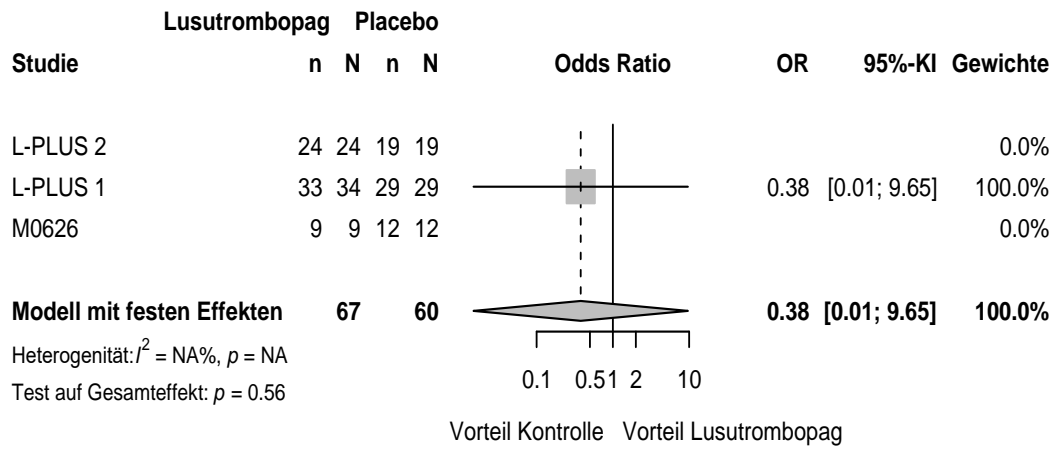
56 Vermeidung_Notfalltherapie_RR Treatment duration (days) - 7



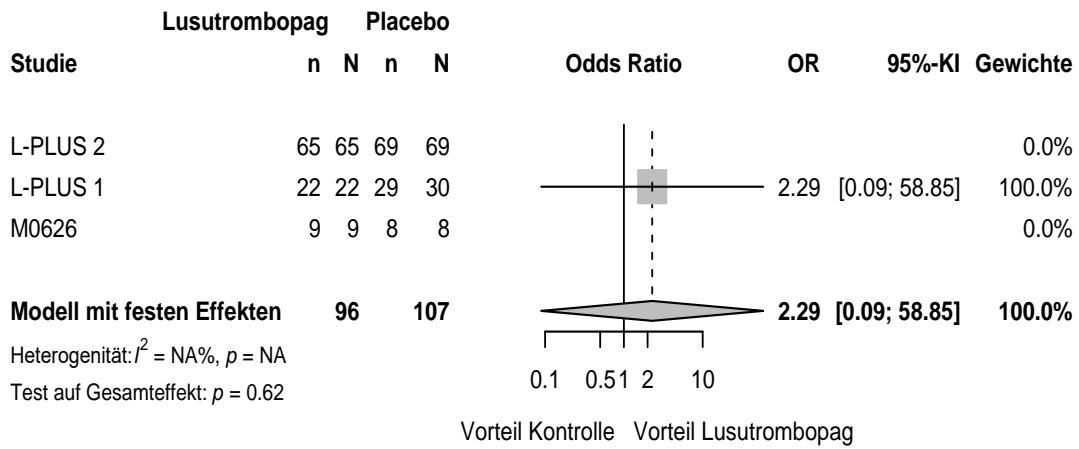
57 Vermeidung_Notfalltherapie_OR Age (years) - < 65



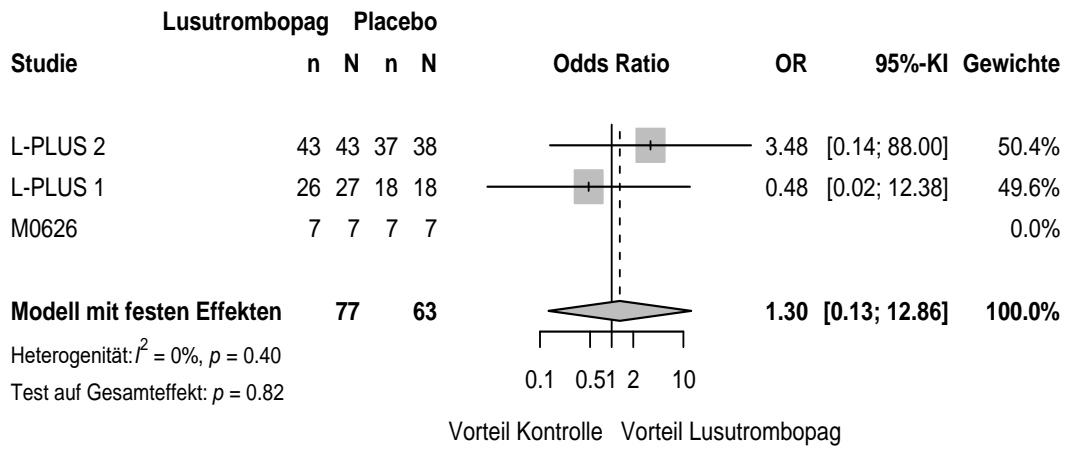
58 Vermeidung_Notfalltherapie_OR Age (years) - >=65



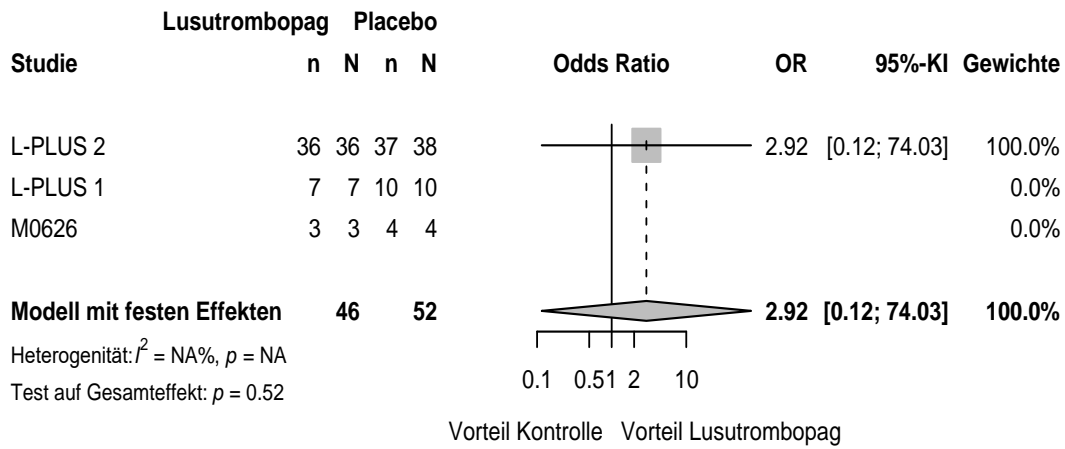
59 Vermeidung_Notfalltherapie_OR Gender - Male



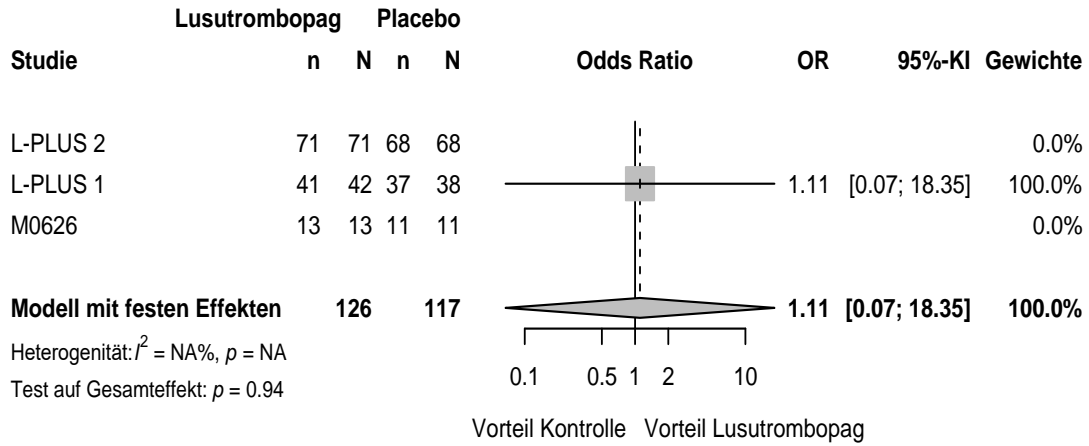
60 Vermeidung_Notfalltherapie_OR Gender - Female



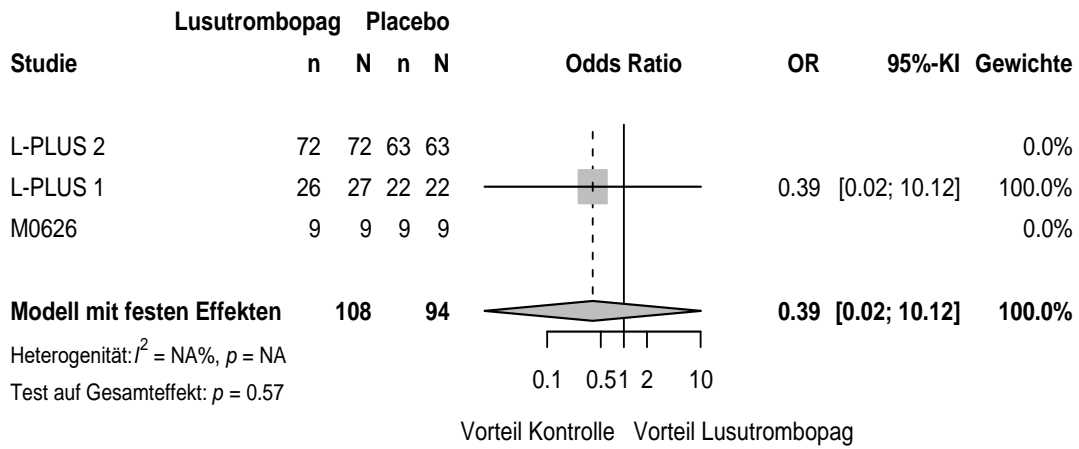
61 Vermeidung_Notfalltherapie_OR Baseline platelet count ($\cdot 10^4/uL$) - < 3.5



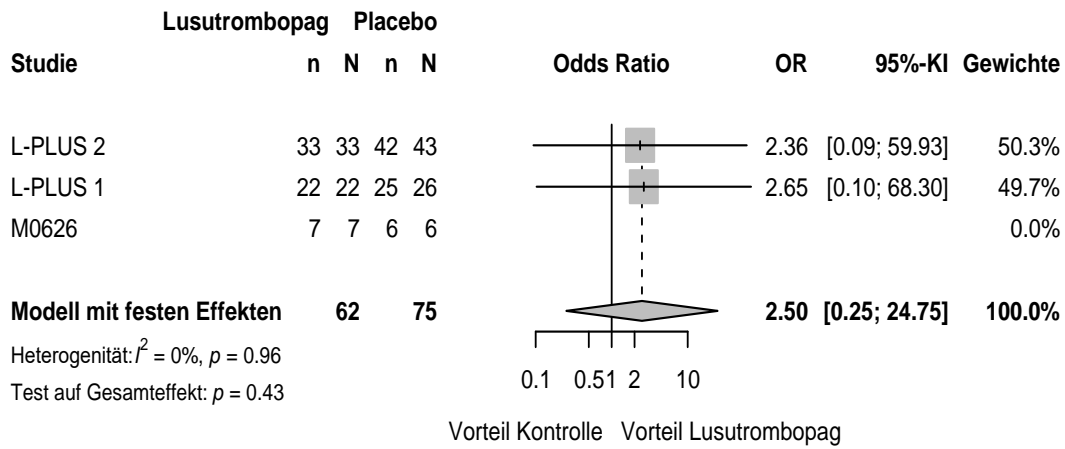
62 Vermeidung_Notfalltherapie_OR Baseline platelet count (*10⁴/uL) - >= 3.5



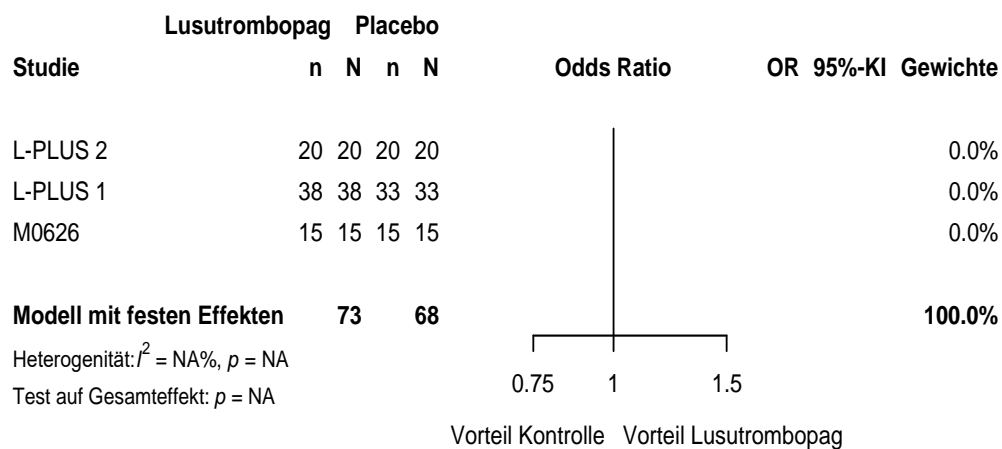
63 Vermeidung_Notfalltherapie_OR Child-Pugh class - A



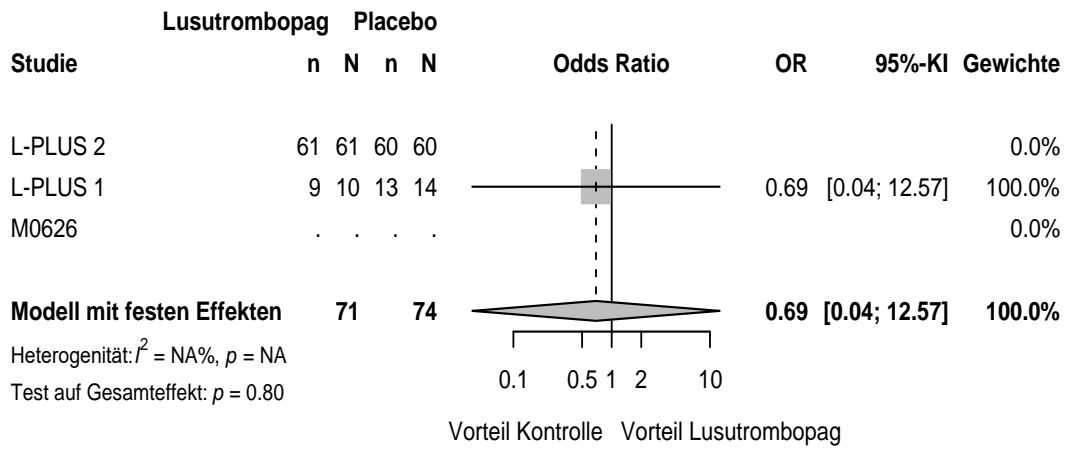
64 Vermeidung_Notfalltherapie_OR Child-Pugh class - B



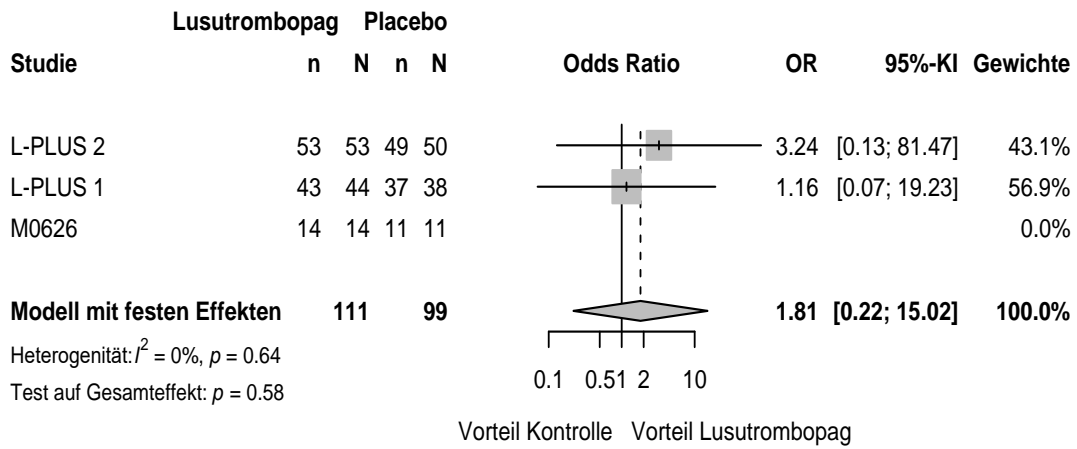
65 Vermeidung_Notfalltherapie_OR Invasive procedure liver-related



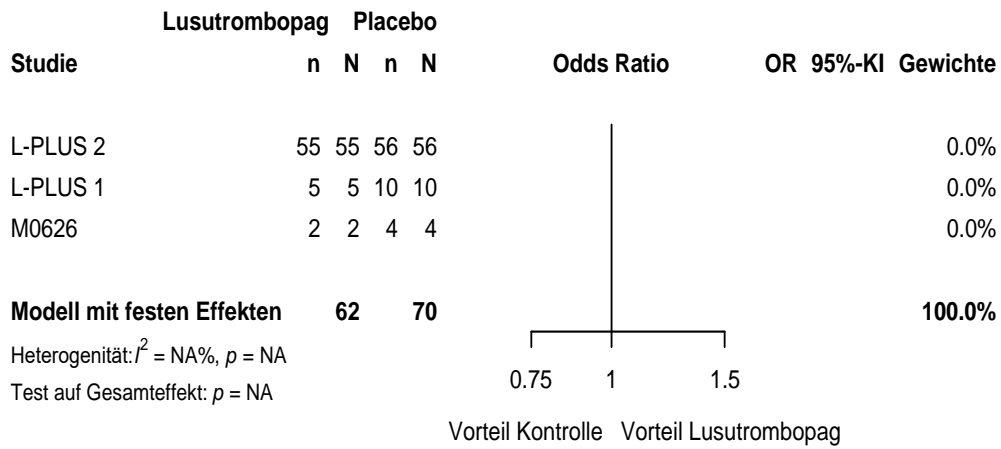
66 Vermeidung_Notfalltherapie_OR Invasive procedure gi-related



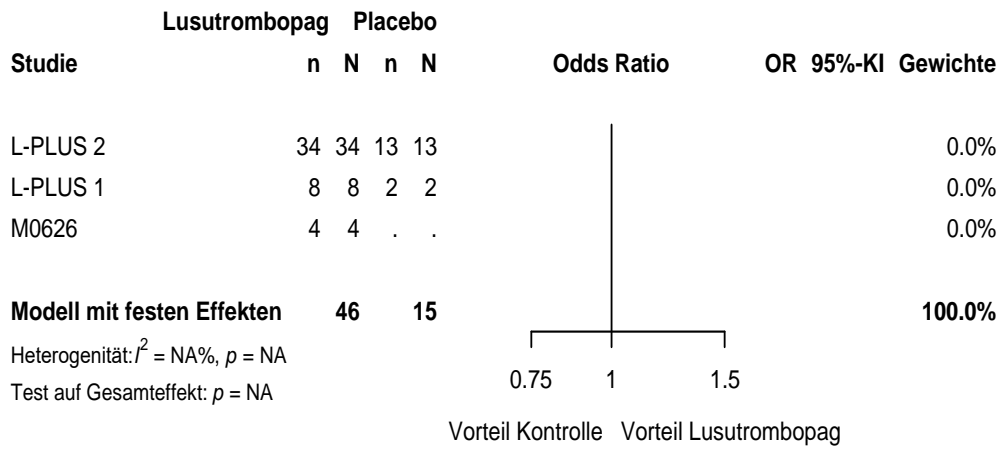
67 Vermeidung_Notfalltherapie_OR Baseline body weight (kg) - < 75



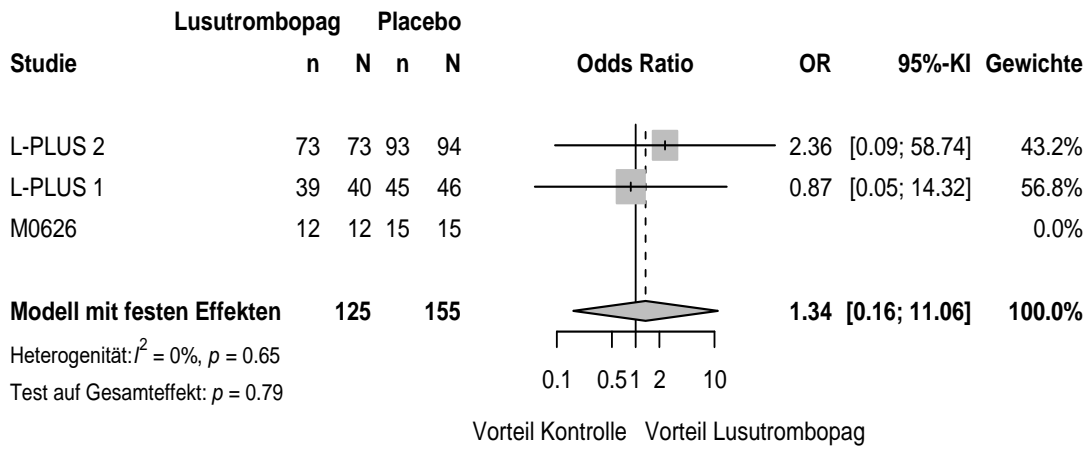
68 Vermeidung_Notfalltherapie_OR Baseline body weight (kg) - >= 75



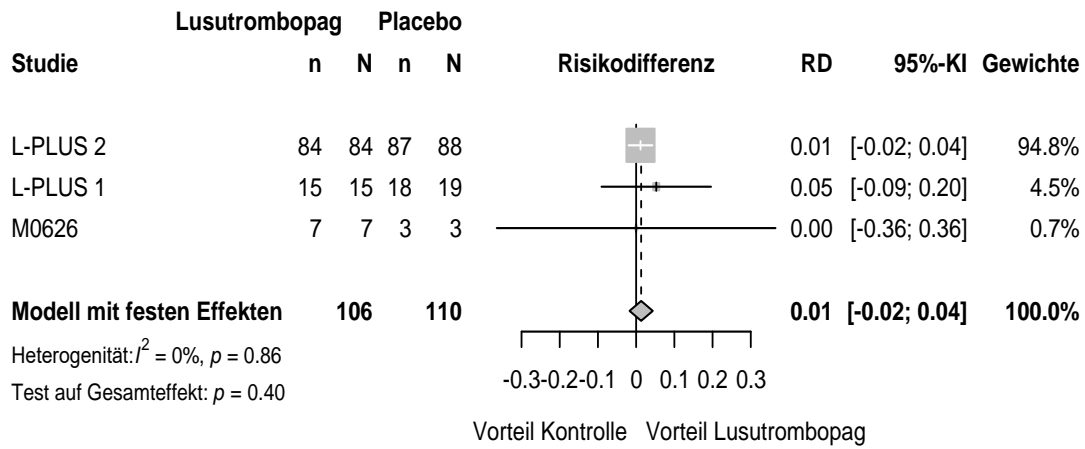
69 Vermeidung_Notfalltherapie_OR Treatment duration (days) - < 7



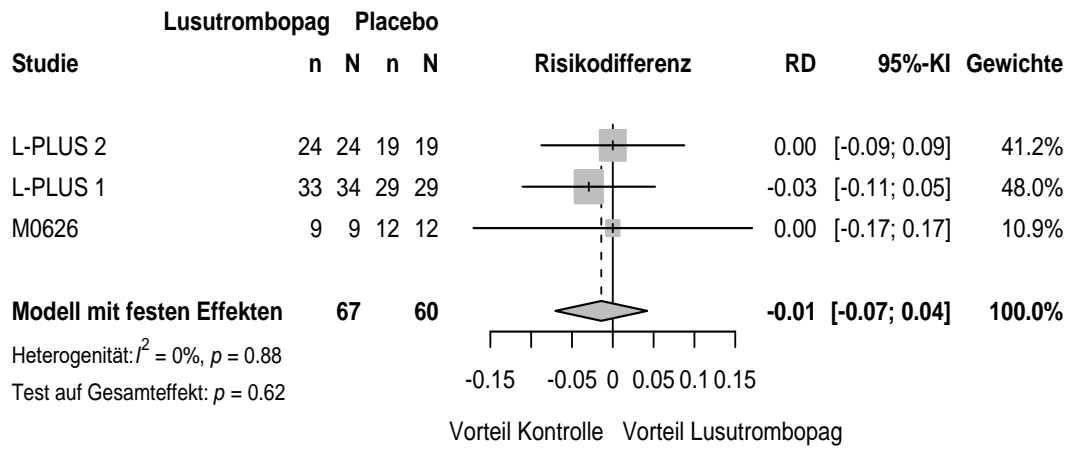
70 Vermeidung_Notfalltherapie_OR Treatment duration (days) - 7



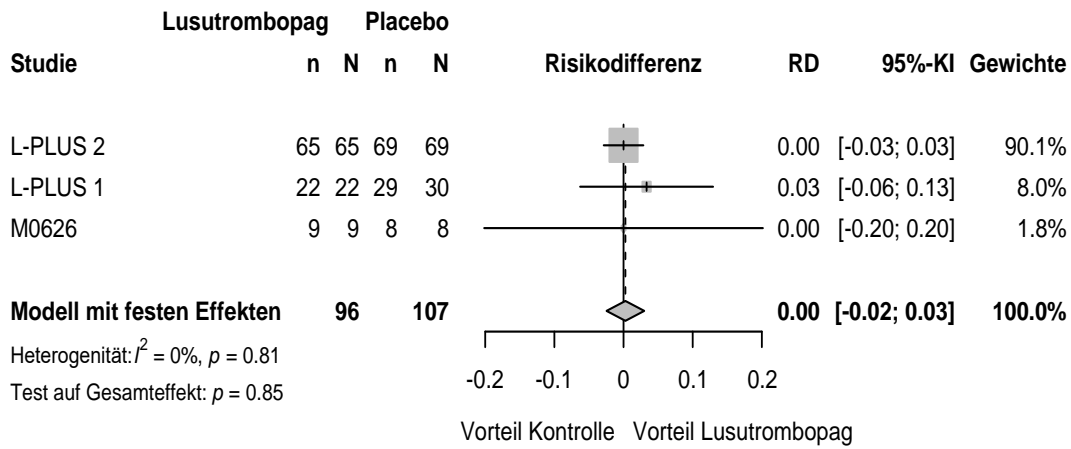
71 Vermeidung_Notfalltherapie_RD Age (years) - < 65



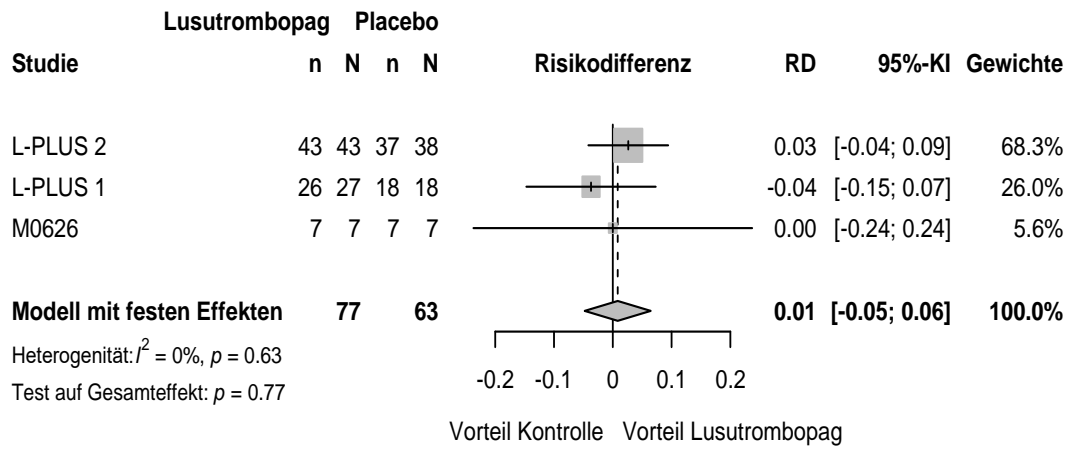
72 Vermeidung_Notfalltherapie_RD Age (years) - >=65



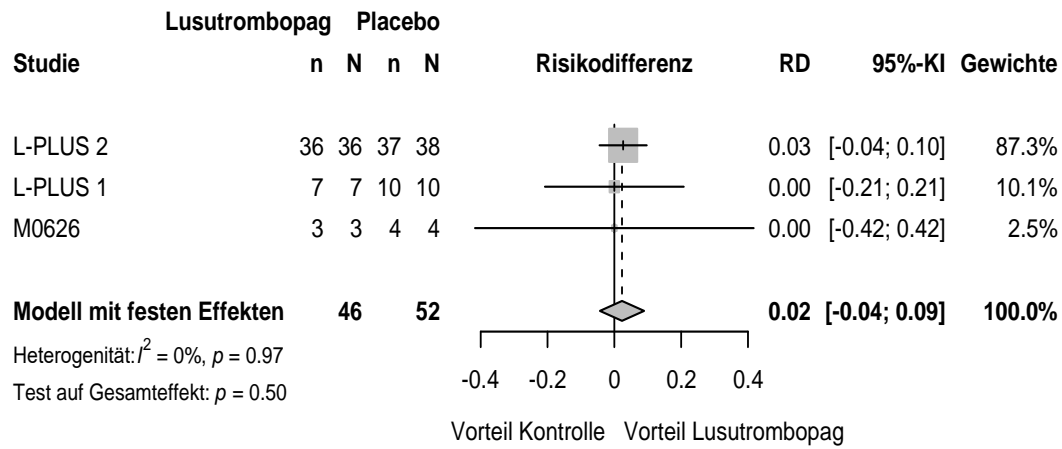
73 Vermeidung_Notfalltherapie_RD Gender - Male



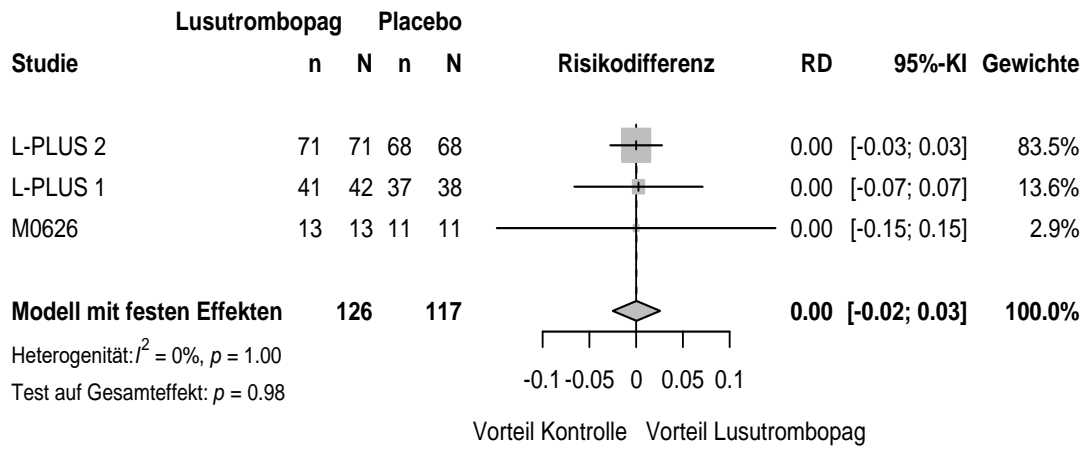
74 Vermeidung_Notfalltherapie_RD Gender - Female



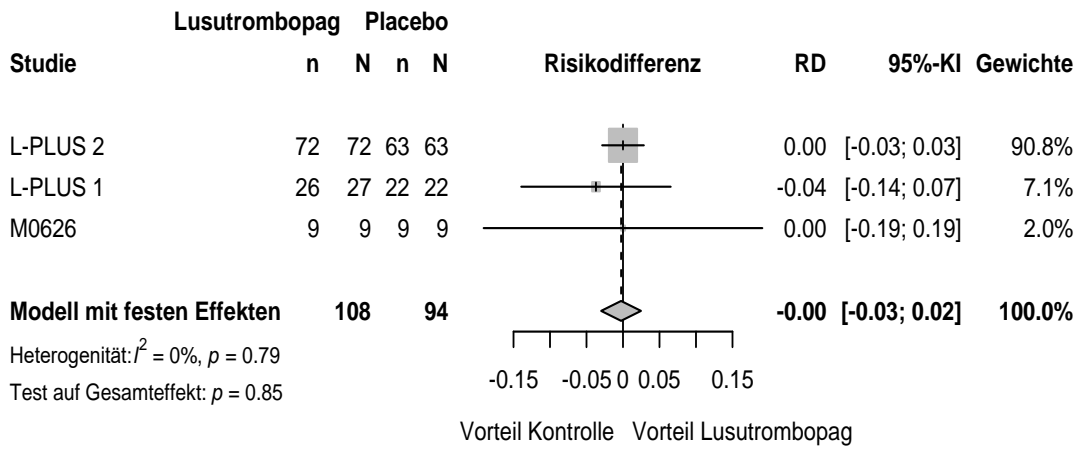
75 Vermeidung_Notfalltherapie_RD Baseline platelet count ($\cdot 10^4/uL$) - < 3.5



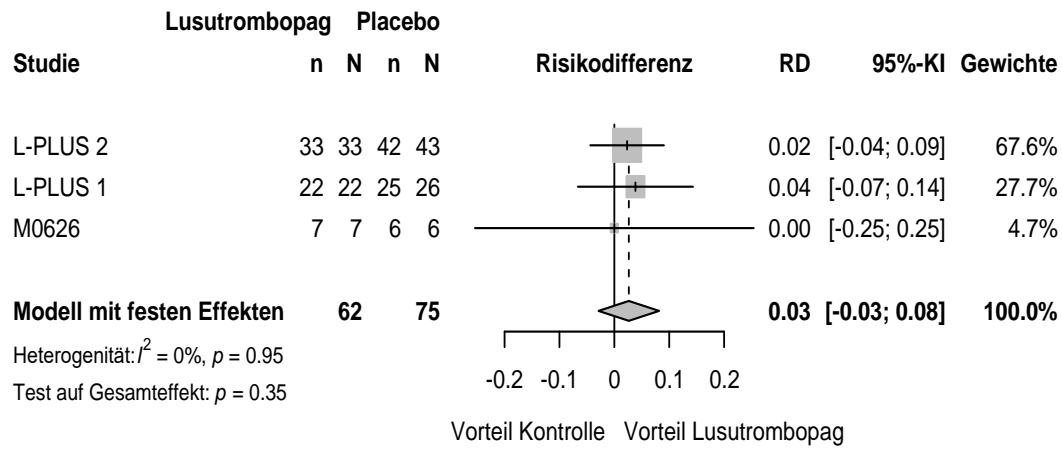
76 Vermeidung_Notfalltherapie_RD Baseline platelet count (*10⁴/uL) - >= 3.5



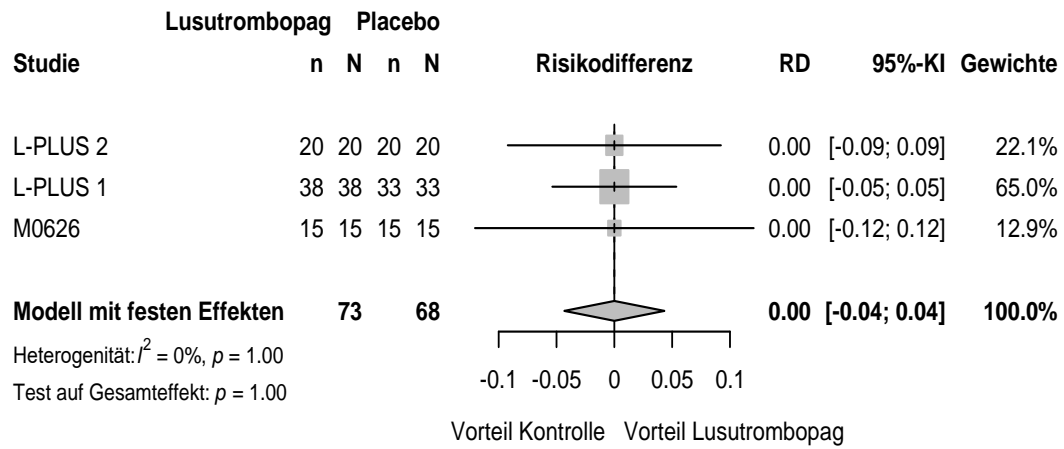
77 Vermeidung_Notfalltherapie_RD Child-Pugh class - A



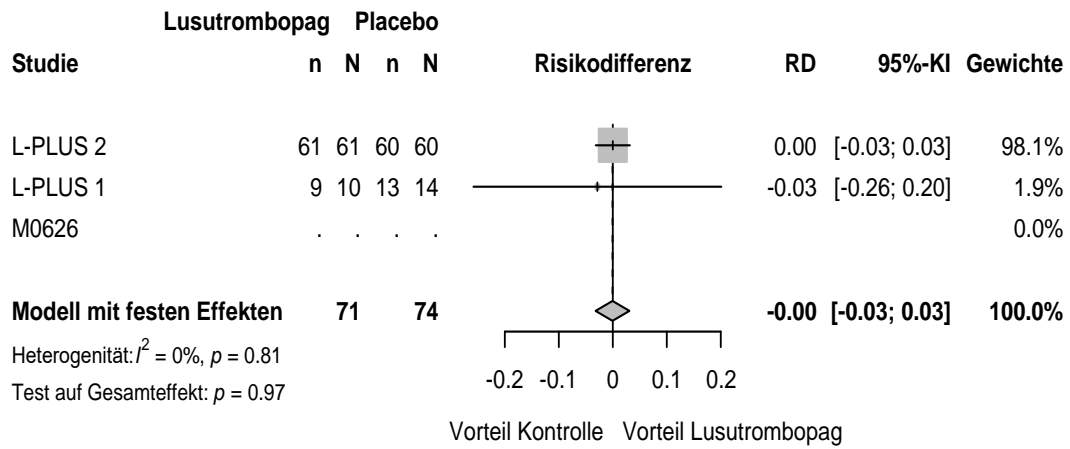
78 Vermeidung_Notfalltherapie_RD Child-Pugh class - B



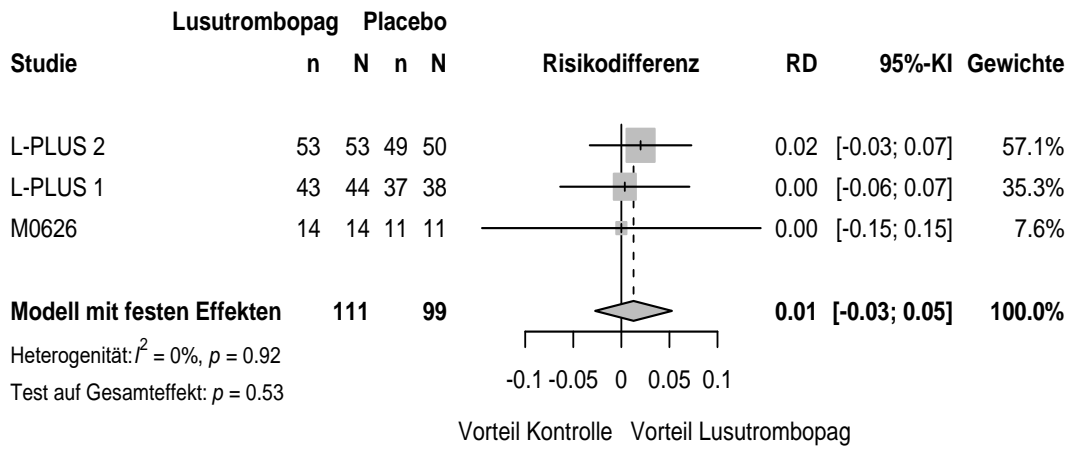
79 Vermeidung_Notfalltherapie_RD Invasive procedure liver-related



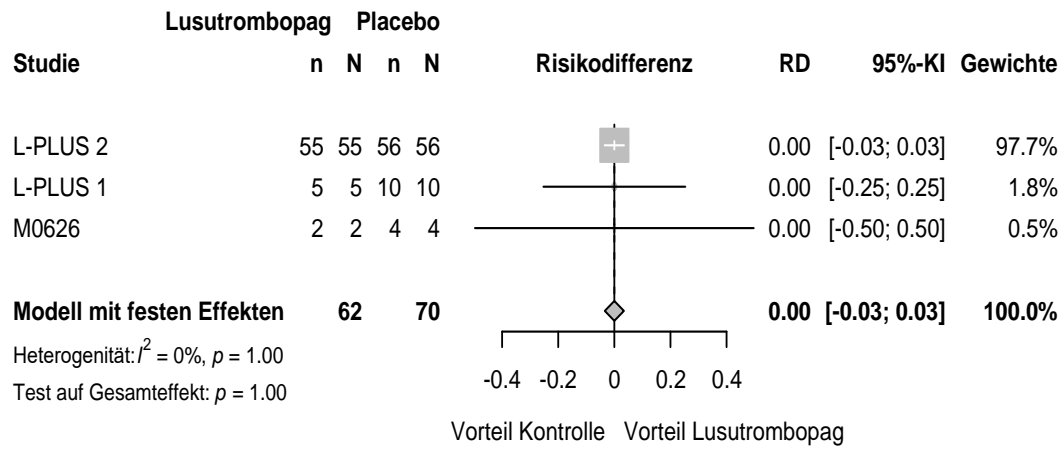
80 Vermeidung_Notfalltherapie_RD Invasive procedure gi-related



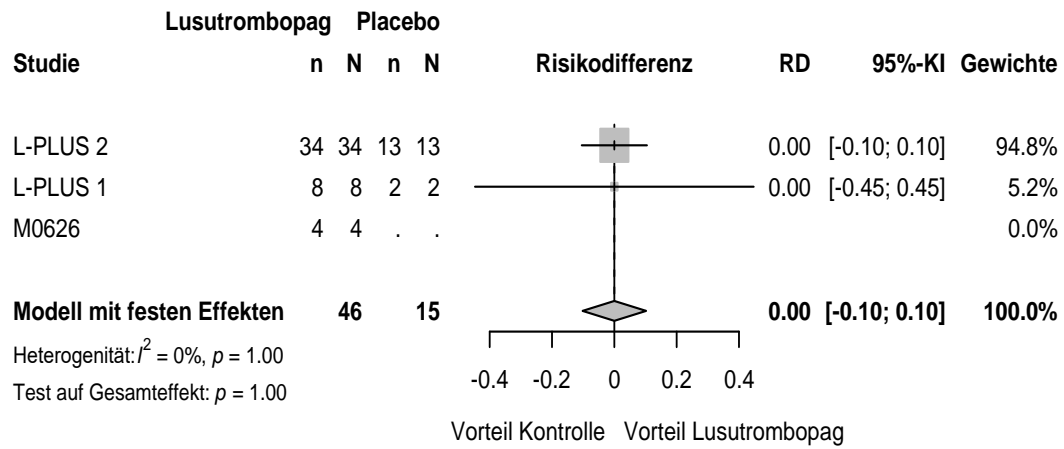
81 Vermeidung_Notfalltherapie_RD Baseline body weight (kg) - < 75



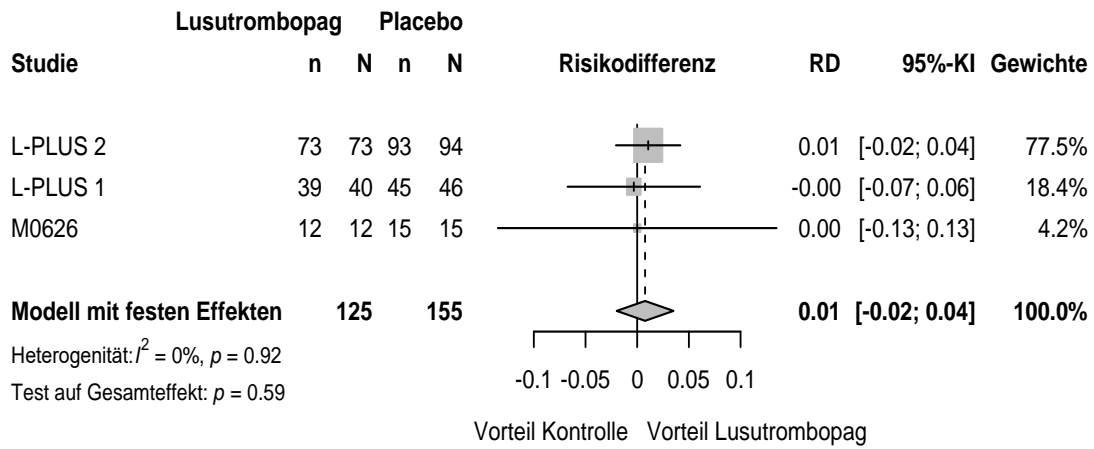
82 Vermeidung_Notfalltherapie_RD Baseline body weight (kg) - >= 75



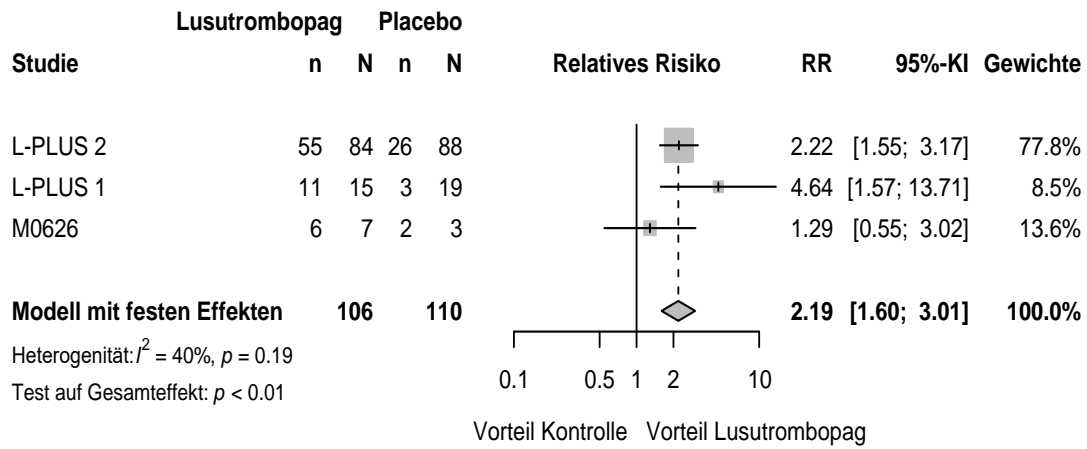
83 Vermeidung_Notfalltherapie_RD Treatment duration (days) - < 7



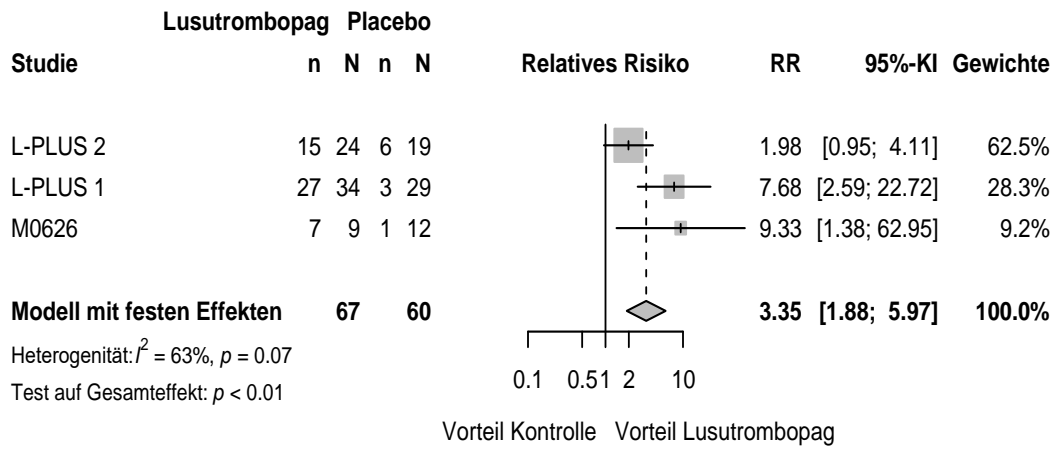
84 Vermeidung_Notfalltherapie_RD Treatment duration (days) - 7



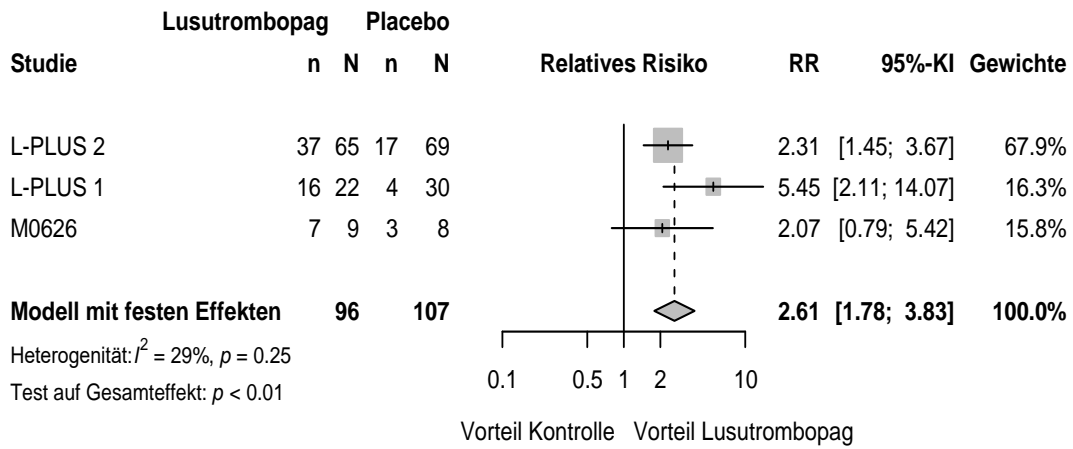
85 Vermeidung_TK-Transfusion_RR Age (years) - < 65



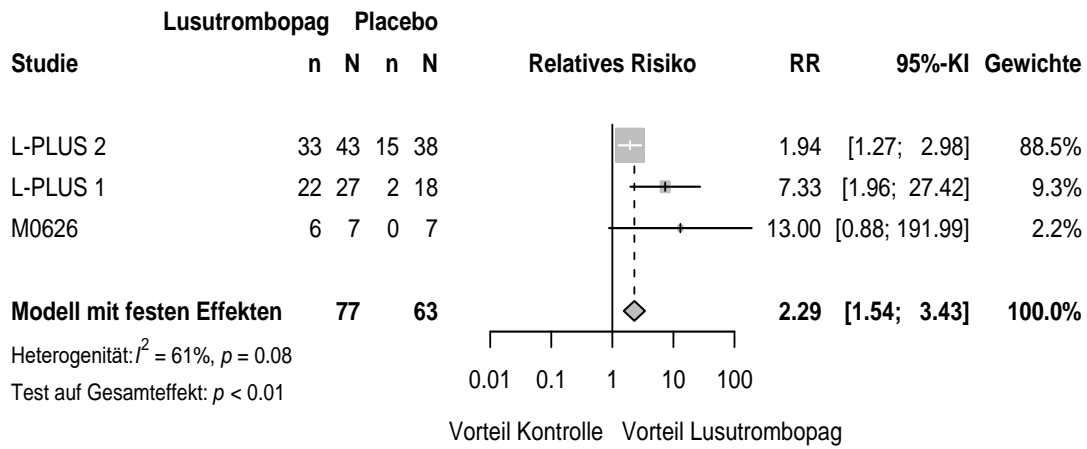
86 Vermeidung_TK-Transfusion_RR Age (years) - >=65



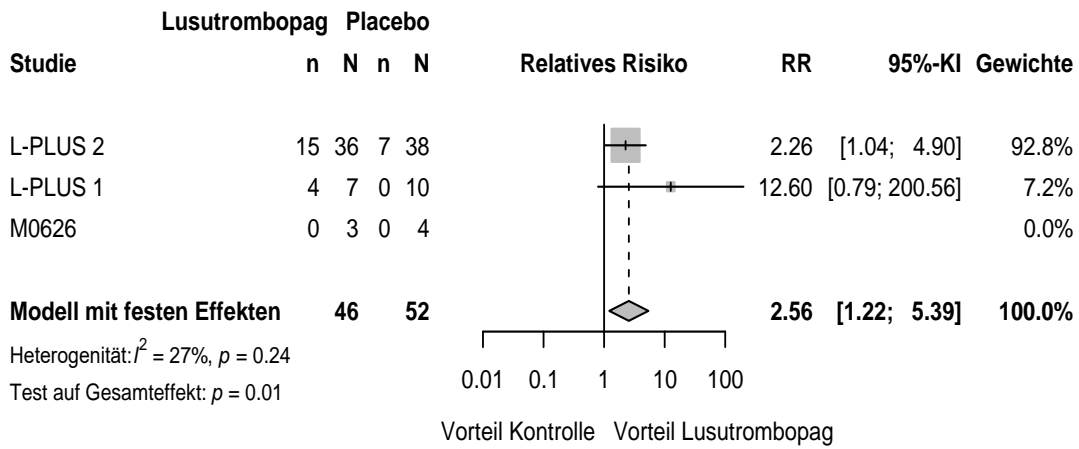
87 Vermeidung_TK-Transfusion_RR Gender - Male



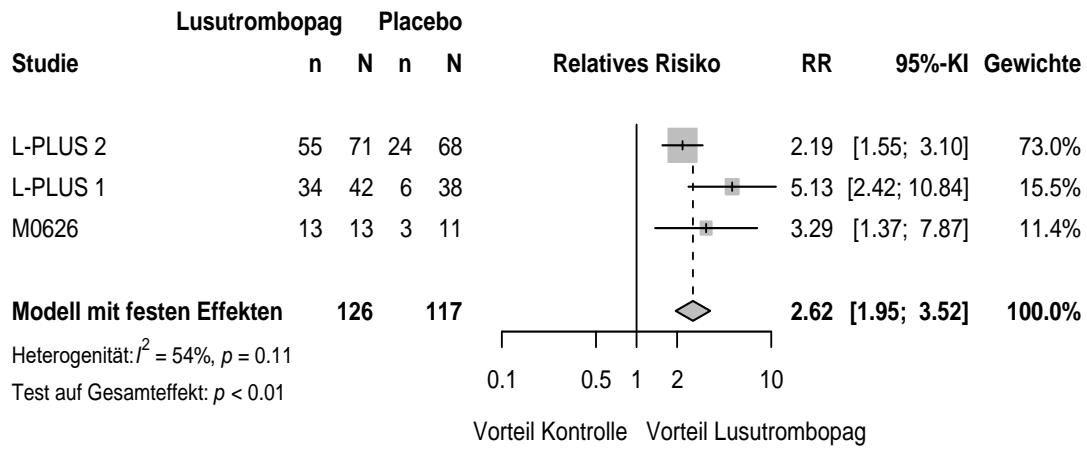
88 Vermeidung_TK-Transfusion_RR Gender - Female



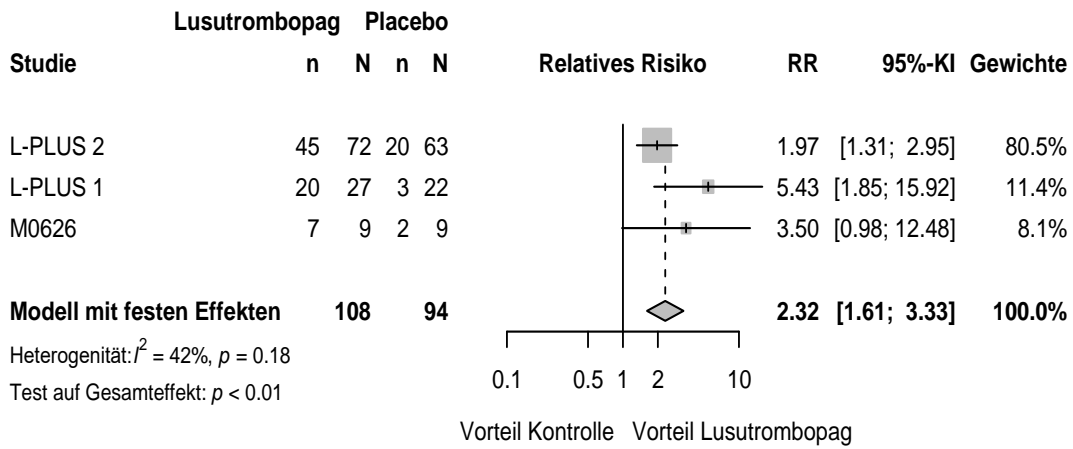
89 Vermeidung_TK-Transfusion_RR Baseline platelet count (*10⁴/uL) - < 3.5



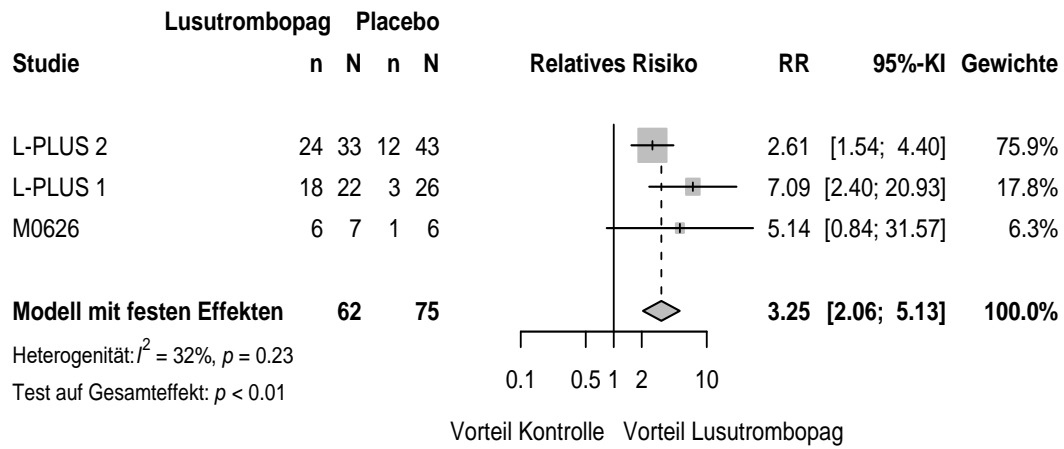
90 Vermeidung_TK-Transfusion_RR Baseline platelet count (*10⁴/uL) - >= 3.5



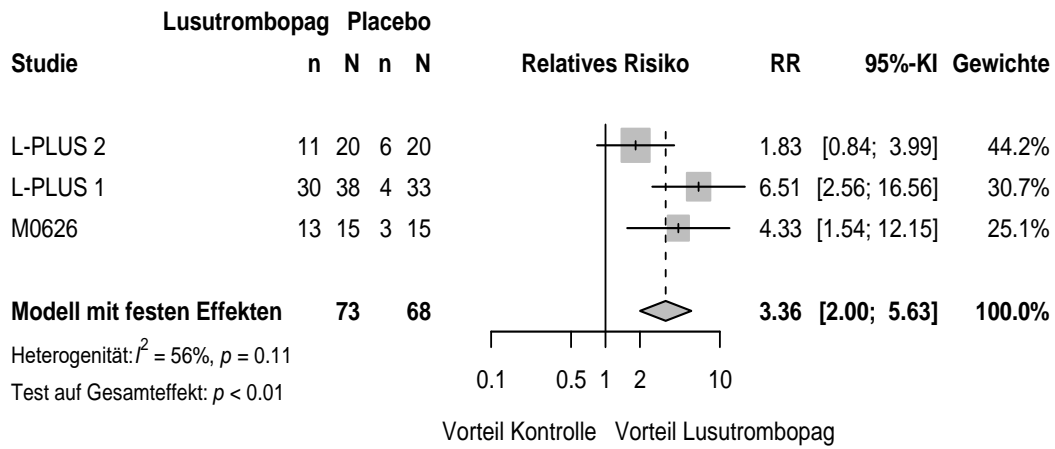
91 Vermeidung_TK-Transfusion_RR Child-Pugh class - A



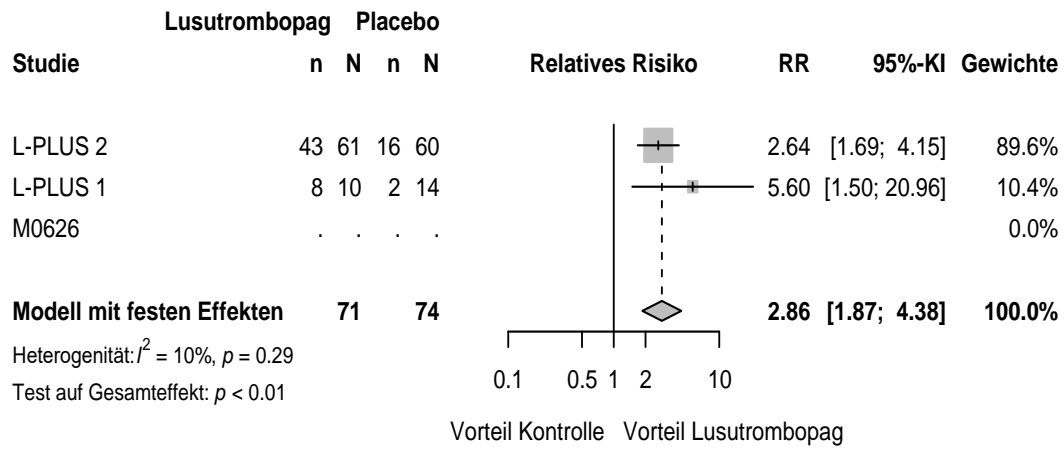
92 Vermeidung_TK-Transfusion_RR Child-Pugh class - B



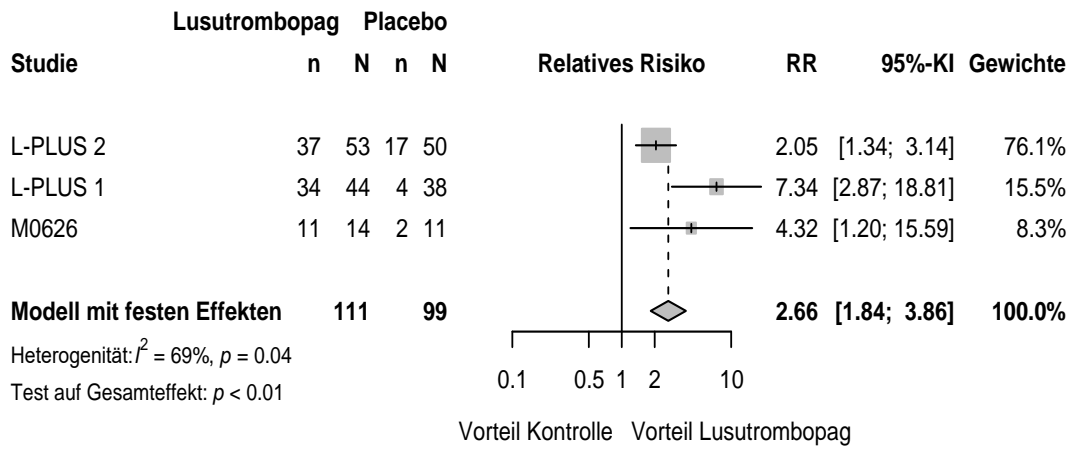
93 Vermeidung_TK-Transfusion_RR Invasive procedure liver-related



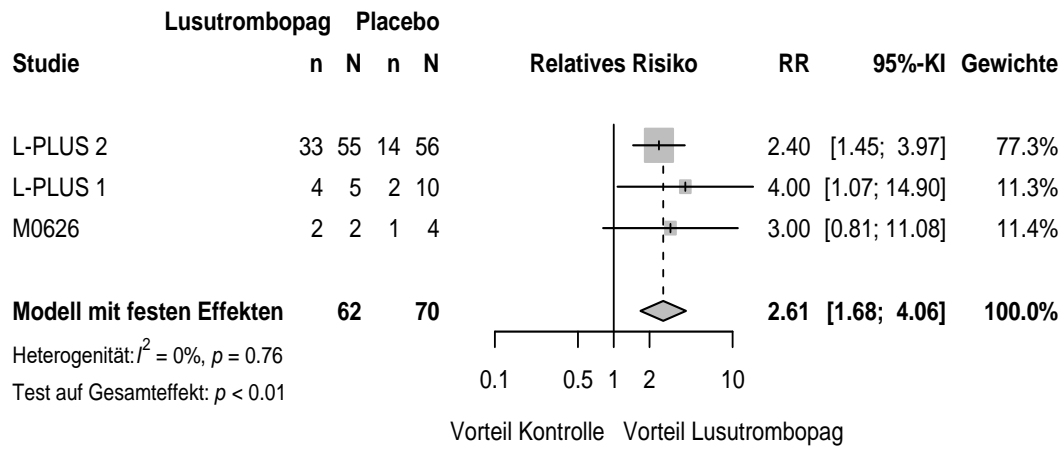
94 Vermeidung_TK-Transfusion_RR Invasive procedure gi-related



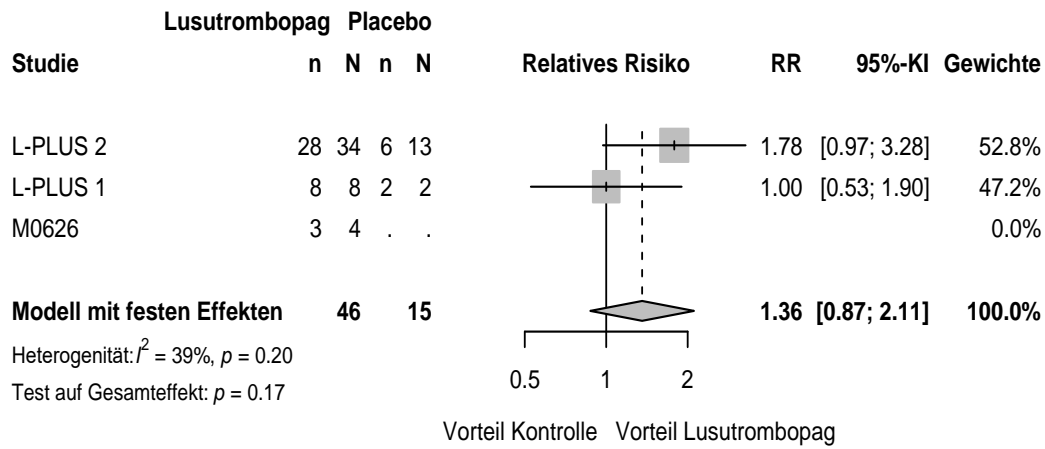
95 Vermeidung_TK-Transfusion_RR Baseline body weight (kg) - < 75



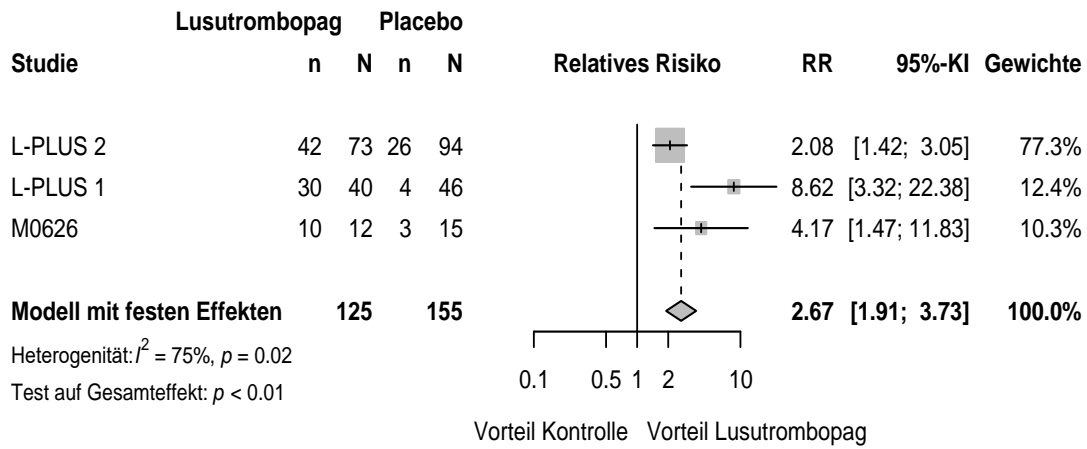
96 Vermeidung_TK-Transfusion_RR Baseline body weight (kg) - >= 75



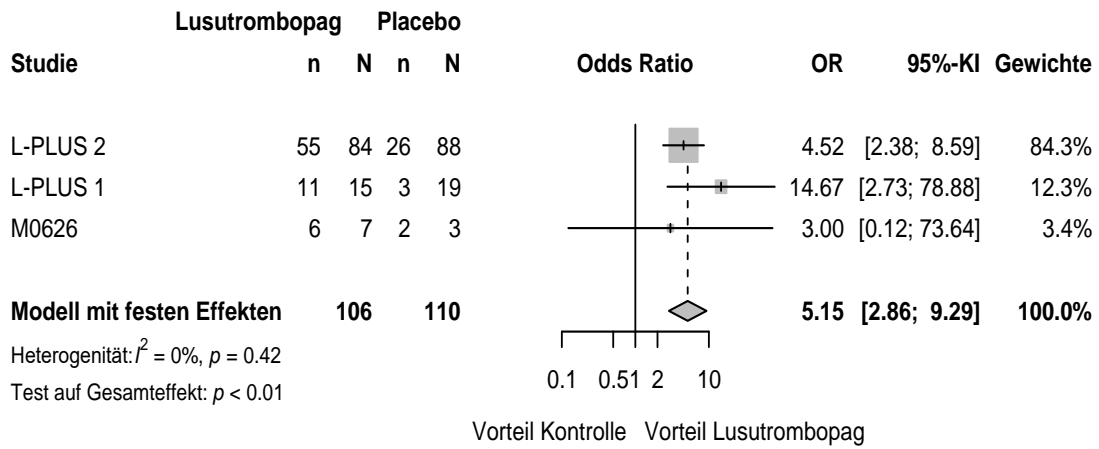
97 Vermeidung_TK-Transfusion_RR Treatment duration (days) - < 7



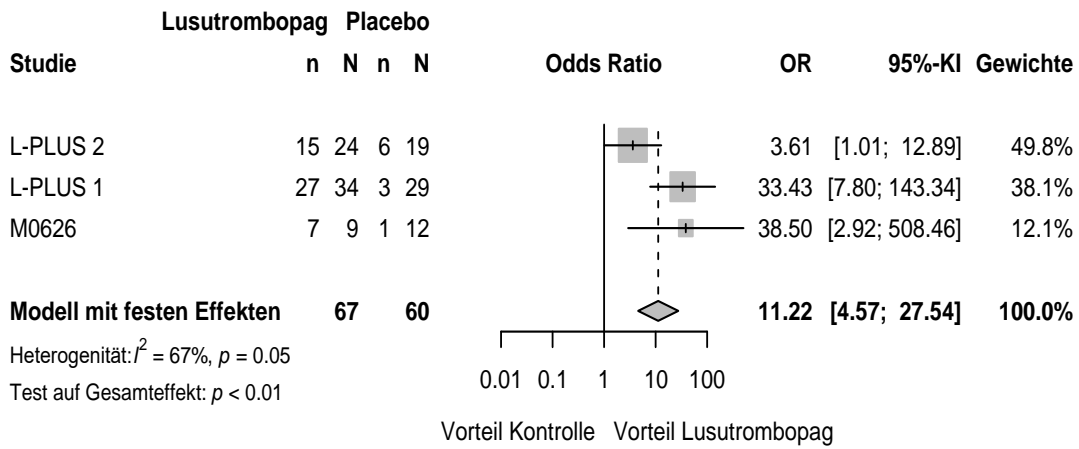
98 Vermeidung_TK-Transfusion_RR Treatment duration (days) -7



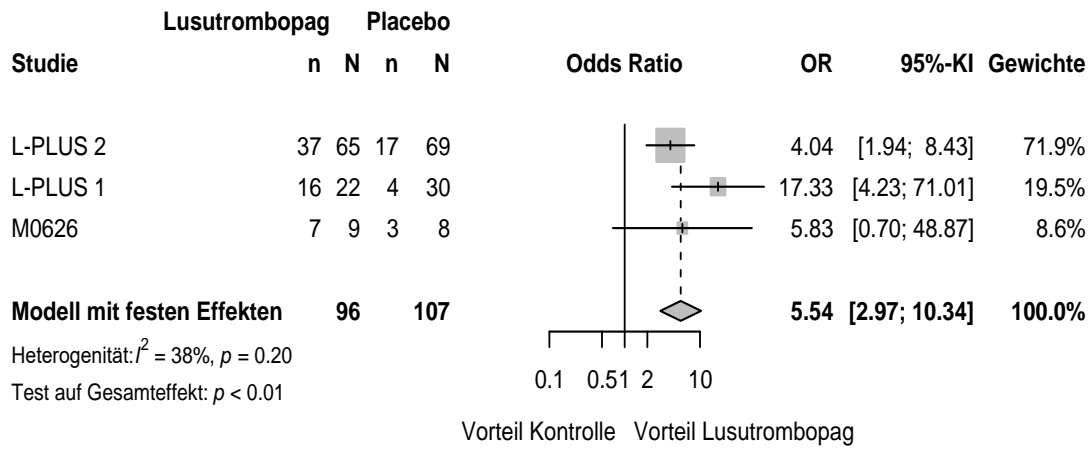
99 Vermeidung_TK-Transfusion_OR Age (years) - < 65



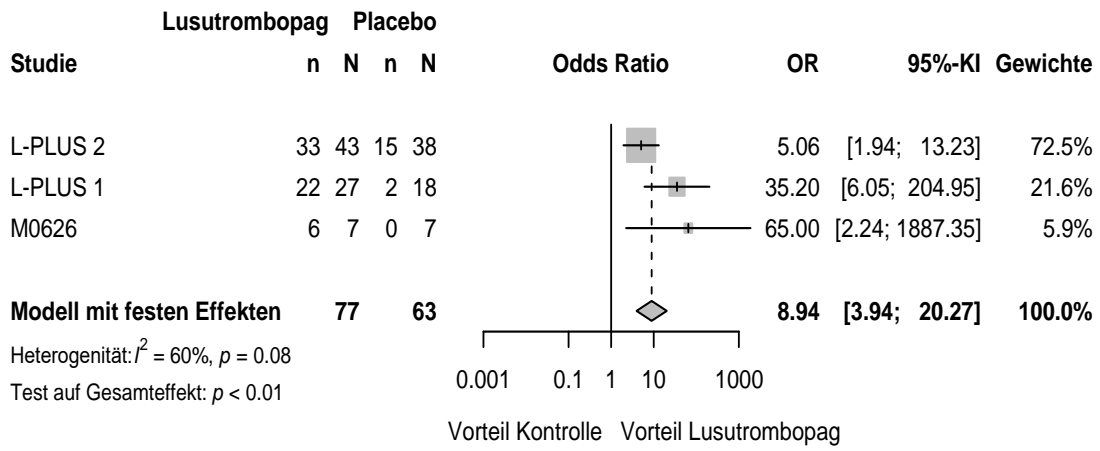
100 Vermeidung_TK-Transfusion_OR Age (years) - >=65



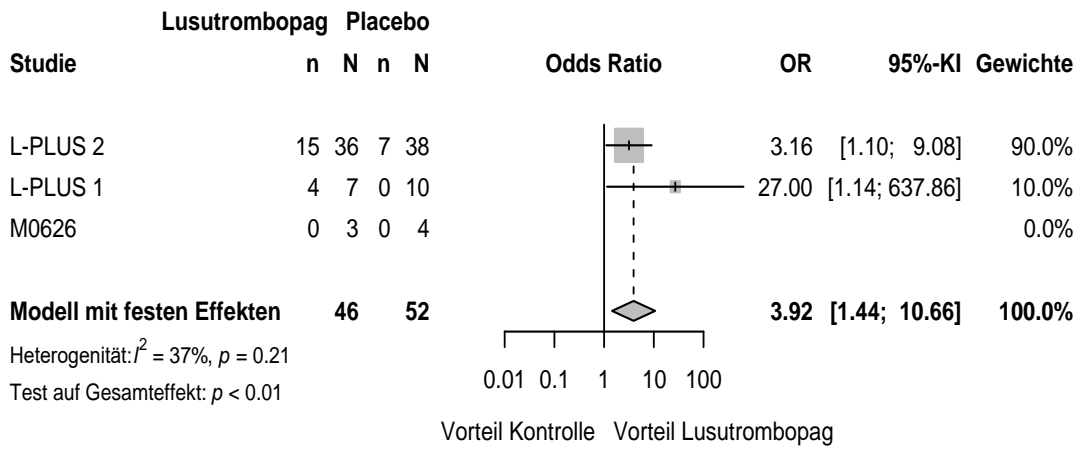
101 Vermeidung_TK-Transfusion_OR Gender - Male



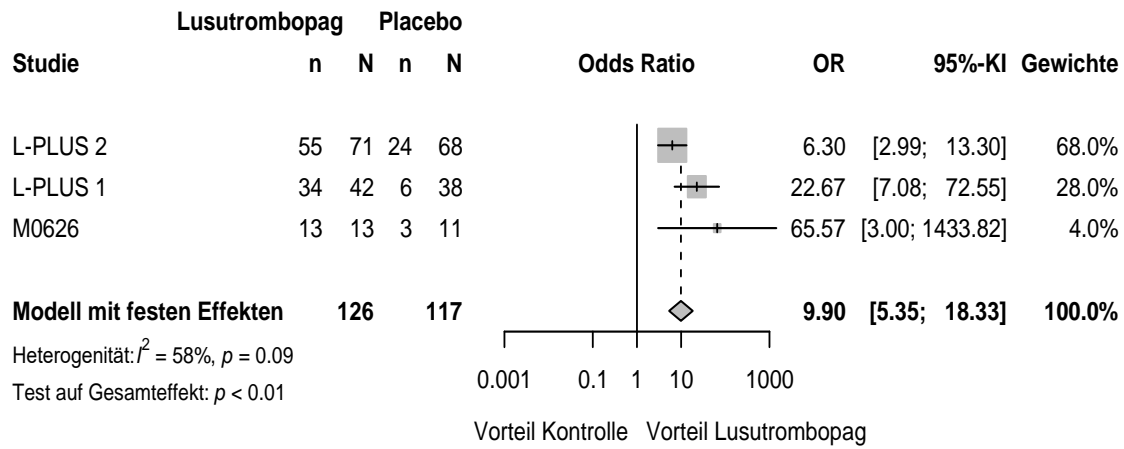
102 Vermeidung_TK-Transfusion_OR Gender - Female



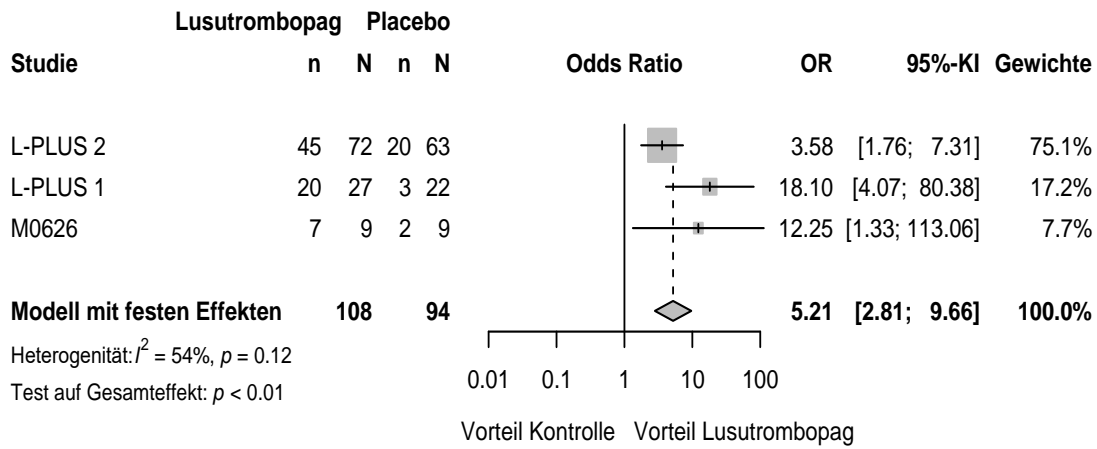
103 Vermeidung_TK-Transfusion_OR Baseline platelet count (*10⁴/uL) - < 3.5



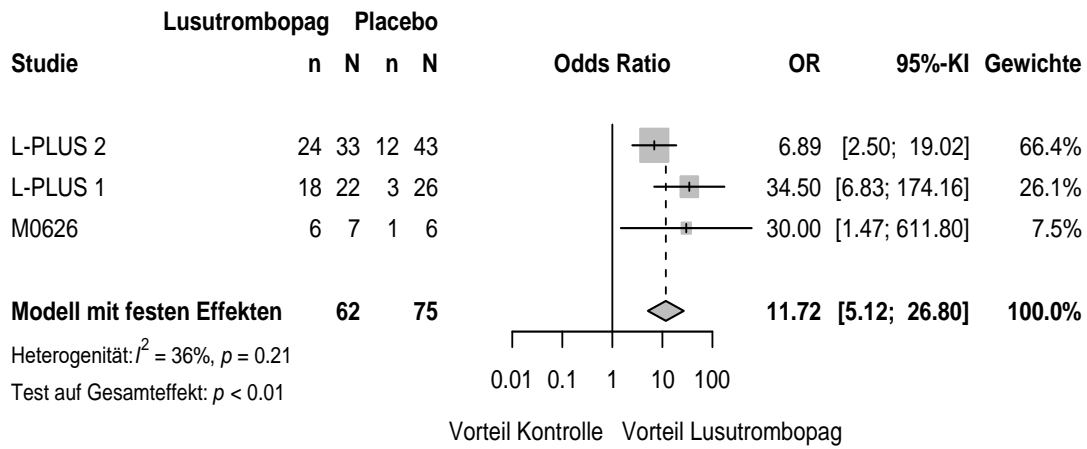
104 Vermeidung_TK-Transfusion_OR Baseline platelet count (*10⁴/uL) - >= 3.5



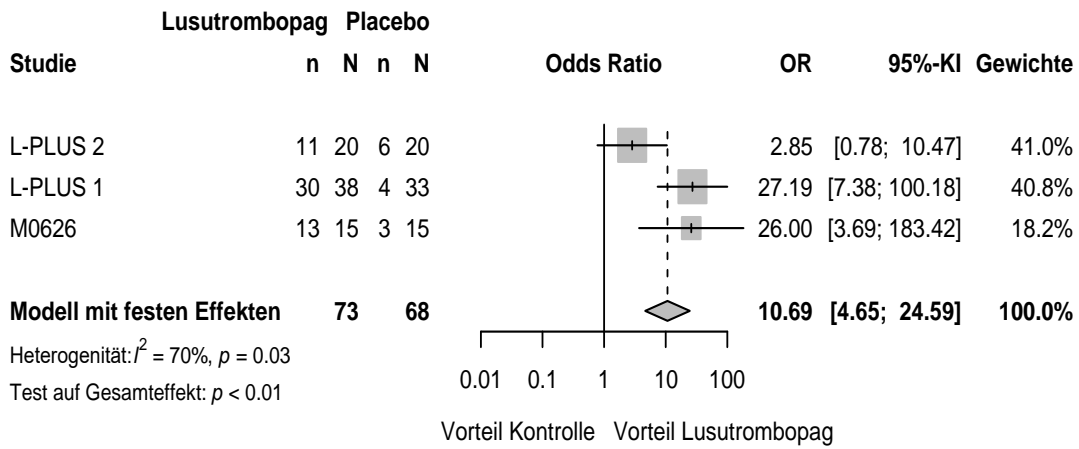
105 Vermeidung_TK-Transfusion_OR Child-Pugh class - A



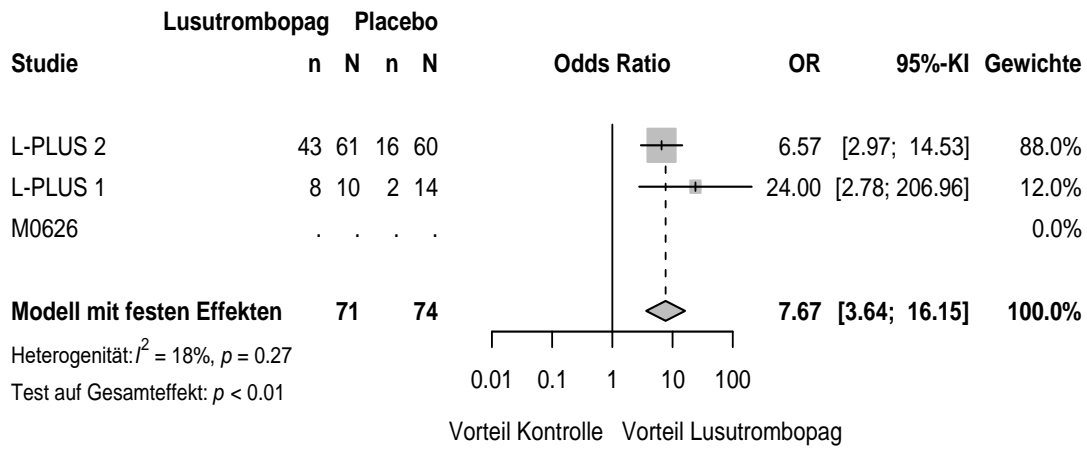
106 Vermeidung_TK-Transfusion_OR Child-Pugh class - B



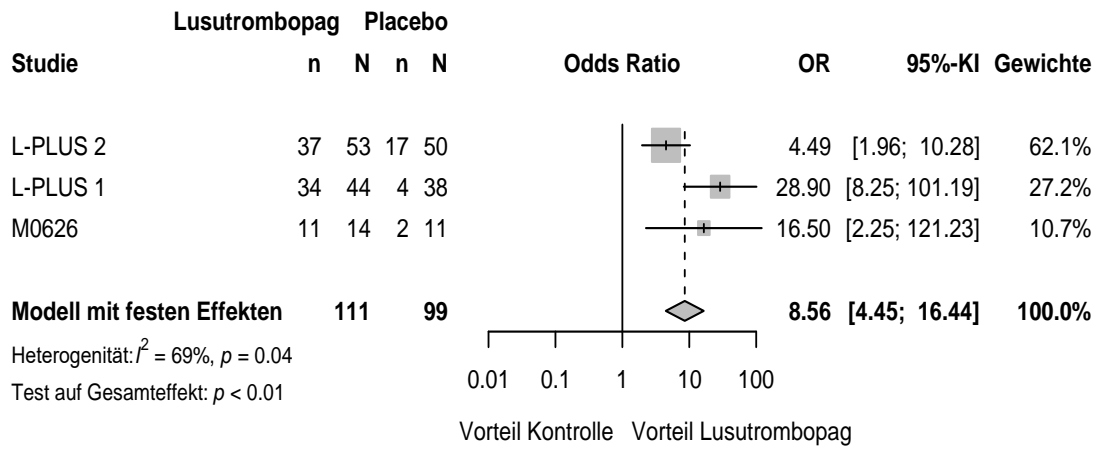
107 Vermeidung_TK-Transfusion_OR Invasive procedure liver-related



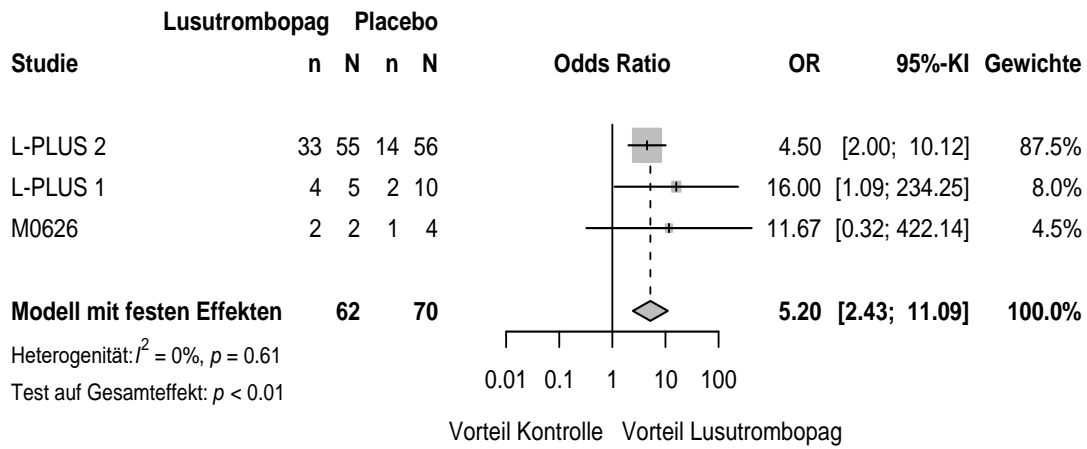
108 Vermeidung_TK-Transfusion_OR Invasive procedure gi-related



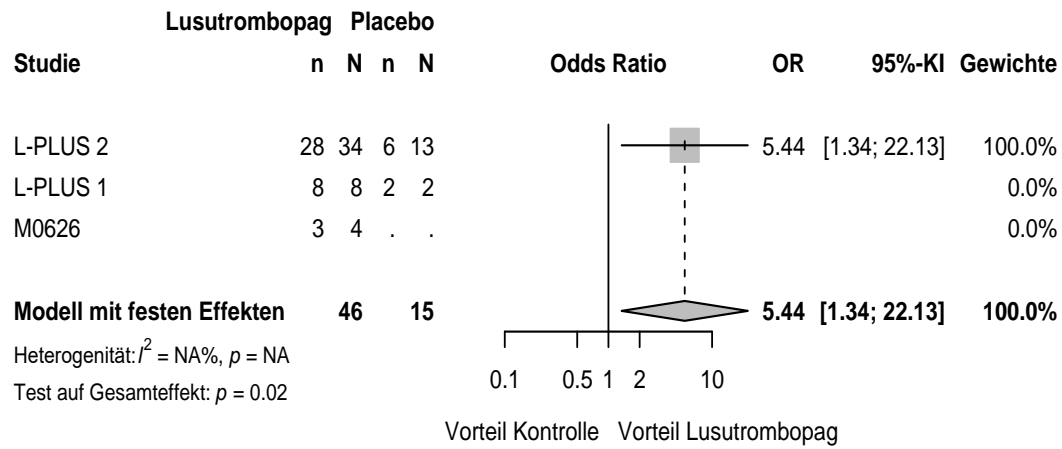
109 Vermeidung_TK-Transfusion_OR Baseline body weight (kg) - < 75



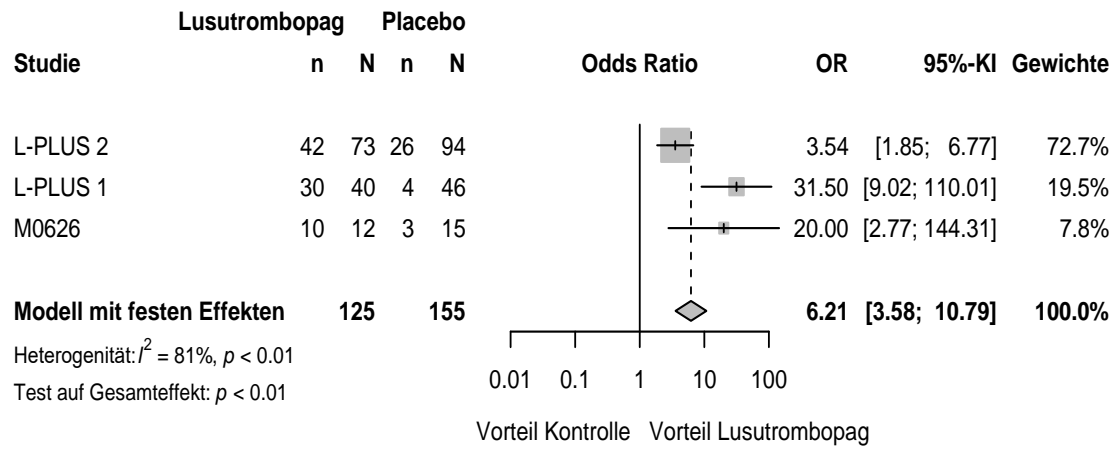
110 Vermeidung_TK-Transfusion_OR Baseline body weight (kg) - >= 75



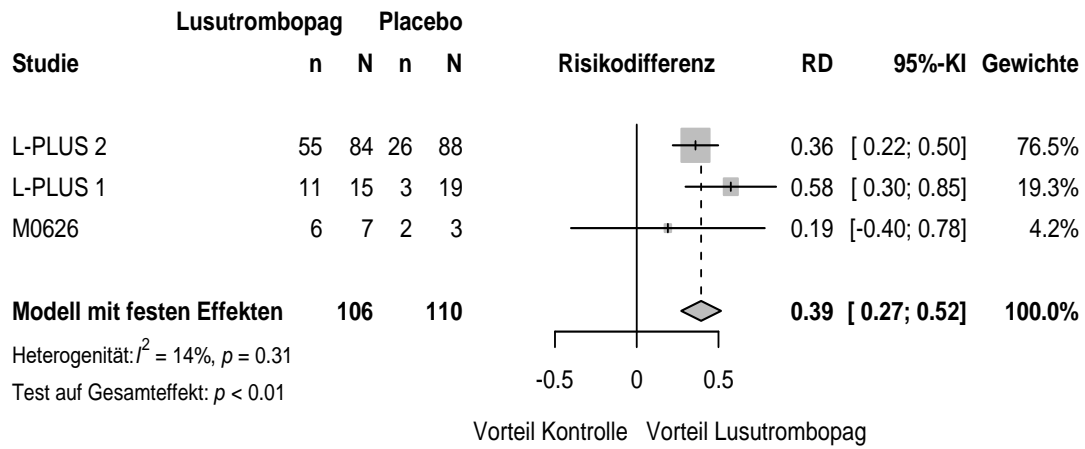
111 Vermeidung_TK-Transfusion_OR Treatment duration (days) - < 7



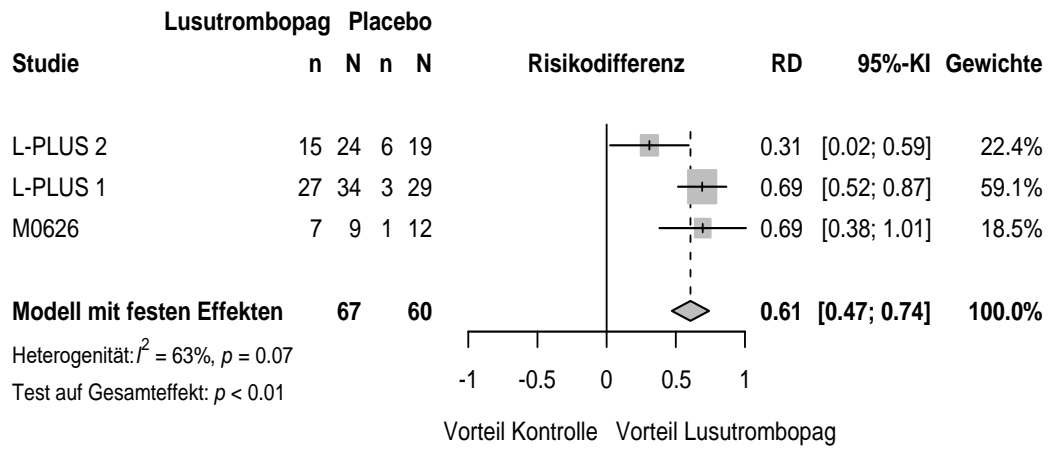
112 Vermeidung_TK-Transfusion_OR Treatment duration (days) -7



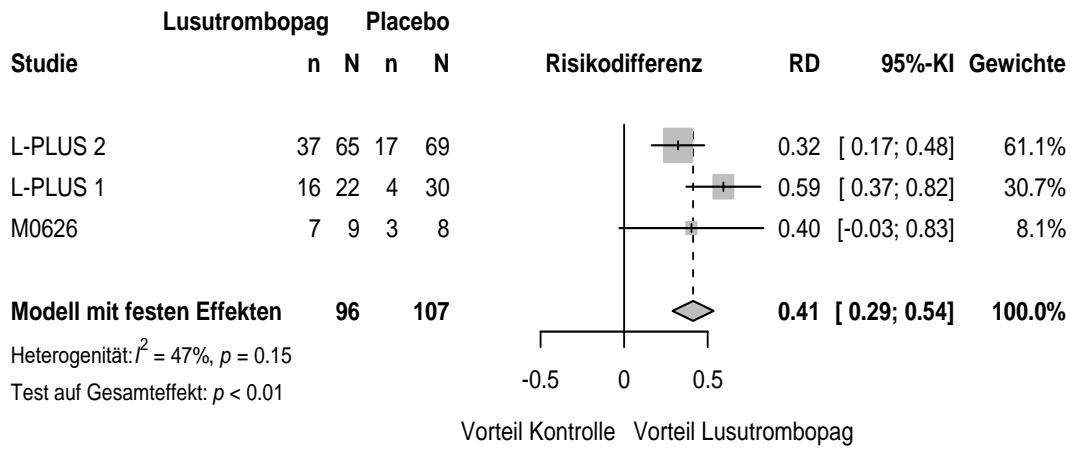
113 Vermeidung_TK-Transfusion_RD Age (years) - < 65



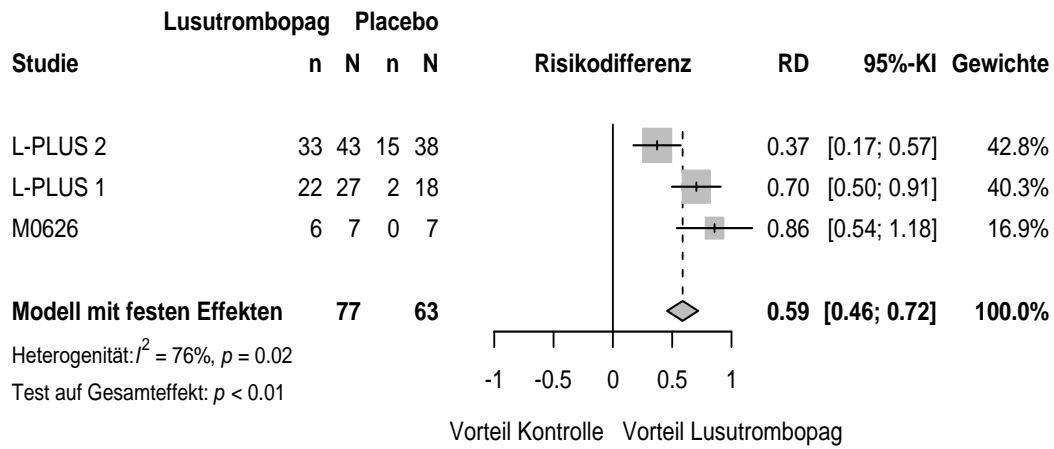
114 Vermeidung_TK-Transfusion_RD Age (years) - >=65



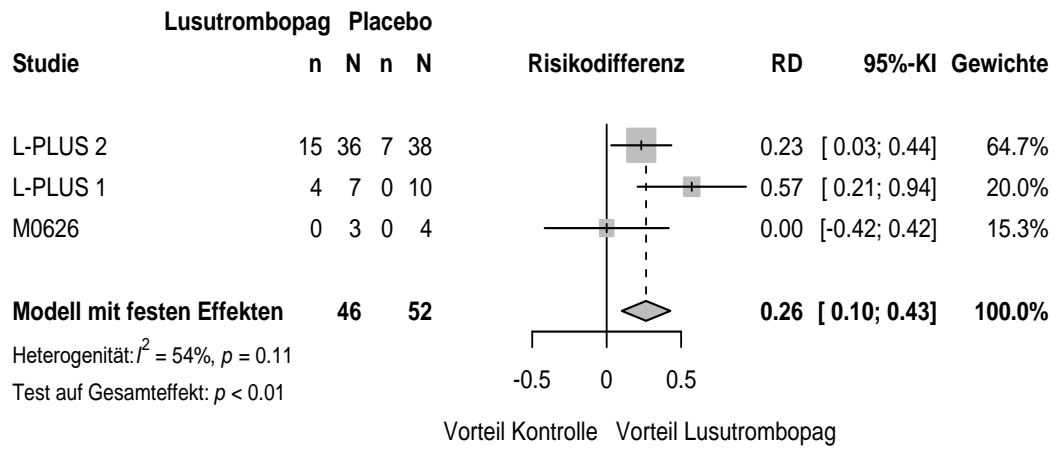
115 Vermeidung_TK-Transfusion_RD Gender - Male



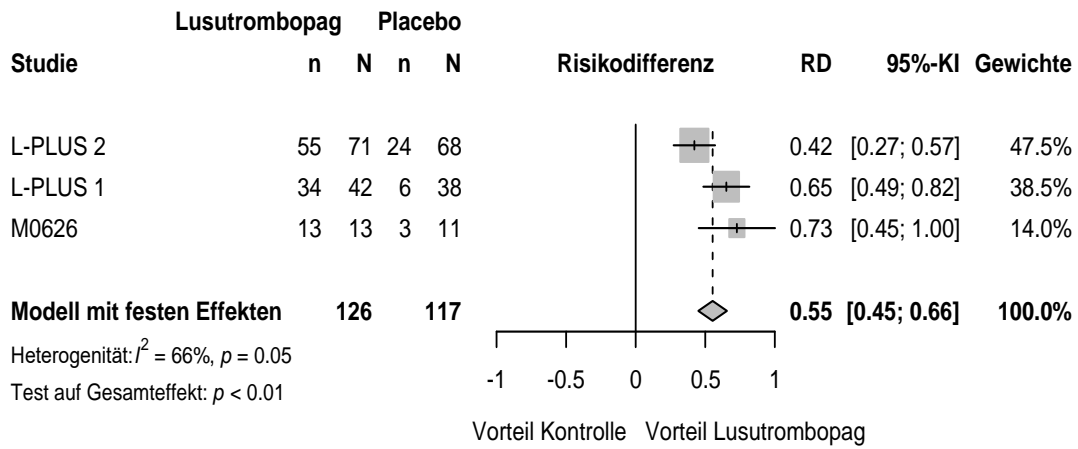
116 Vermeidung_TK-Transfusion_RD Gender - Female



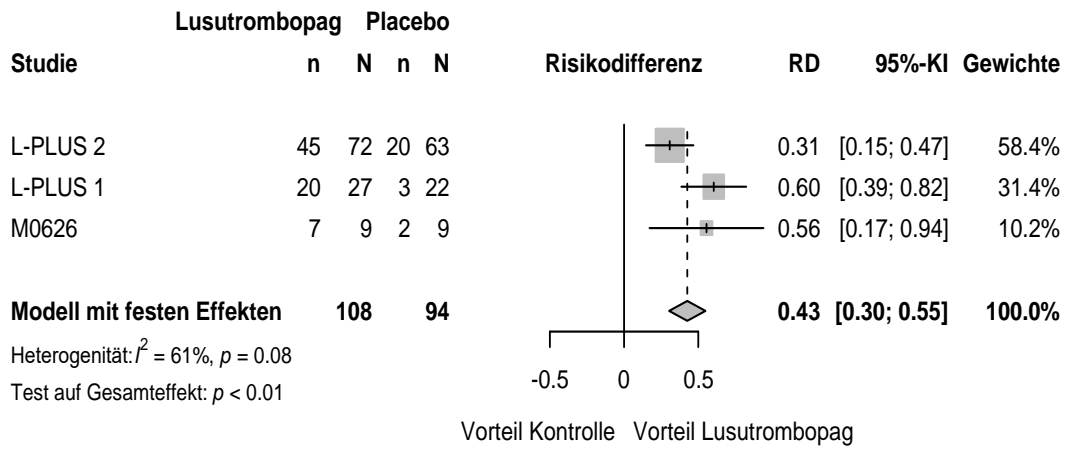
117 Vermeidung_TK-Transfusion_RD Baseline platelet count ($\cdot 10^4/\mu\text{L}$) - < 3.5



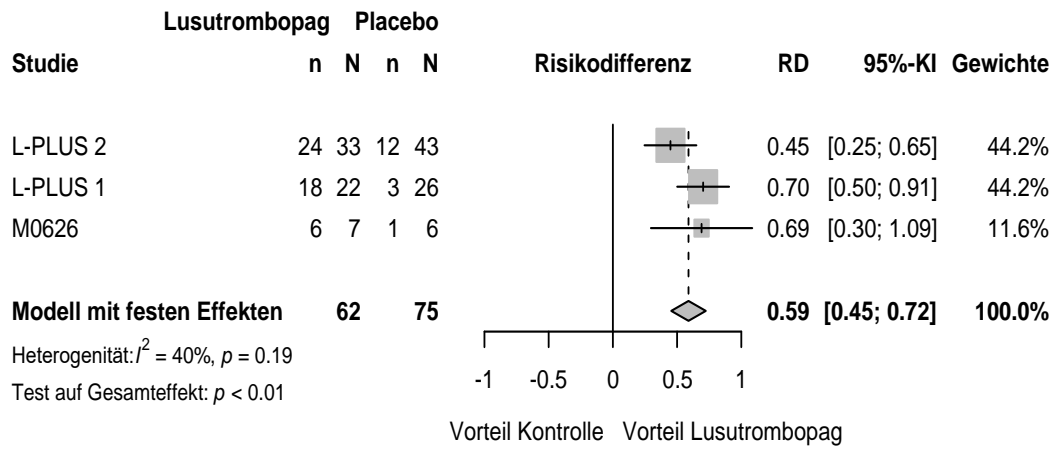
118 Vermeidung_TK-Transfusion_RD Baseline platelet count (*10⁴/uL) - >= 3.5



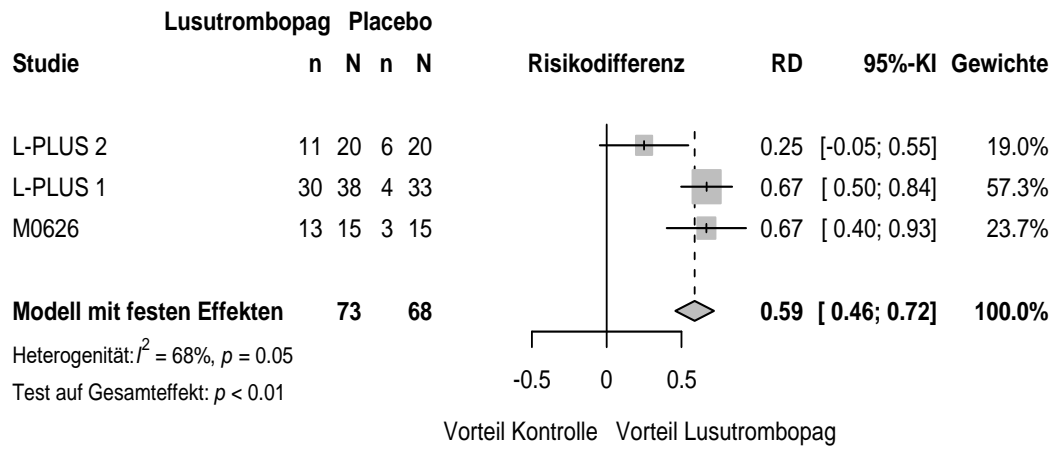
119 Vermeidung_TK-Transfusion_RD Child-Pugh class - A



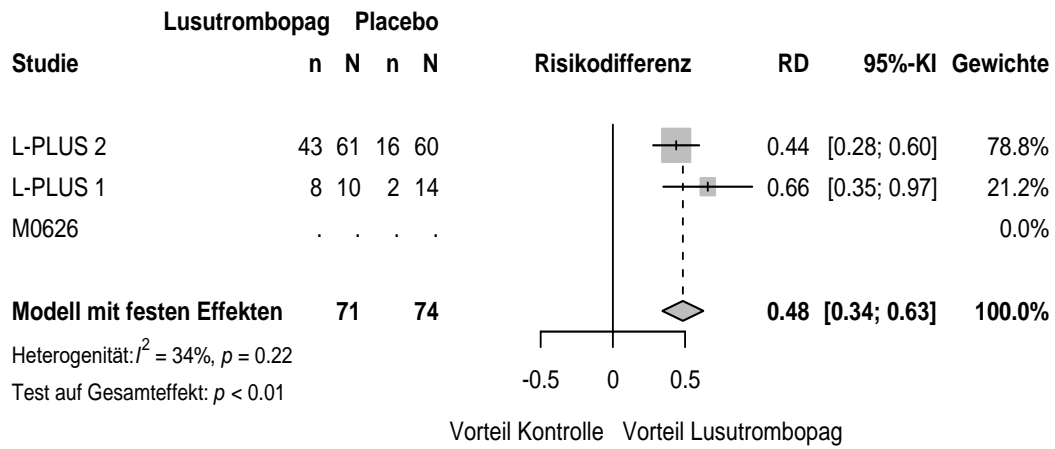
120 Vermeidung_TK-Transfusion_RD Child-Pugh class - B



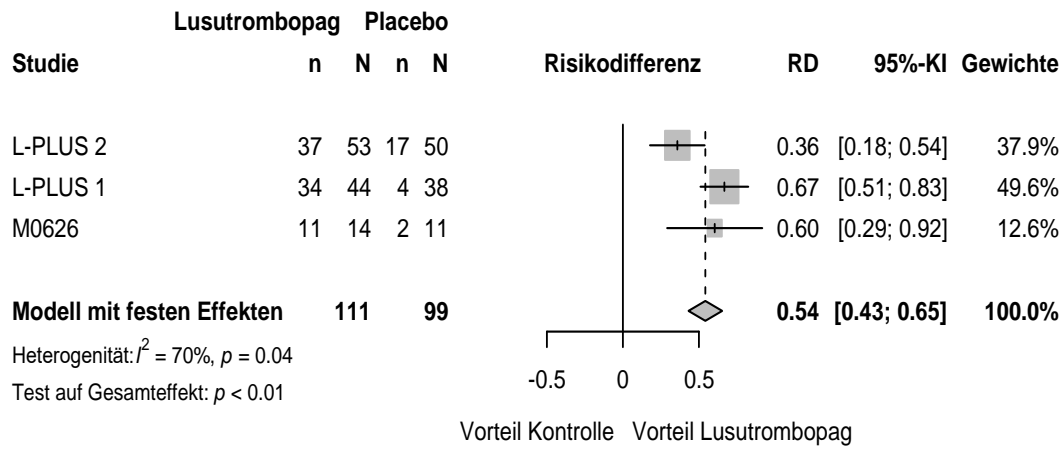
121 Vermeidung_TK-Transfusion_RD Invasive procedure liver-related



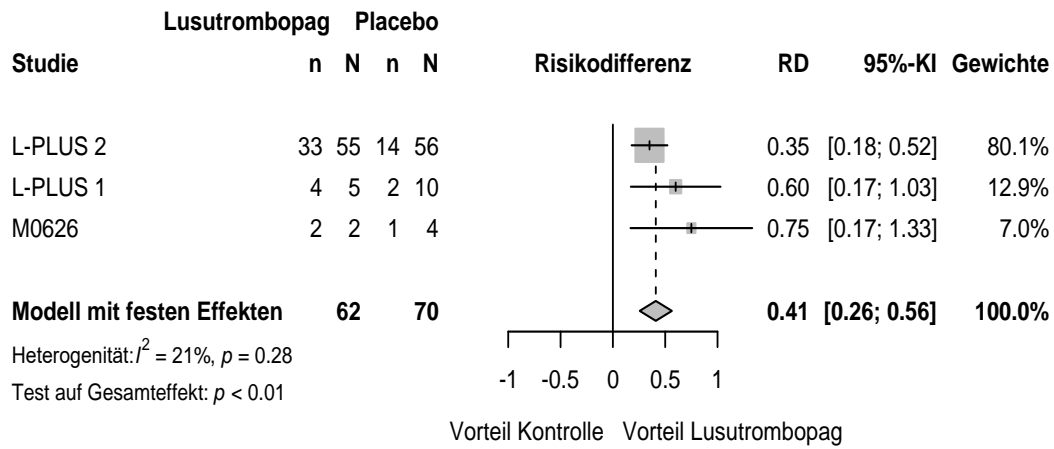
122 Vermeidung_TK-Transfusion_RD Invasive procedure gi-related



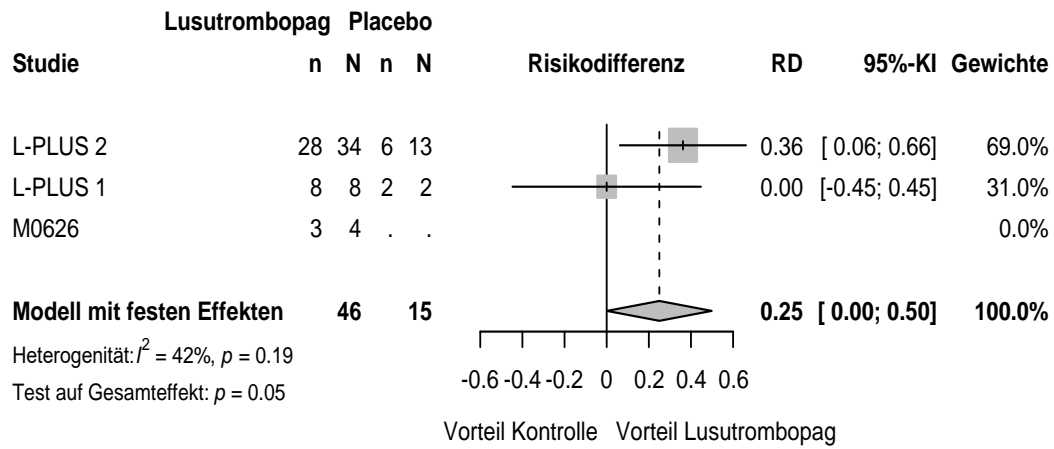
123 Vermeidung_TK-Transfusion_RD Baseline body weight (kg) - < 75



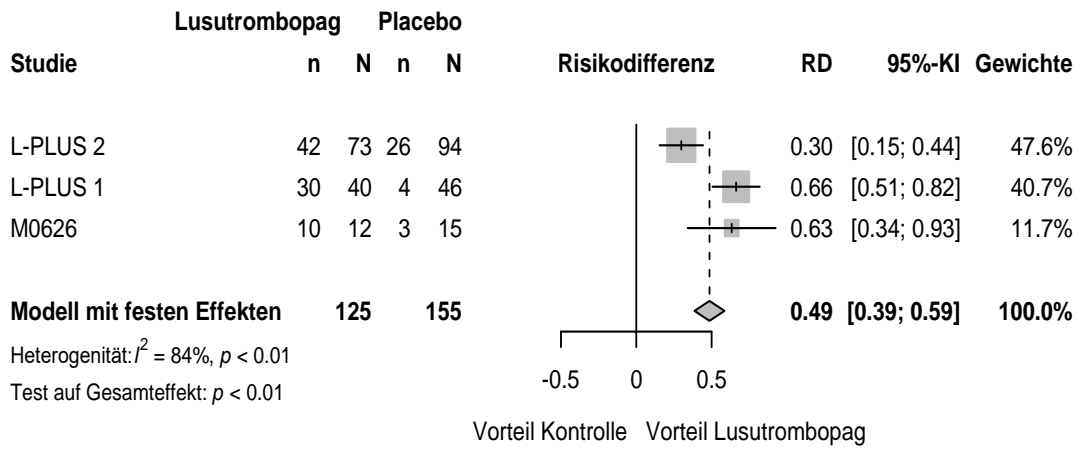
124 Vermeidung_TK-Transfusion_RD Baseline body weight (kg) - >= 75



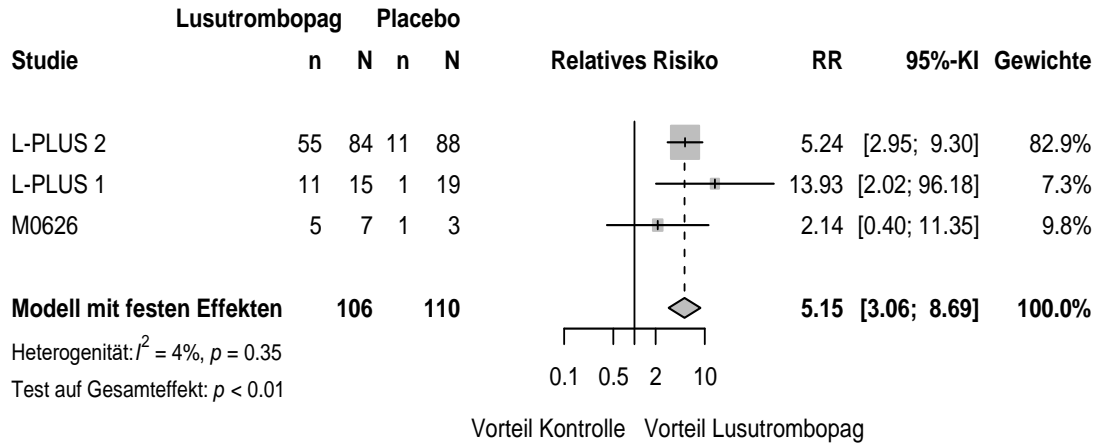
125 Vermeidung_TK-Transfusion_RD Treatment duration (days) - < 7



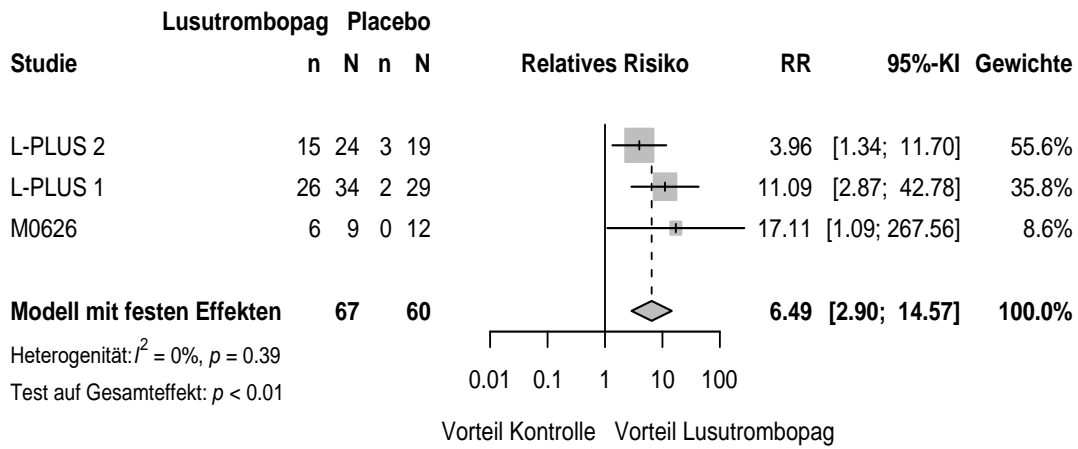
126 Vermeidung_TK-Transfusion_RD Treatment duration (days) -7



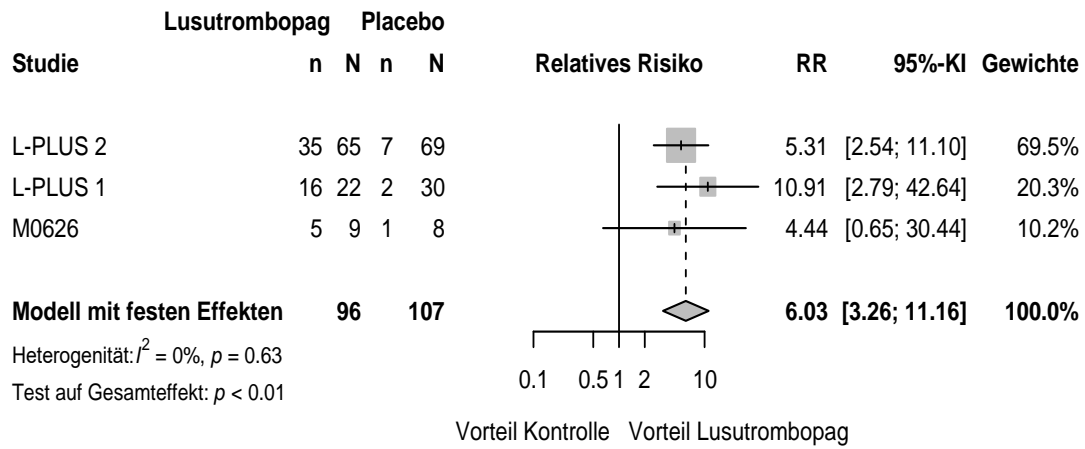
127 Erfolgreiche_Behandlung_Thrombozytopenie_RR Age (years) - < 65



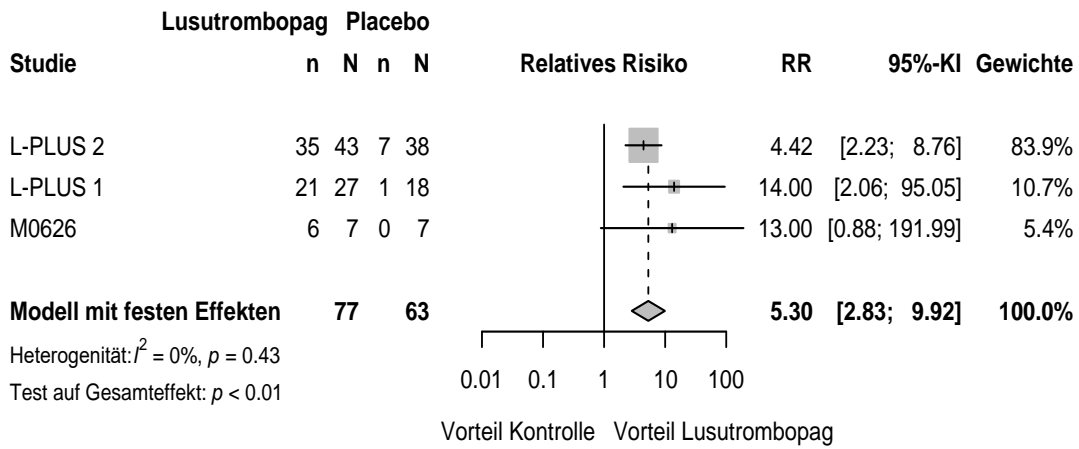
128 Erfolgreiche_Behandlung_Thrombozytopenie_RR Age (years) - >=65



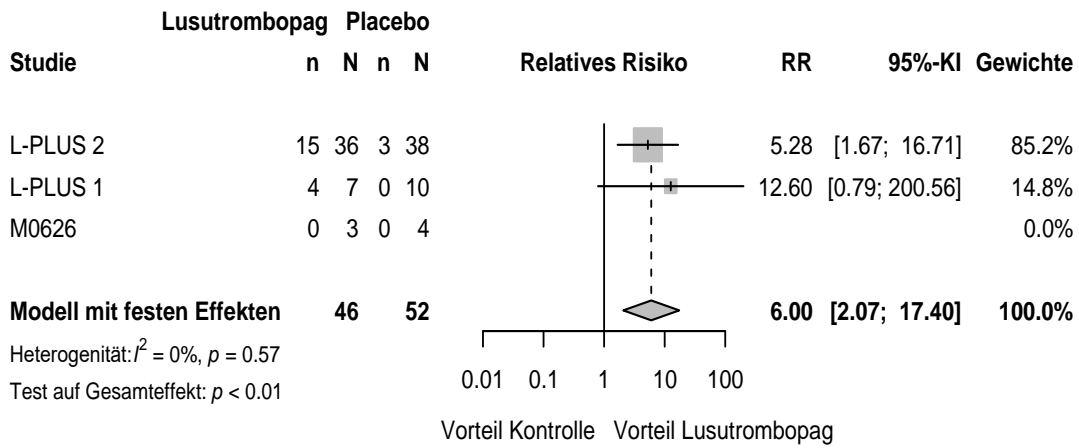
129 Erfolgreiche_Behandlung_Thrombozytopenie_RR Gender - Male



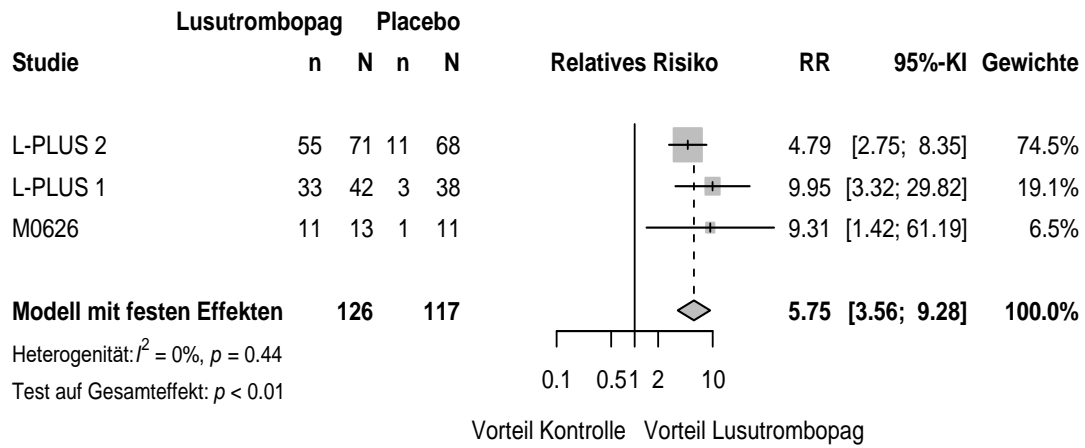
130 Erfolgreiche_Behandlung_Thrombozytopenie_RR Gender - Female



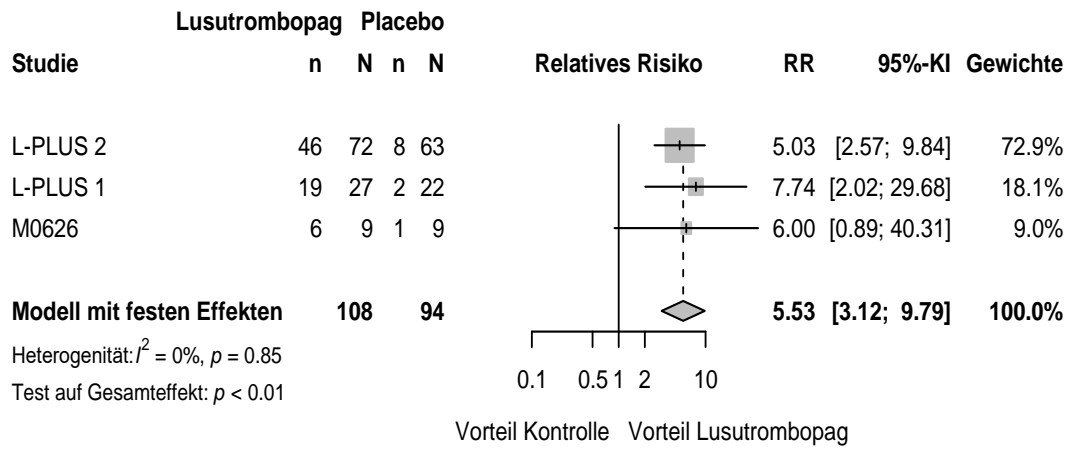
**131 Erfolgreiche_Behandlung_Thrombozytopenie_RR Baseline platelet count
(*10⁴/uL) - < 3.5**



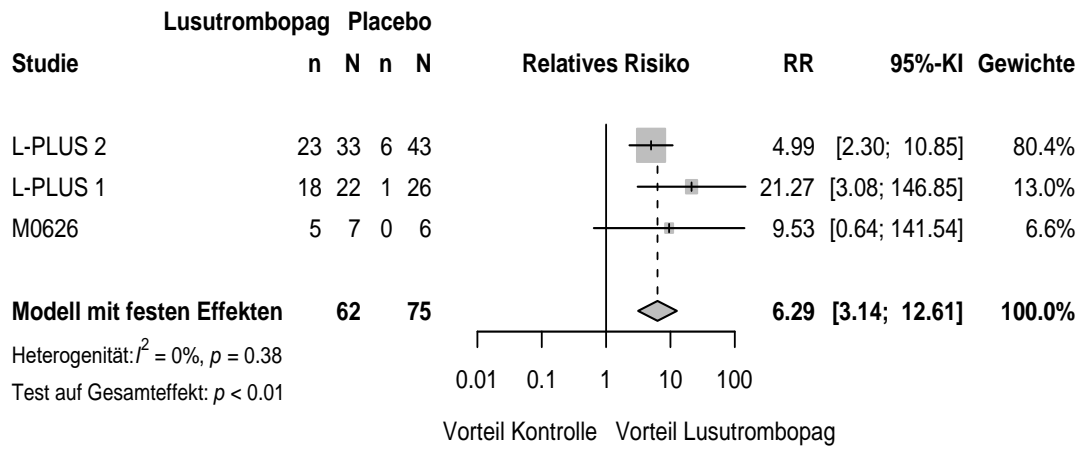
**132 Erfolgreiche_Behandlung_Thrombozytopenie_RR Baseline platelet count
(*10⁴/uL) - >= 3.5**



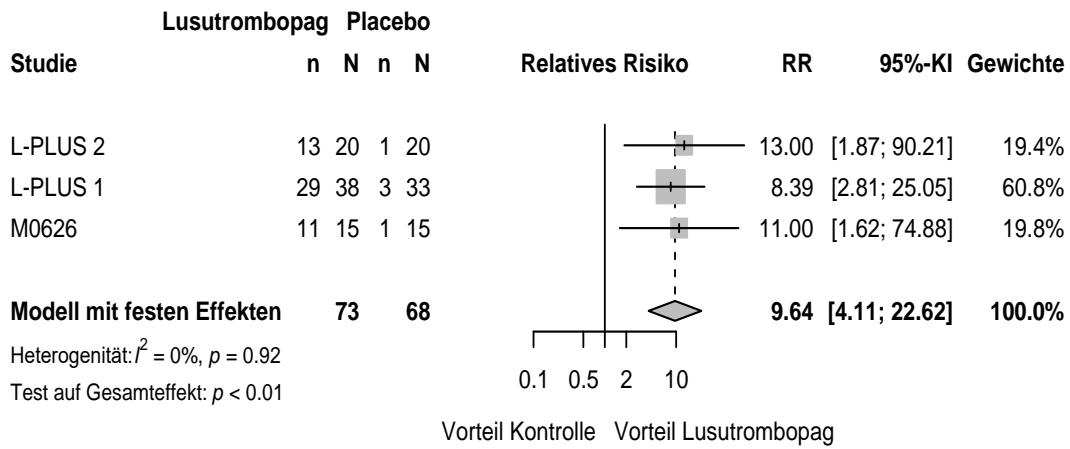
133 Erfolgreiche_Behandlung_Thrombozytopenie_RR Child-Pugh class - A



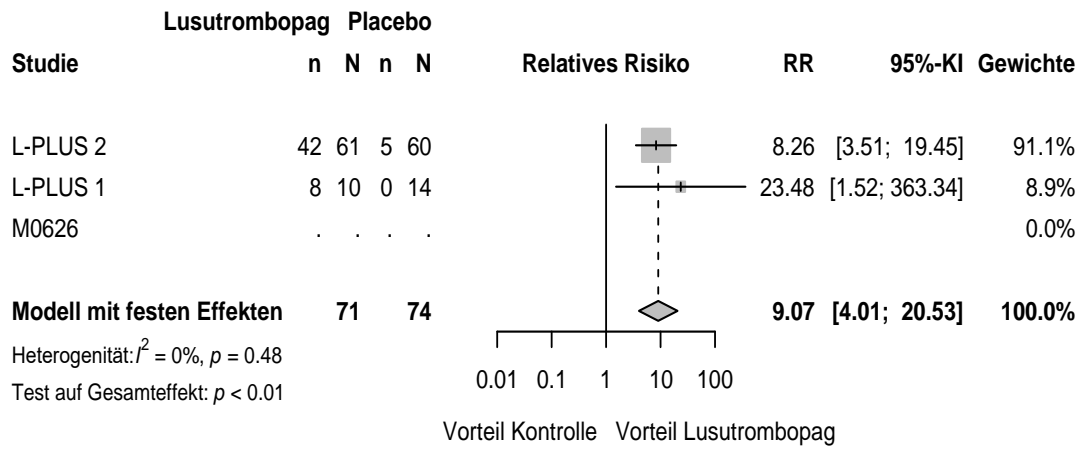
134 Erfolgreiche_Behandlung_Thrombozytopenie_RR Child-Pugh class - B



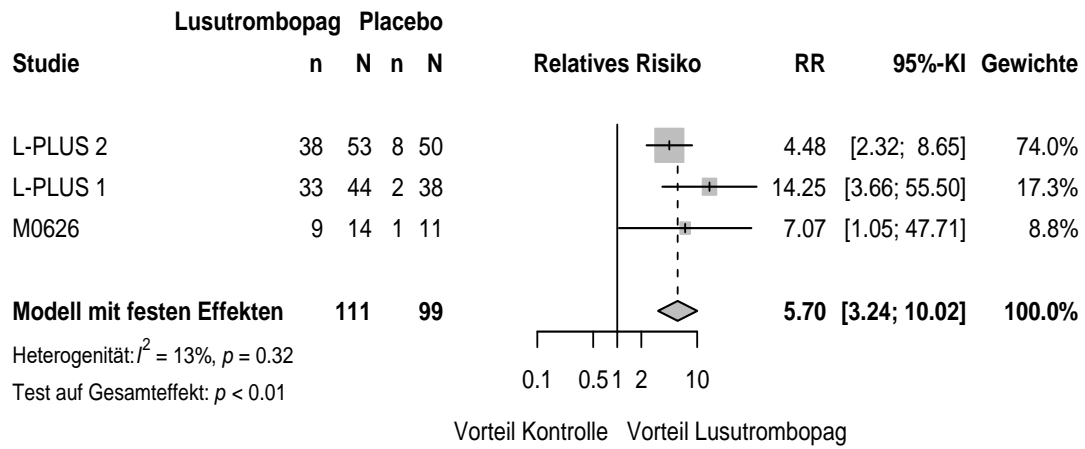
135 Erfolgreiche_Behandlung_Thrombozytopenie_RR Invasive procedure liver-related



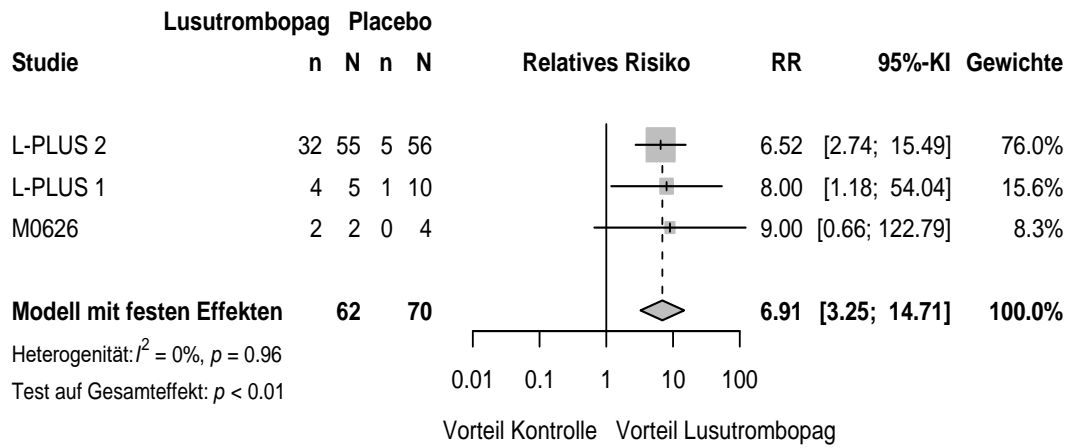
136 Erfolgreiche_Behandlung_Thrombozytopenie_RR Invasive procedure gi-related



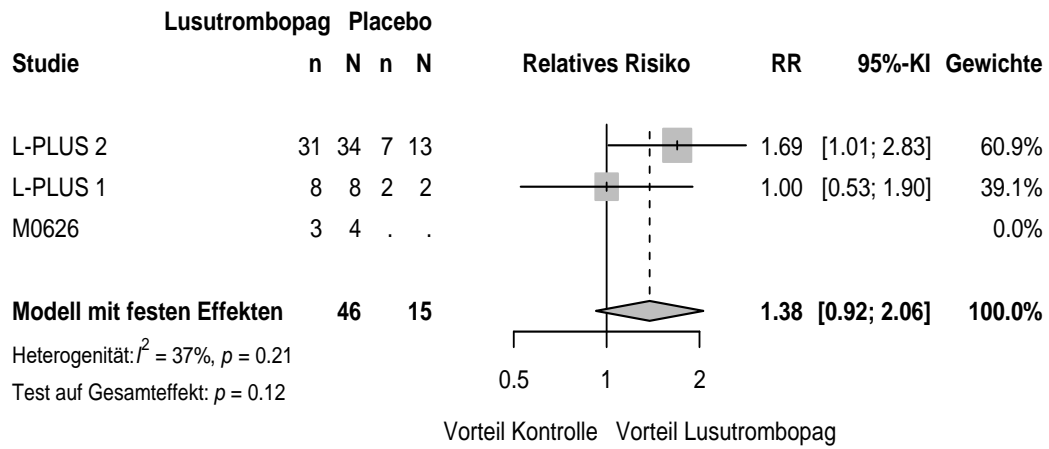
137 Erfolgreiche_Behandlung_Thrombozytopenie_RR Baseline body weight (kg) - < 75



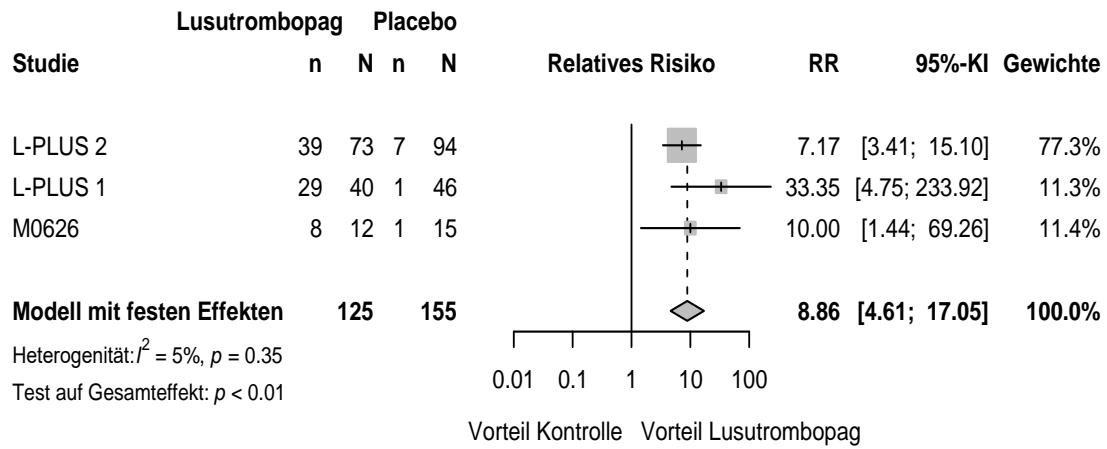
138 Erfolgreiche_Behandlung_Thrombozytopenie_RR Baseline body weight (kg) - >= 75



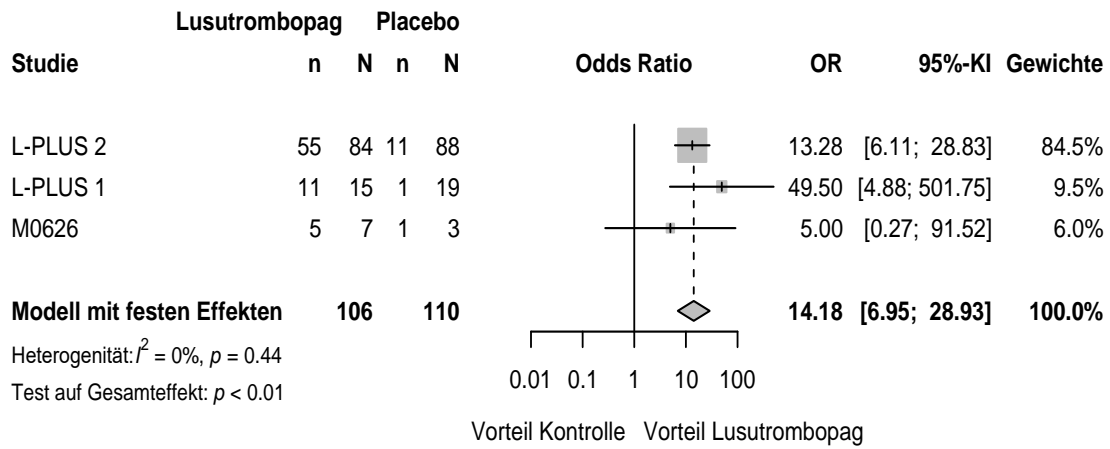
139 Erfolgreiche_Behandlung_Thrombozytopenie_RR Treatment duration (days) - < 7



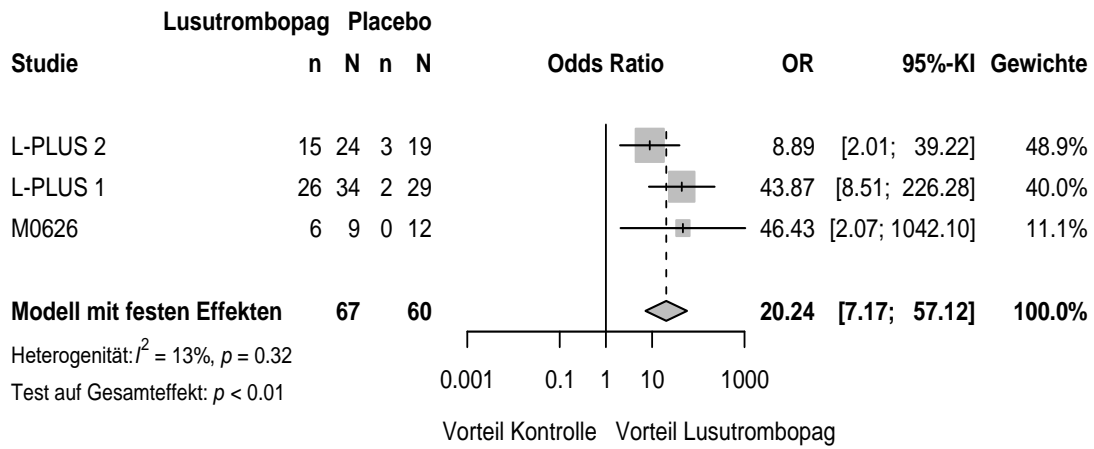
140 Erfolgreiche_Behandlung_Thrombozytopenie_RR Treatment duration (days) -7



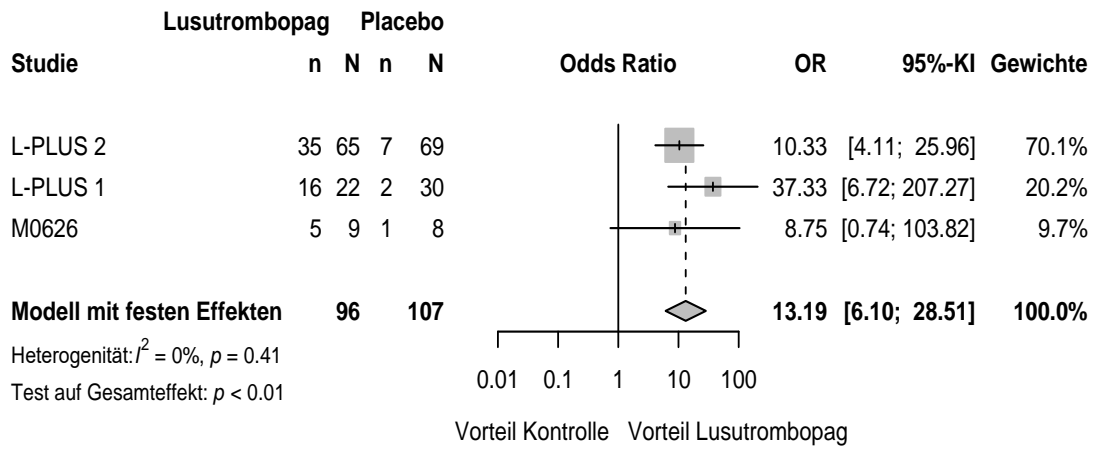
141 Erfolgreiche_Behandlung_Thrombozytopenie_OR Age (years) - < 65



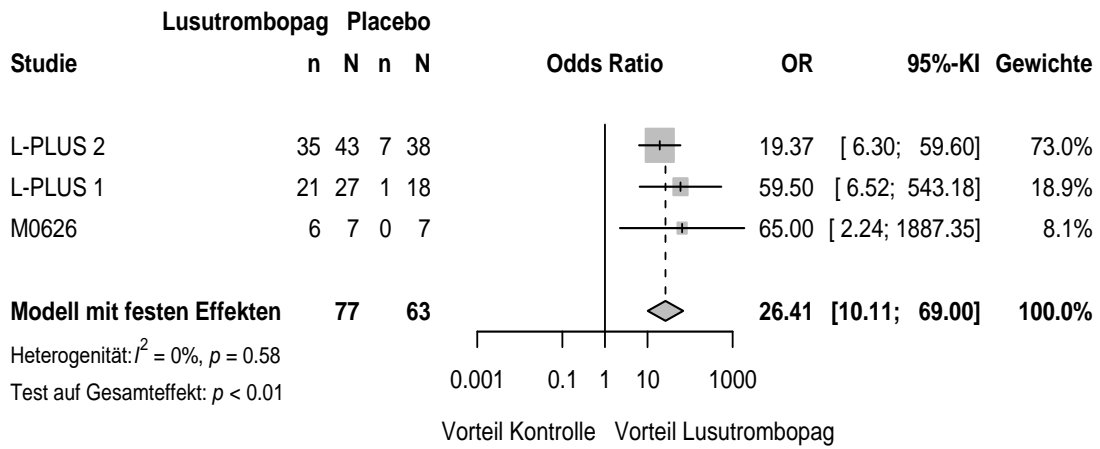
142 Erfolgreiche_Behandlung_Thrombozytopenie_OR Age (years) - >=65



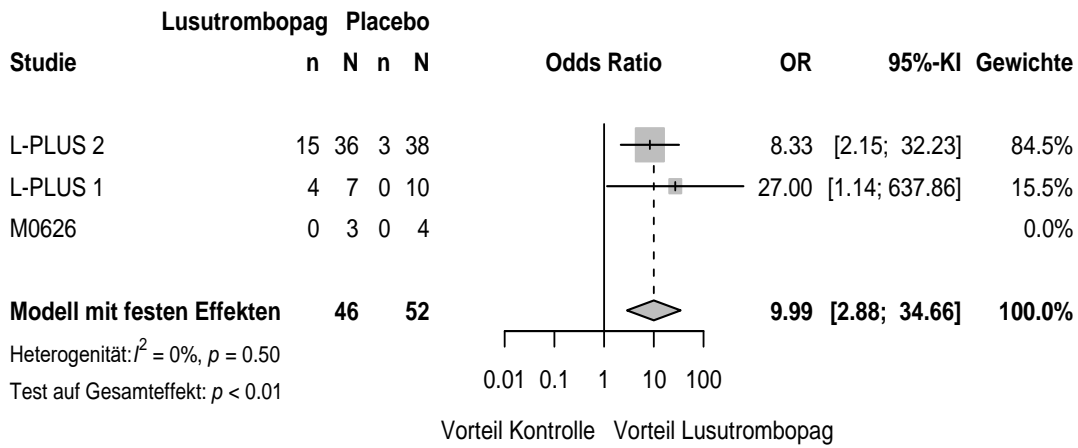
143 Erfolgreiche_Behandlung_Thrombozytopenie_OR Gender - Male



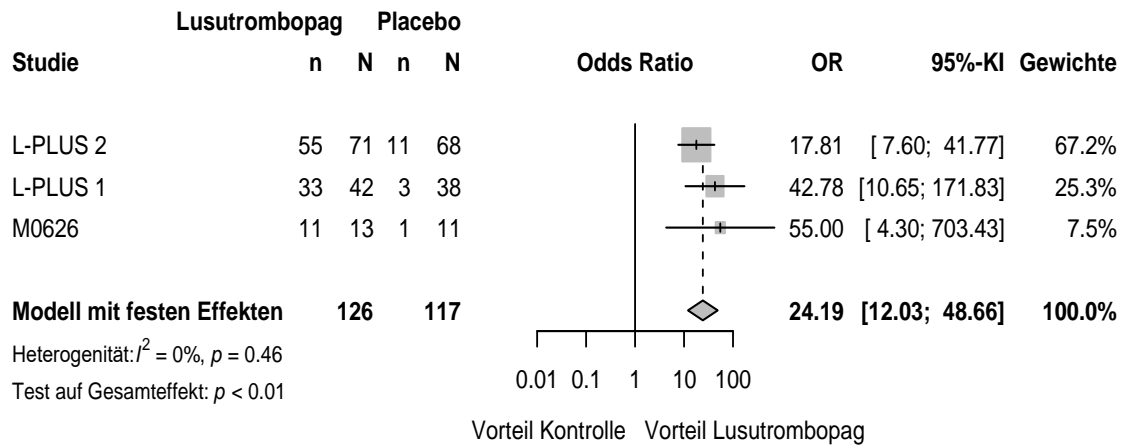
144 Erfolgreiche_Behandlung_Thrombozytopenie_OR Gender - Female



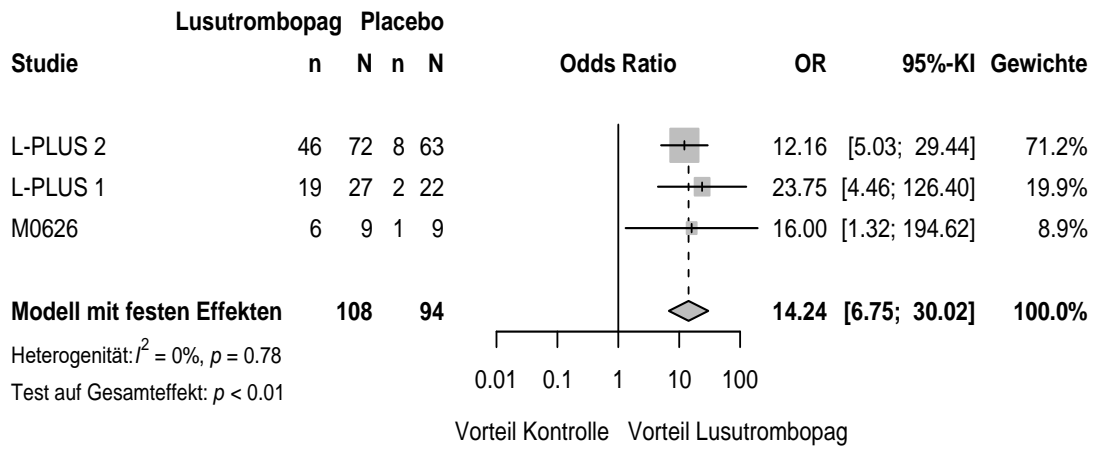
145 Erfolgreiche_Behandlung_Thrombozytopenie_OR Baseline platelet count (*10⁴/uL) - < 3.5



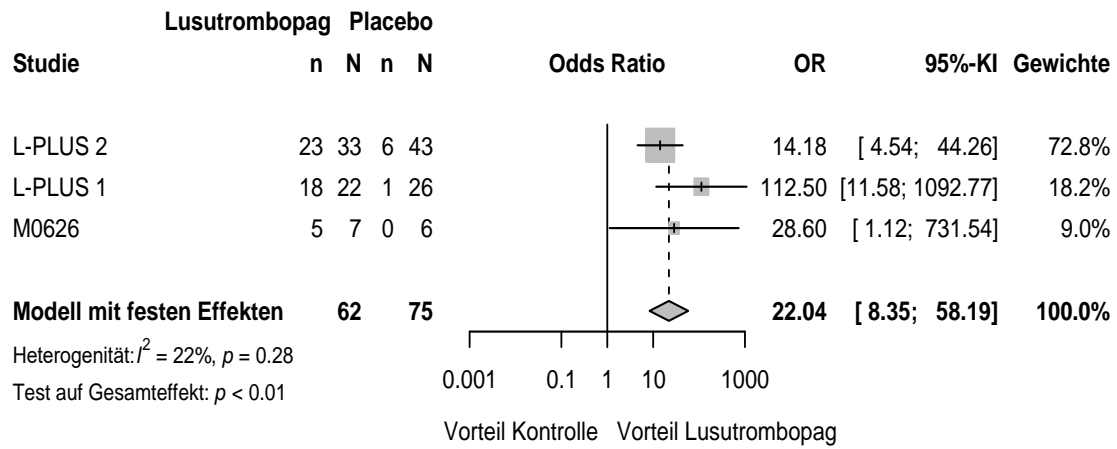
**146 Erfolgreiche_Behandlung_Thrombozytopenie_OR Baseline platelet count
(*10⁴/uL) - >= 3.5**



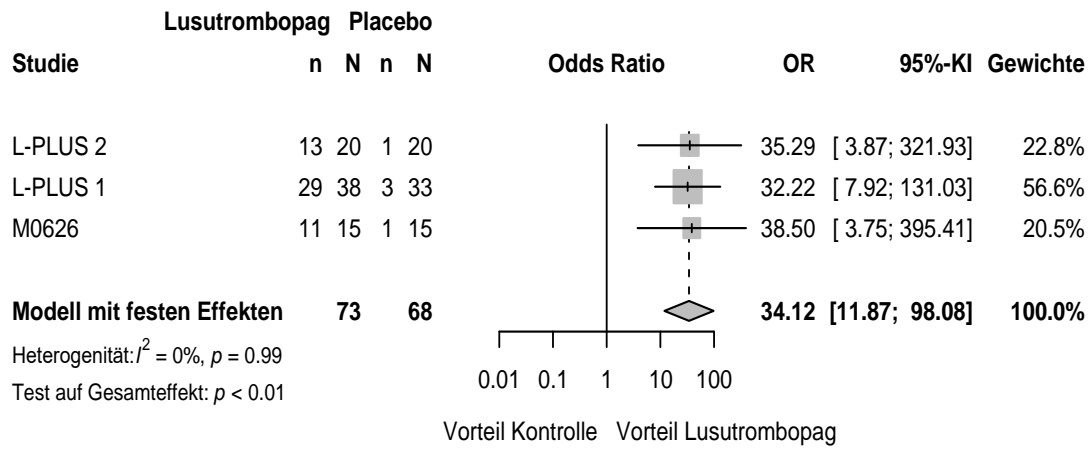
147 Erfolgreiche_Behandlung_Thrombozytopenie_OR Child-Pugh class - A



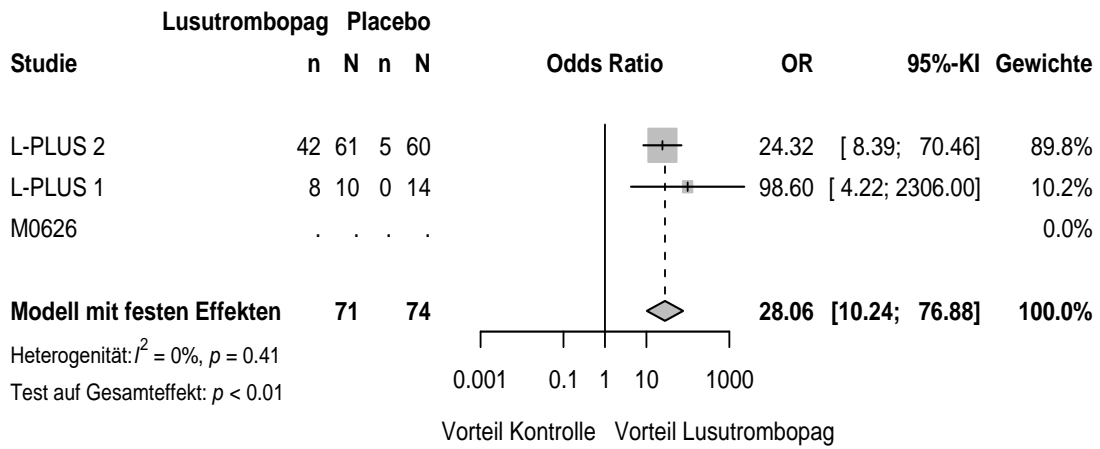
148 Erfolgreiche_Behandlung_Thrombozytopenie_OR Child-Pugh class - B



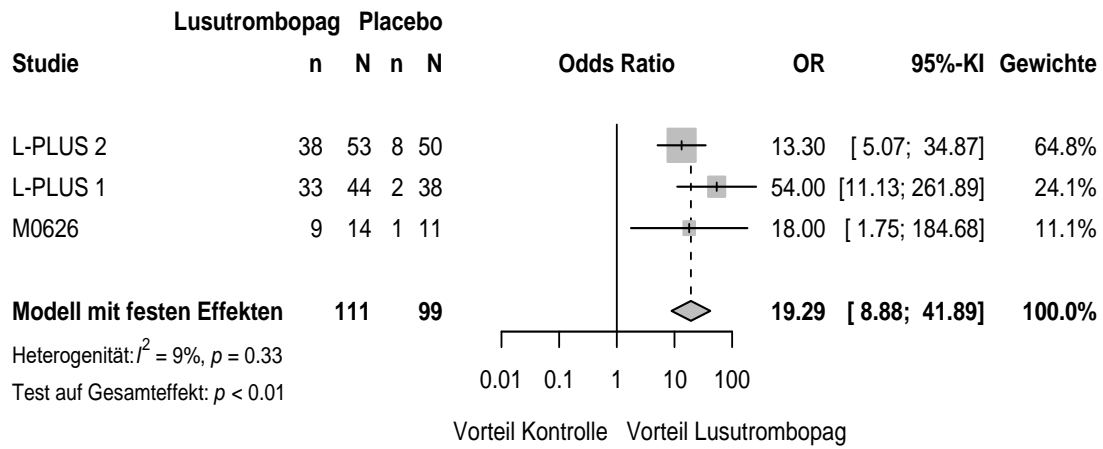
149 Erfolgreiche_Behandlung_Thrombozytopenie_OR Invasive procedure liver-related



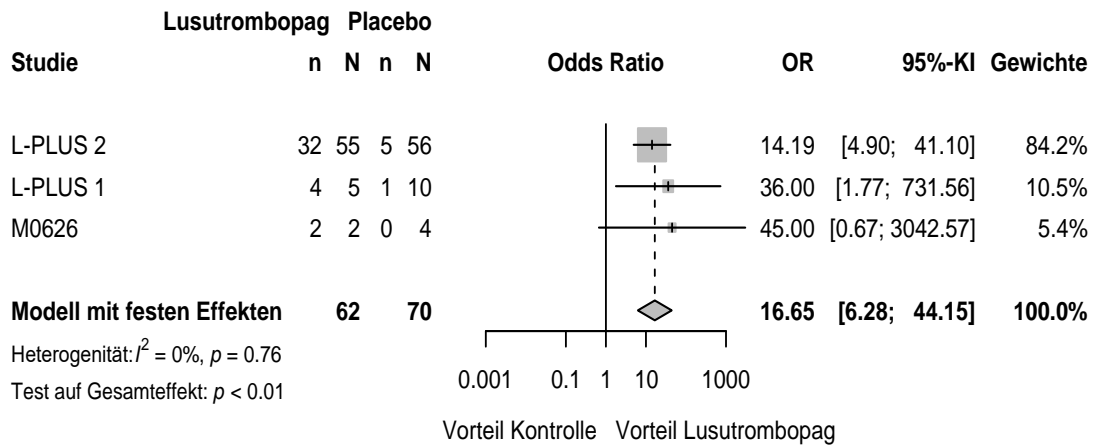
150 Erfolgreiche_Behandlung_Thrombozytopenie_OR Invasive procedure gi-related



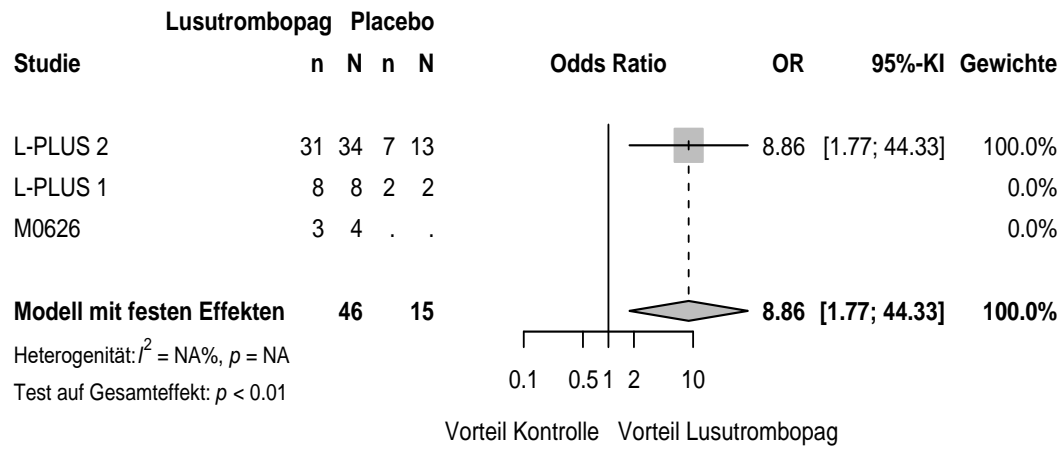
151 Erfolgreiche_Behandlung_Thrombozytopenie_OR Baseline body weight (kg) - < 75



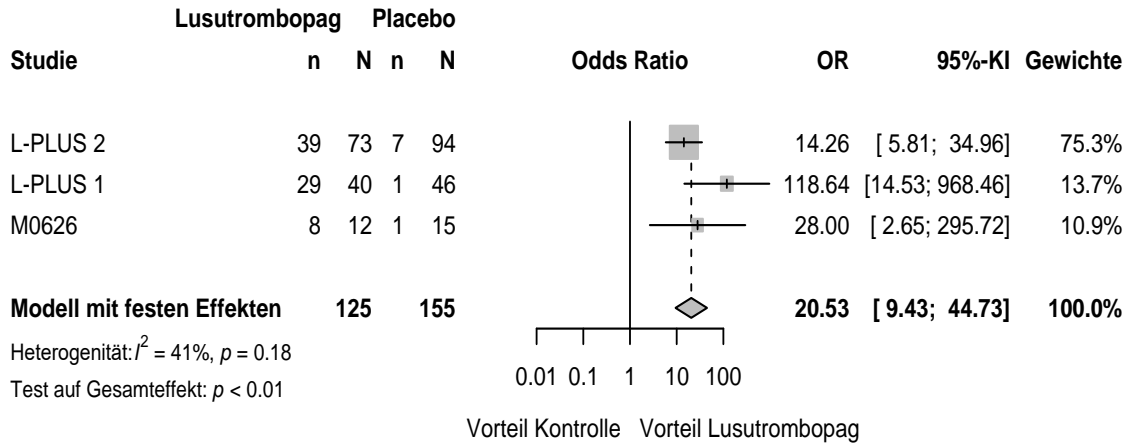
152 Erfolgreiche_Behandlung_Thrombozytopenie_OR Baseline body weight (kg) - >= 75



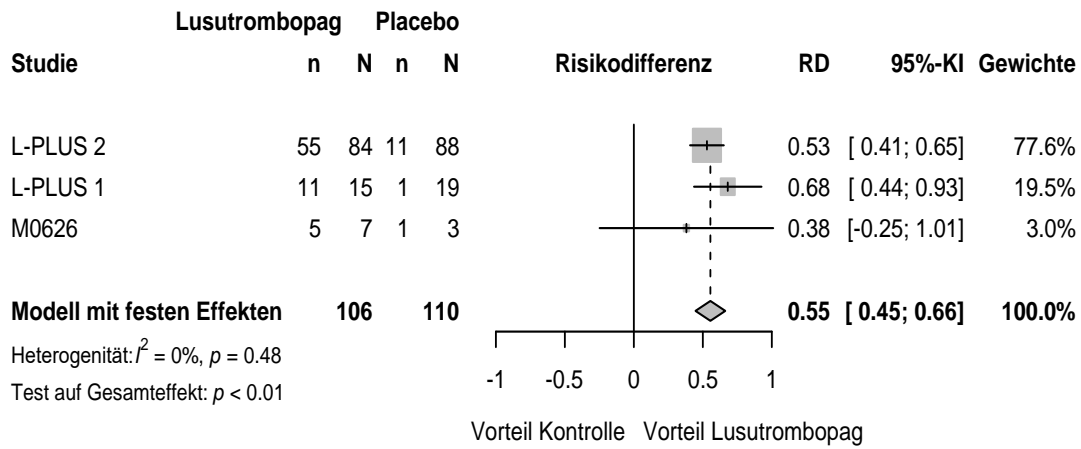
153 Erfolgreiche_Behandlung_Thrombozytopenie_OR Treatment duration (days) - < 7



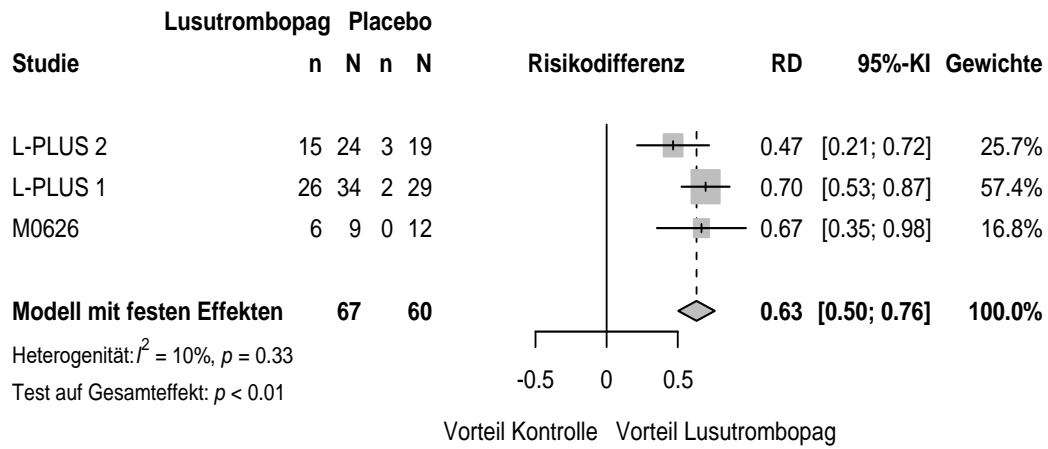
154 Erfolgreiche_Behandlung_Thrombozytopenie_OR Treatment duration (days) -7



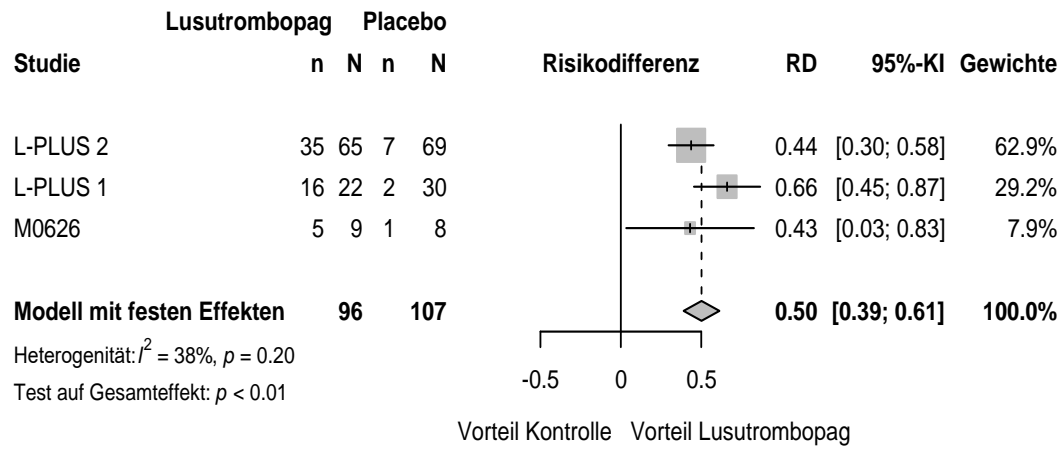
155 Erfolgreiche_Behandlung_Thrombozytopenie_RD Age (years) - < 65



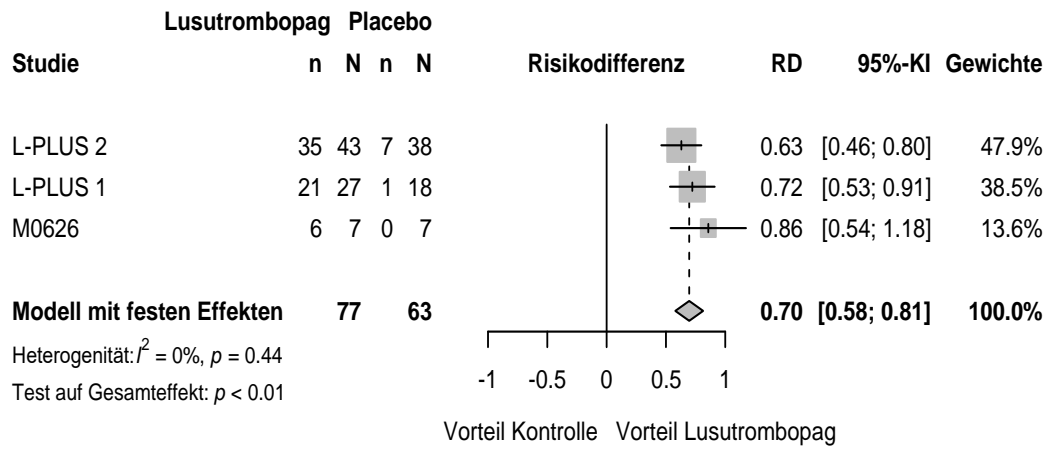
156 Erfolgreiche_Behandlung_Thrombozytopenie_RD Age (years) - >=65



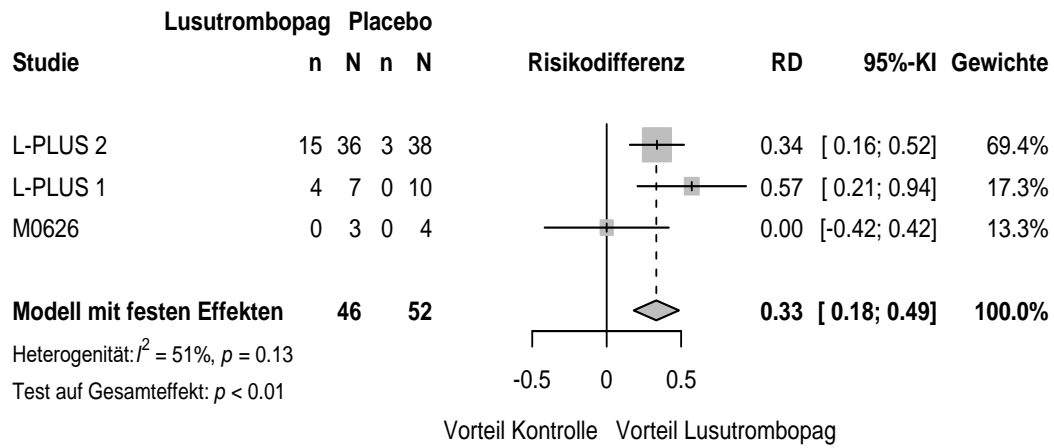
157 Erfolgreiche_Behandlung_Thrombozytopenie_RD Gender - Male



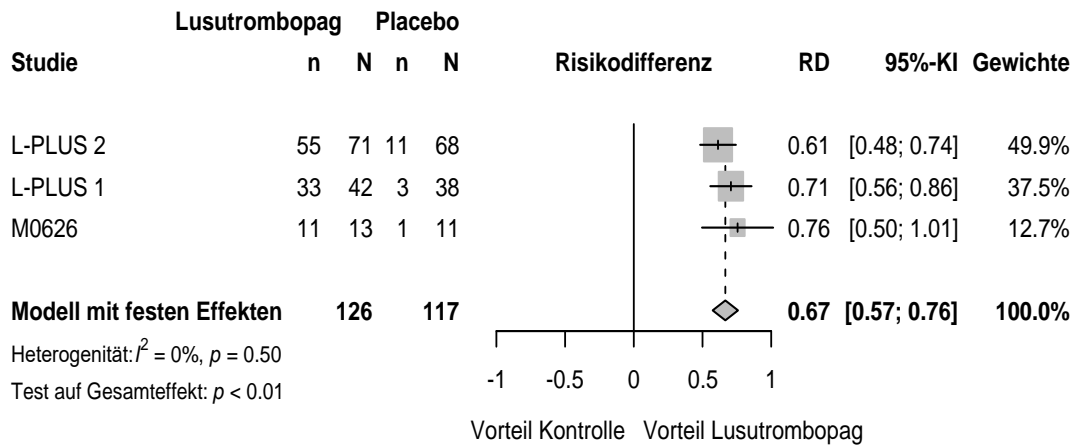
158 Erfolgreiche_Behandlung_Thrombozytopenie_RD Gender - Female



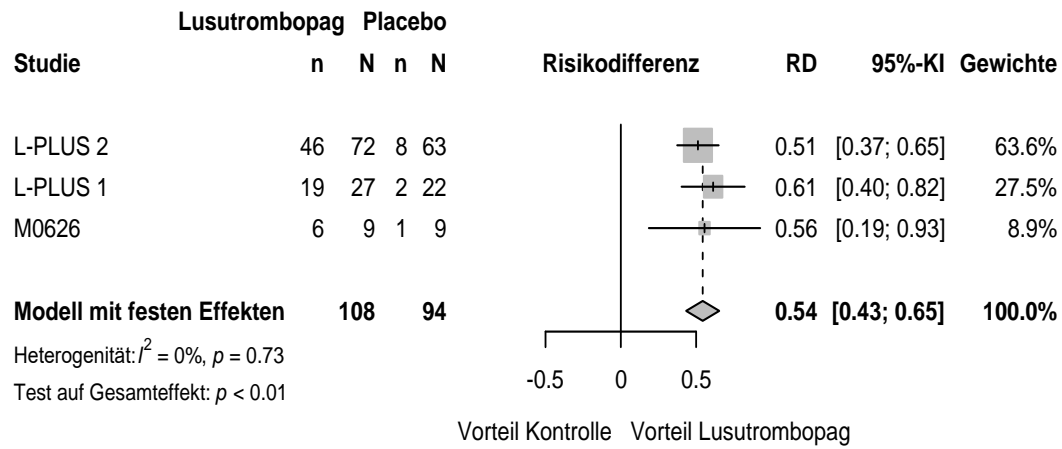
159 Erfolgreiche_Behandlung_Thrombozytopenie_RD Baseline platelet count (*10⁴/uL) - < 3.5



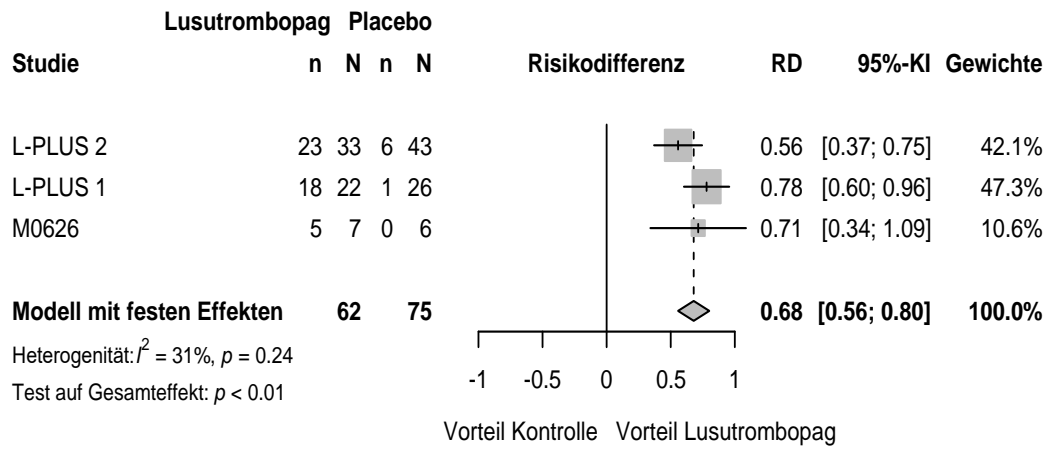
160 Erfolgreiche_Behandlung_Thrombozytopenie_RD Baseline platelet count (*10⁴/uL) - >= 3.5



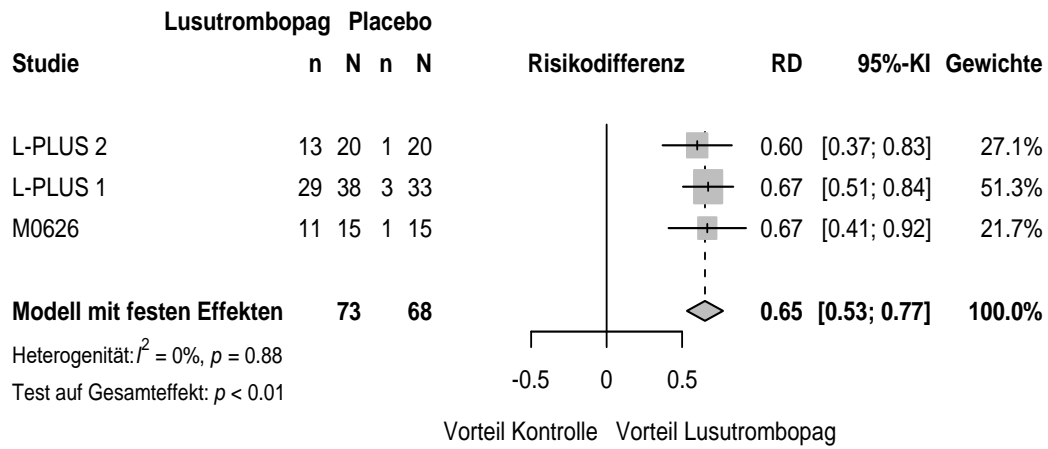
161 Erfolgreiche_Behandlung_Thrombozytopenie_RD Child-Pugh class - A



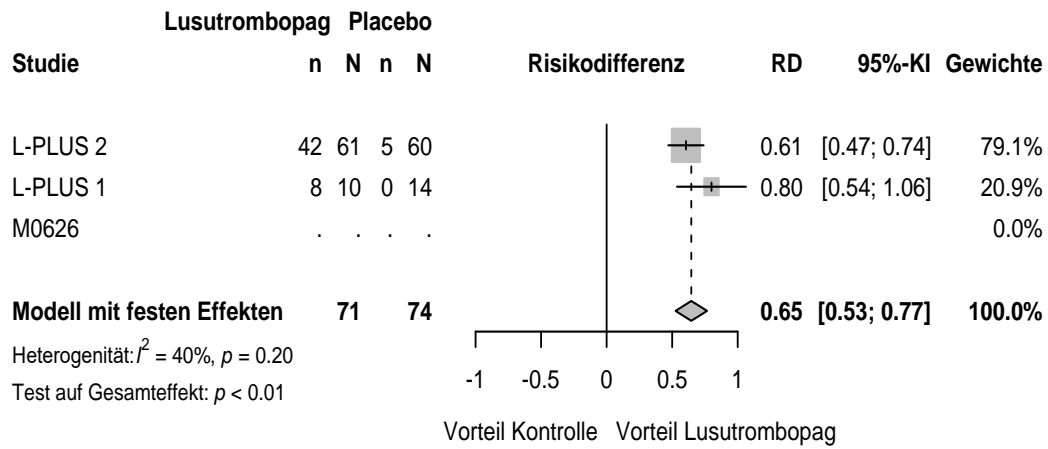
162 Erfolgreiche_Behandlung_Thrombozytopenie_RD Child-Pugh class - B



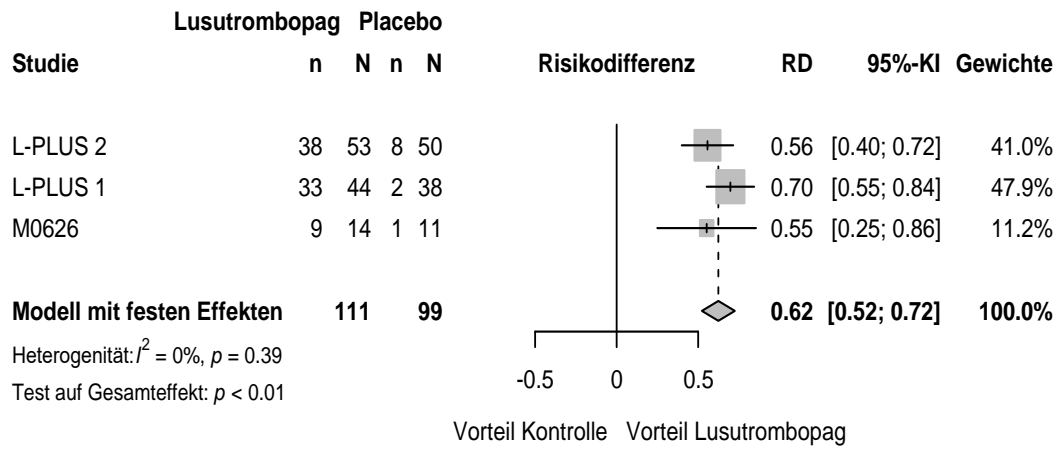
163 Erfolgreiche_Behandlung_Thrombozytopenie_RD Invasive procedure liver-related



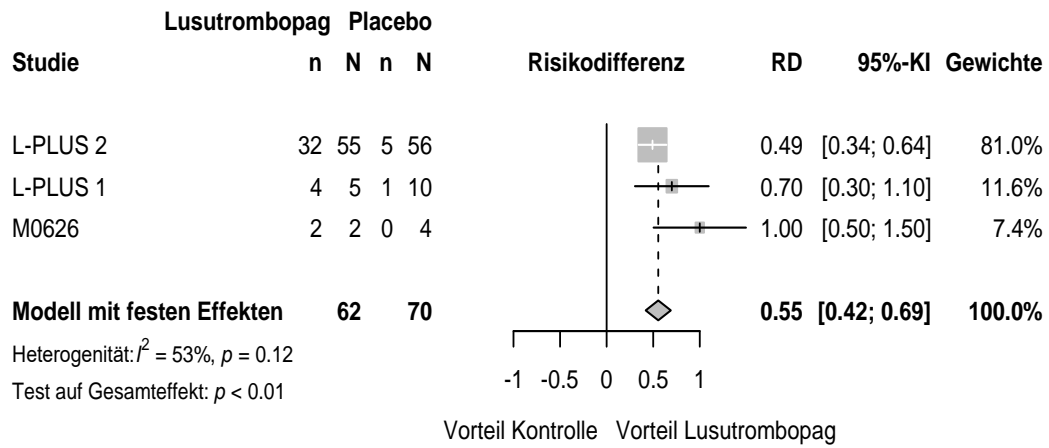
164 Erfolgreiche_Behandlung_Thrombozytopenie_RD Invasive procedure gi-related



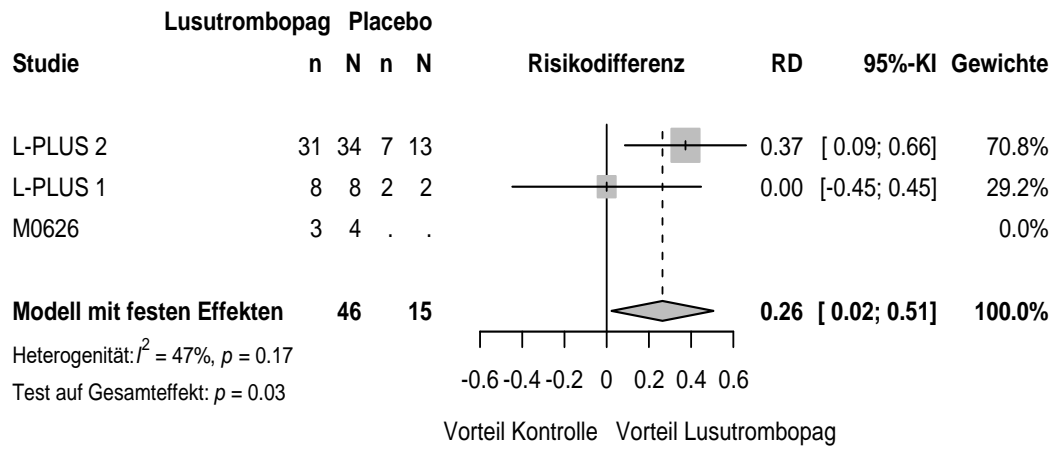
165 Erfolgreiche_Behandlung_Thrombozytopenie_RD Baseline body weight (kg) - < 75



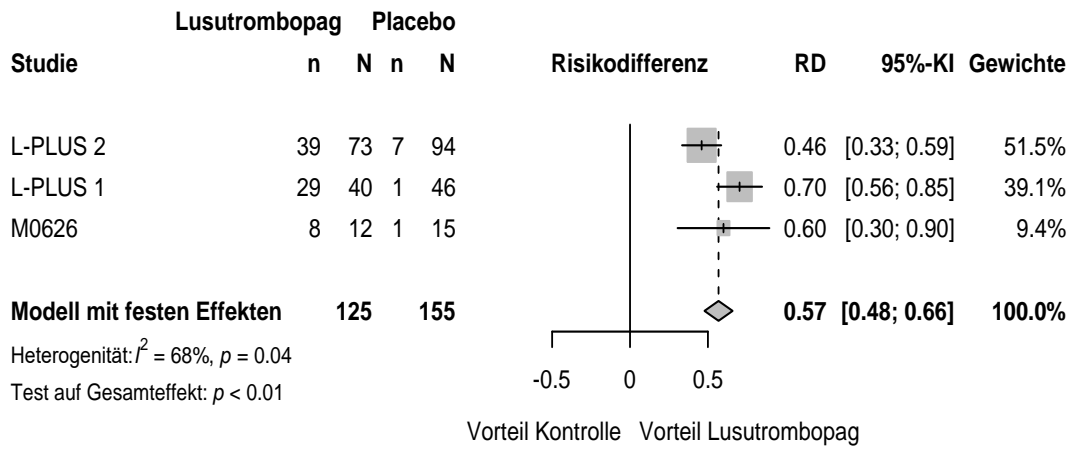
166 Erfolgreiche_Behandlung_Thrombozytopenie_RD Baseline body weight (kg) - >= 75



167 Erfolgreiche_Behandlung_Thrombozytopenie_RD Treatment duration (days) - < 7

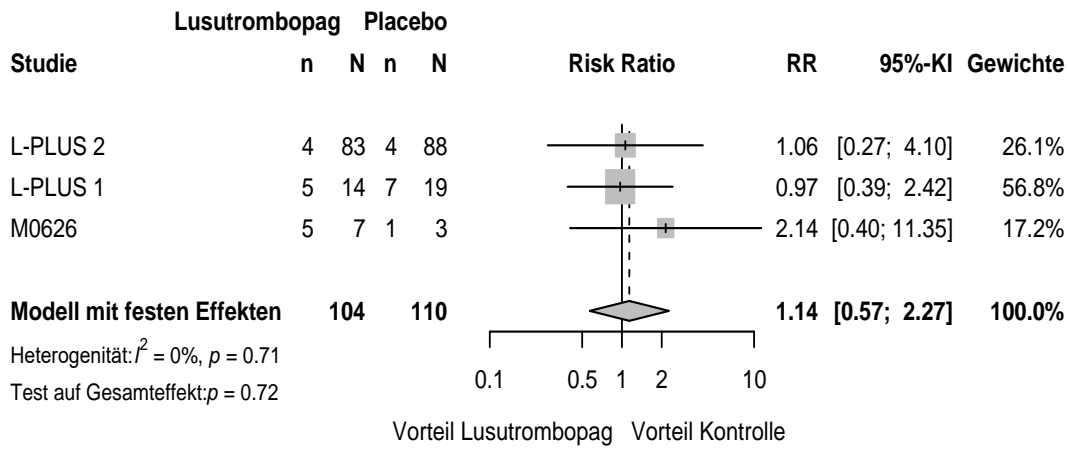


168 Erfolgreiche_Behandlung_Thrombozytopenie_RD Treatment duration (days) -7

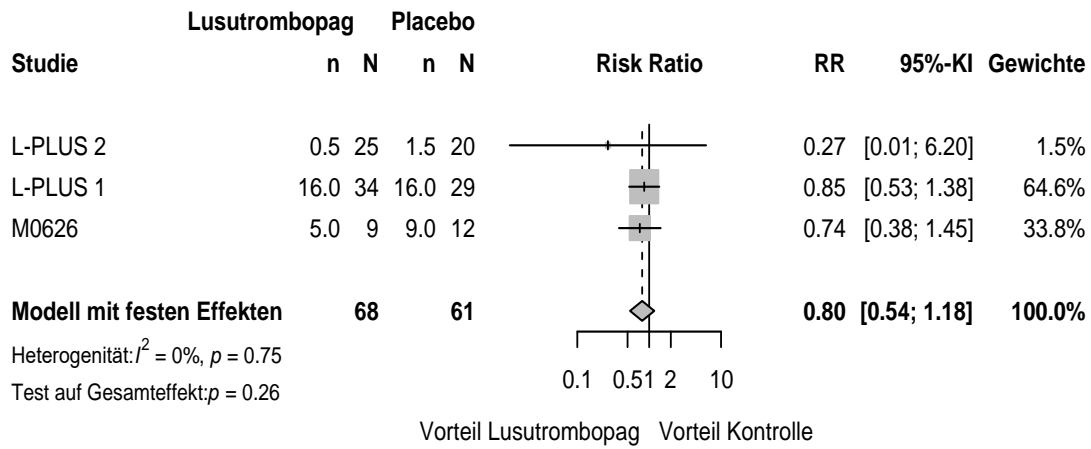


Forest Plots der Subgruppen (Sicherheit)

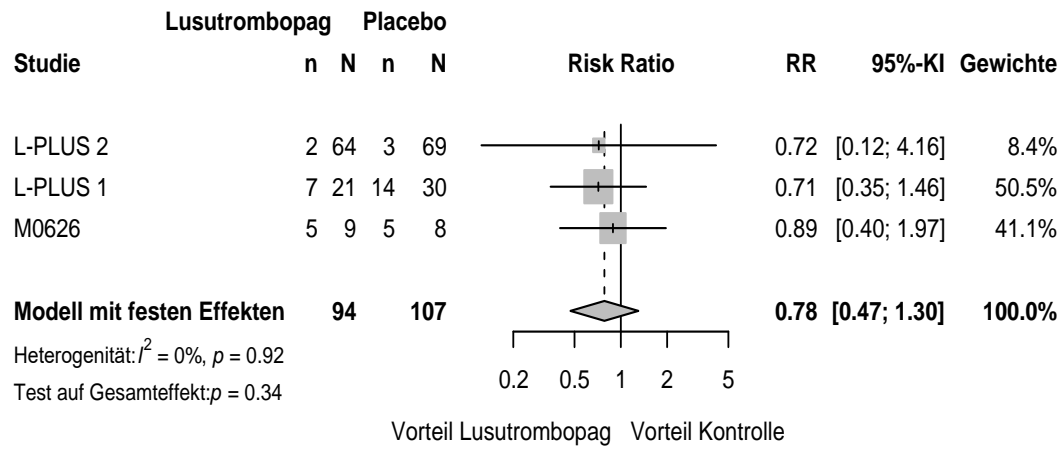
1 Schwere UE_RR Age (years) - < 65



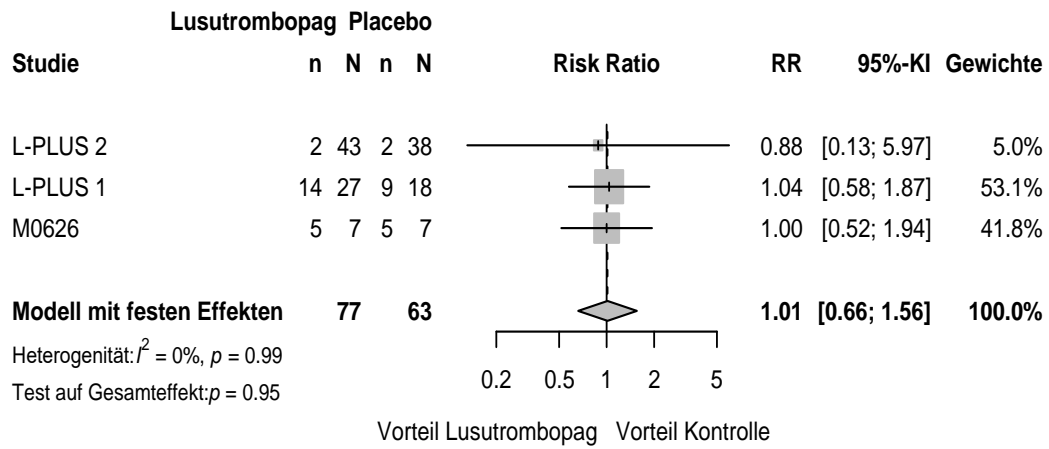
2 Schwere UE_RR Age (years) - >=65



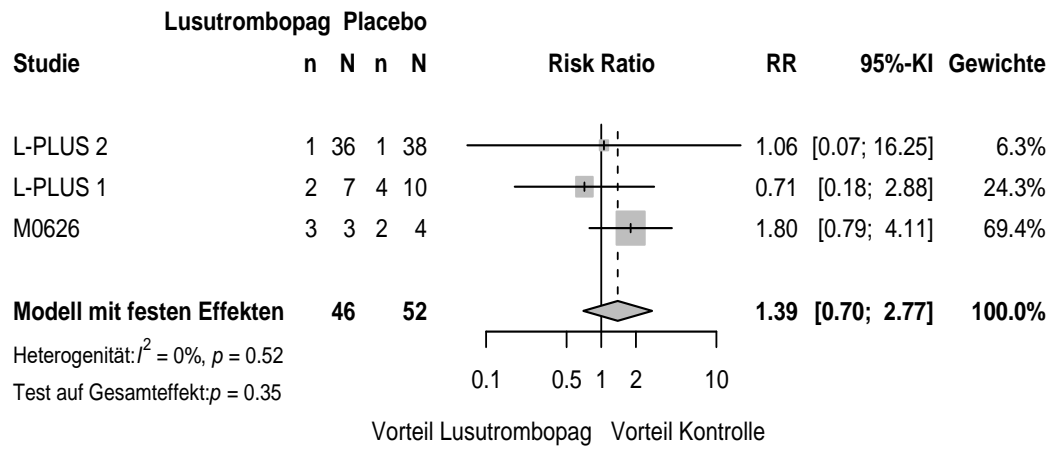
3 Schwere UE_RR Gender - Male



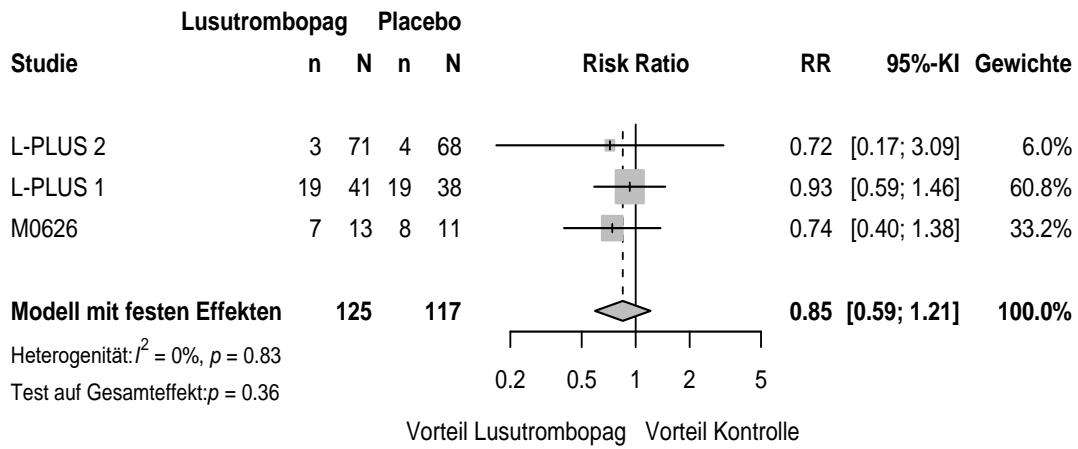
4 Schwere UE_RR Gender - Female



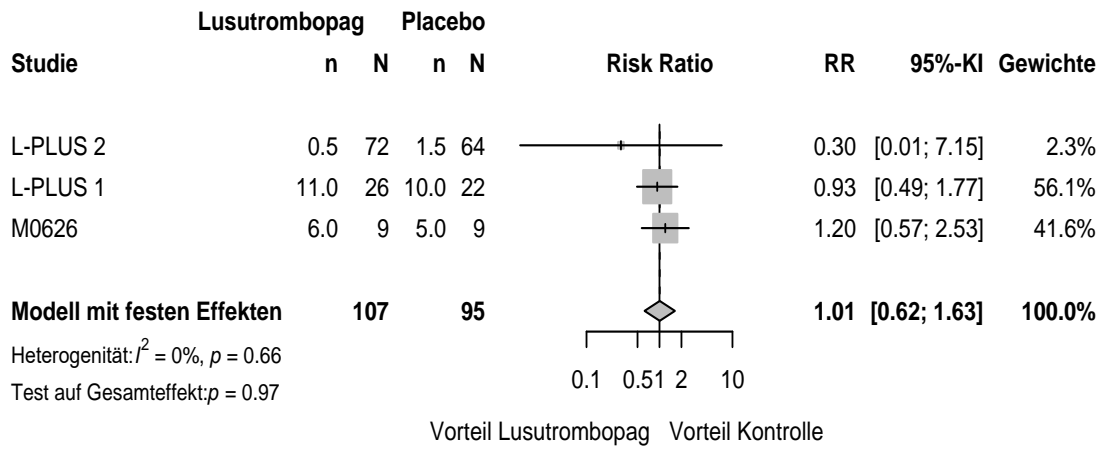
5 Schwere UE_RR Baseline platelet count (*10⁴/uL) - < 3.5



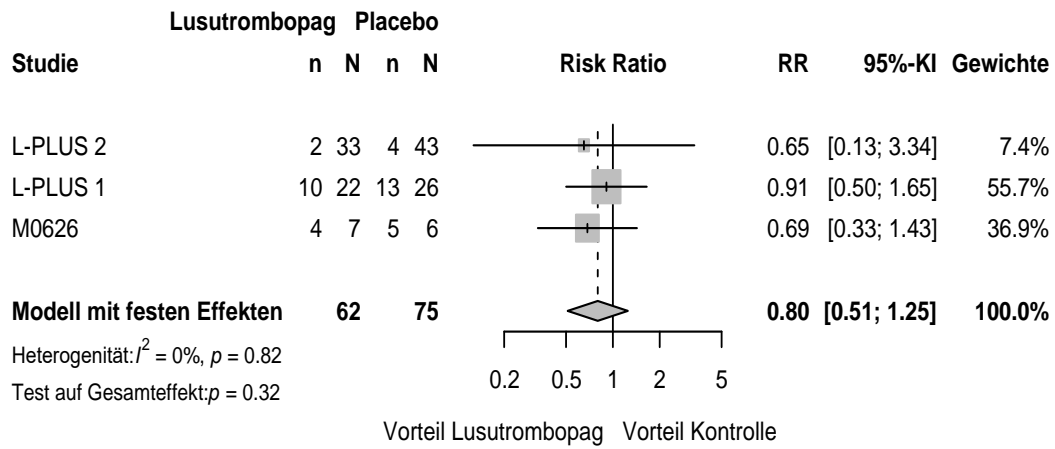
6 Schwere UE_RR Baseline platelet count (*10⁴/uL) - >= 3.5



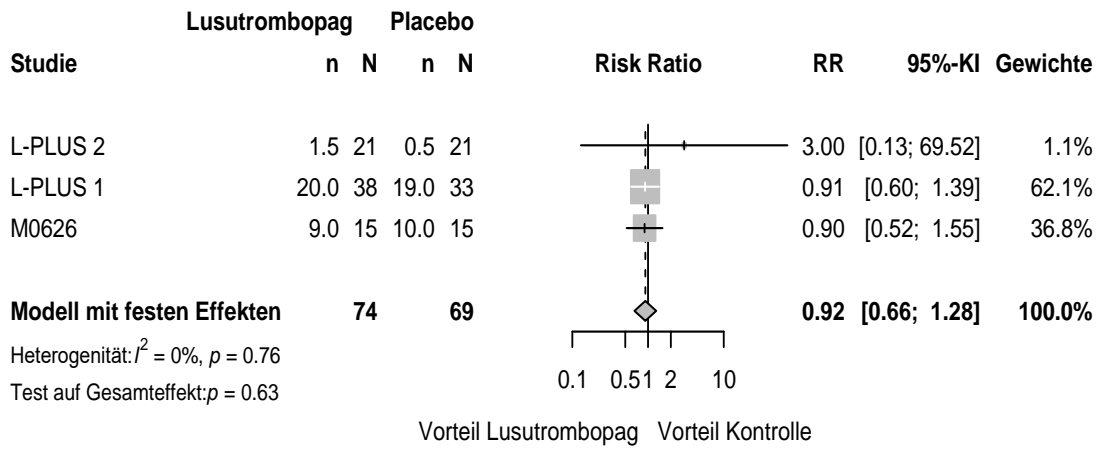
7 Schwere UE_RR Child-Pugh class - A



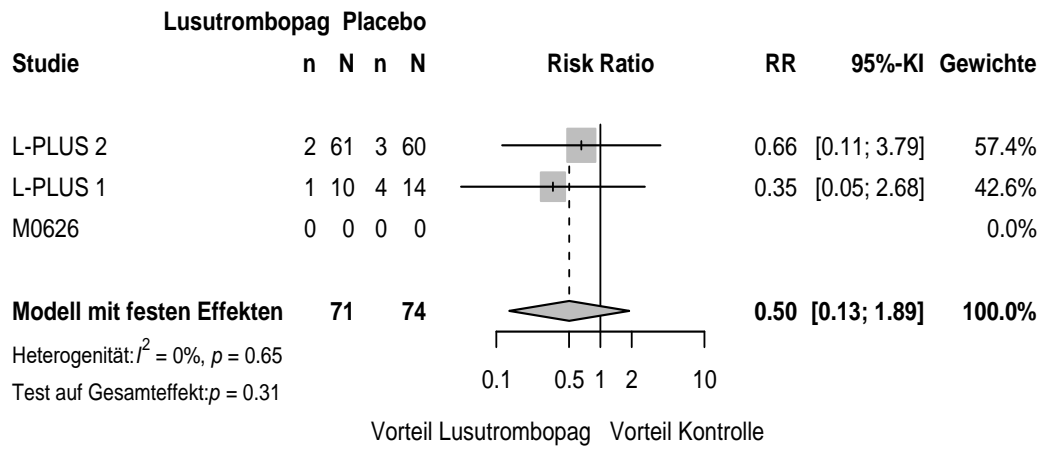
8 Schwere UE_RR Child-Pugh class - B



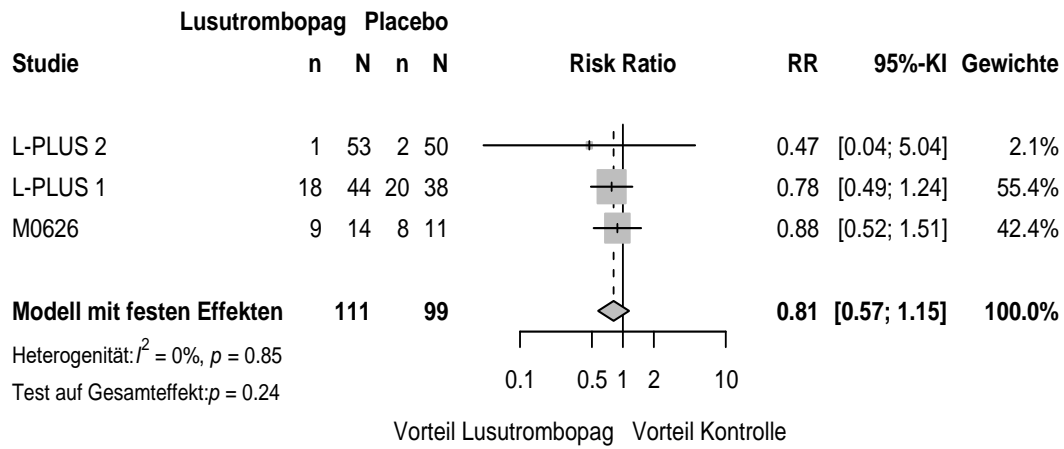
9 Schwere UE_RR Invasive procedure liver-related



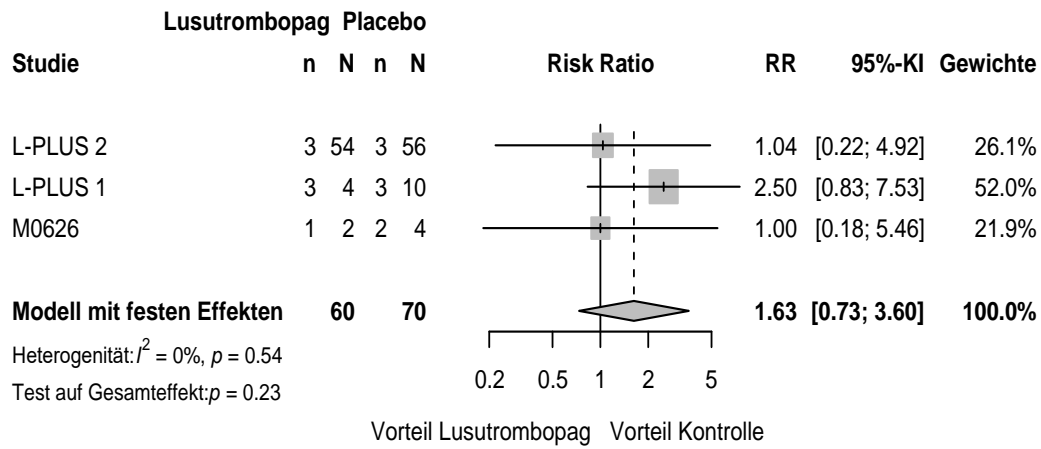
10 Schwere UE_RR Invasive procedure gi-related



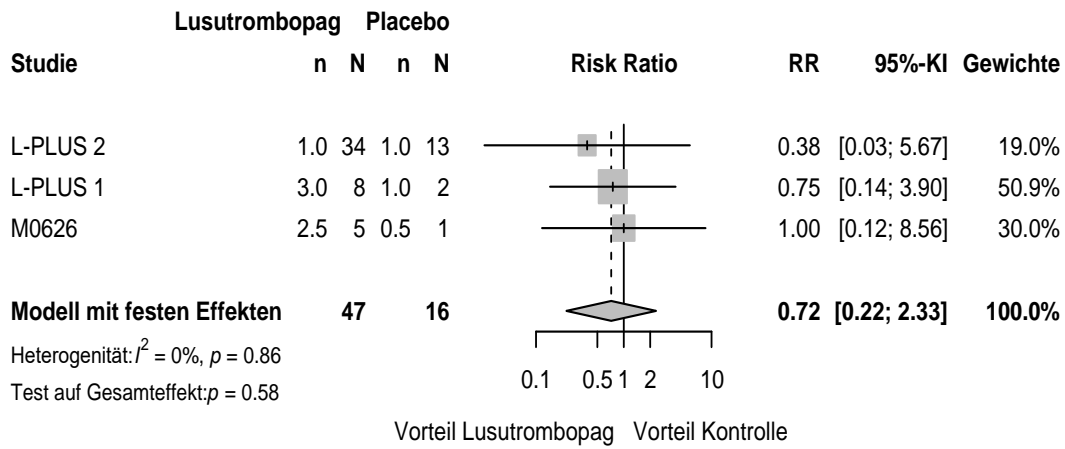
11 Schwere UE_RR Baseline body weight (kg) - < 75



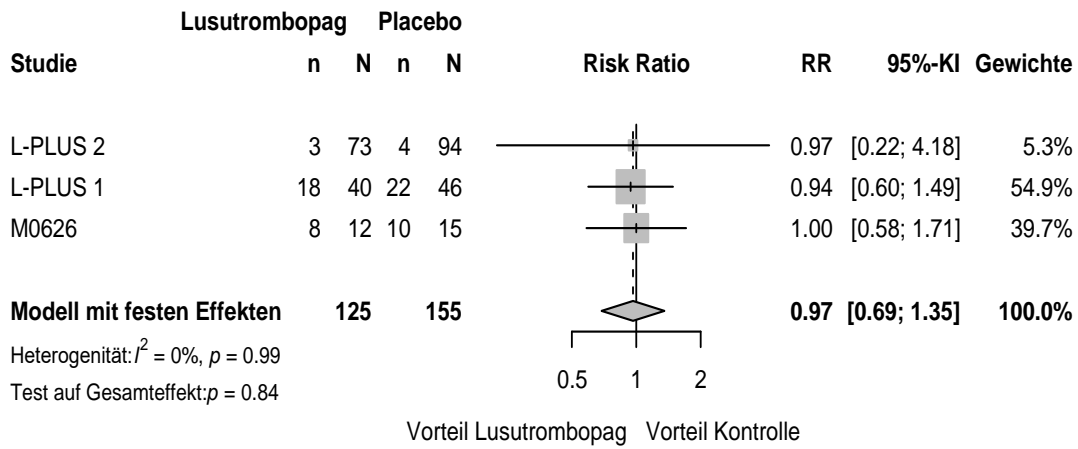
12 Schwere UE_RR Baseline body weight (kg) - >= 75



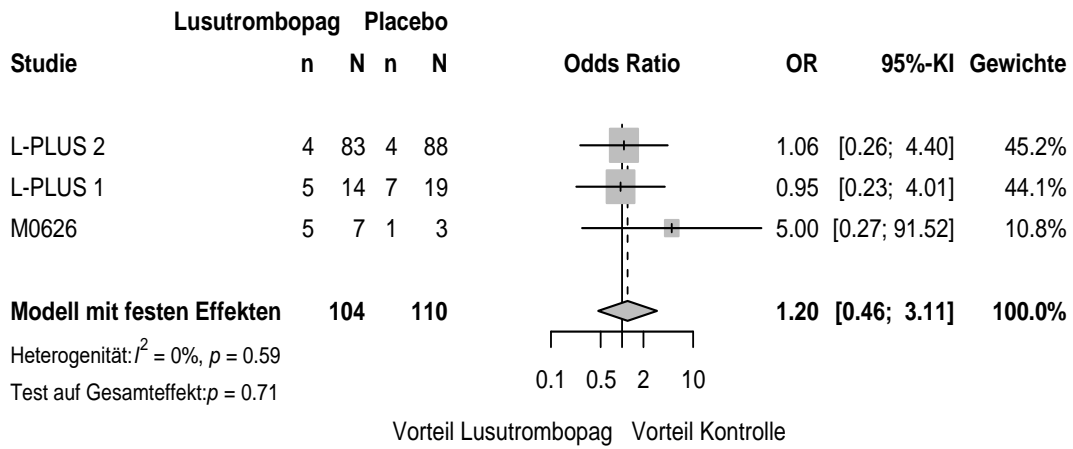
13 Schwere UE_RR Treatment duration (days) - < 7



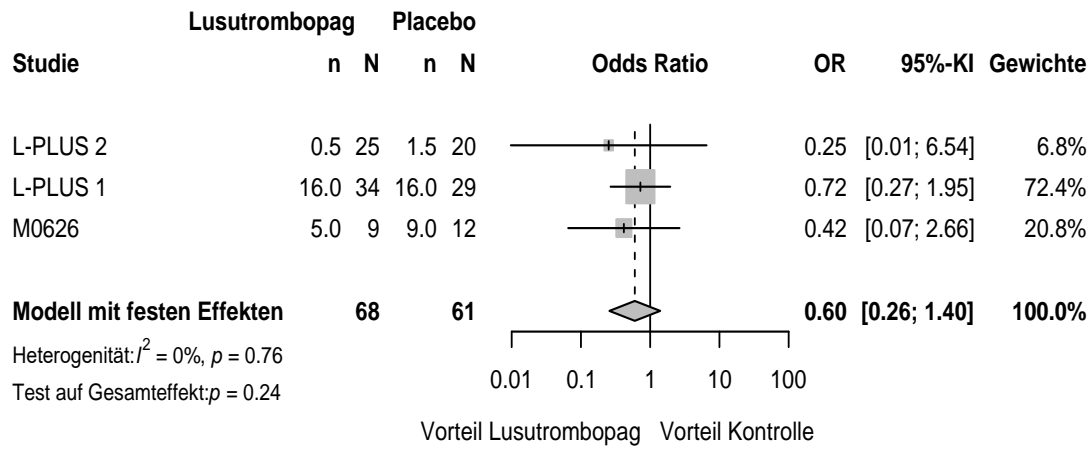
14 Schwere UE_RR Treatment duration (days) -7



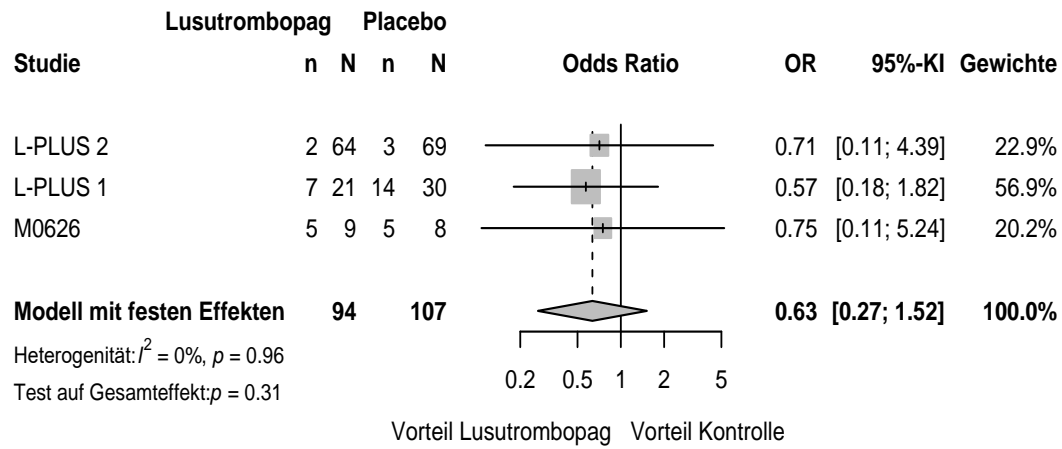
15 Schwere UE_OR Age (years) - < 65



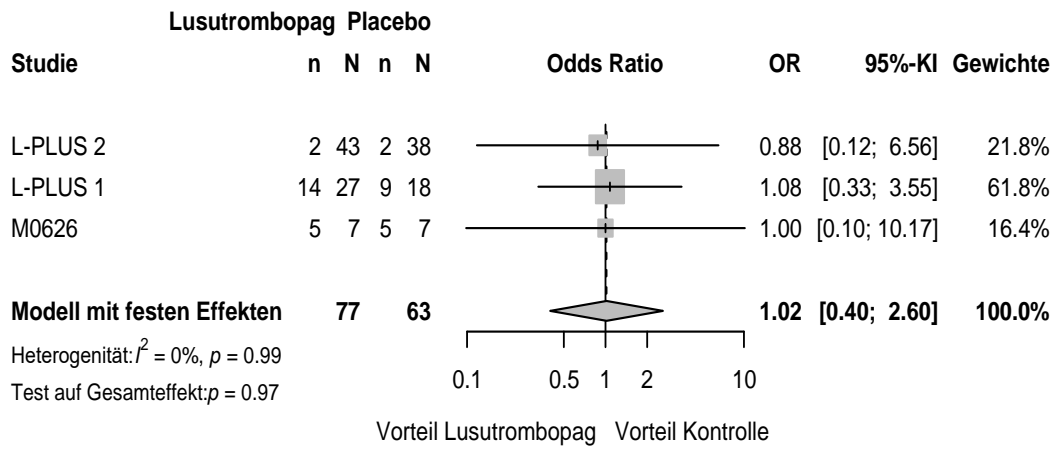
16 Schwere UE_OR Age (years) - >=65



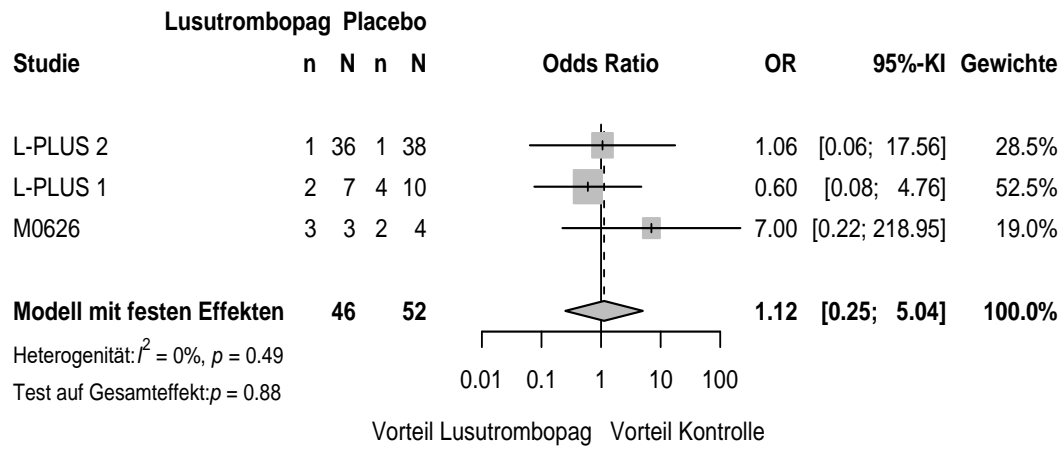
17 Schwere UE_OR Gender - Male



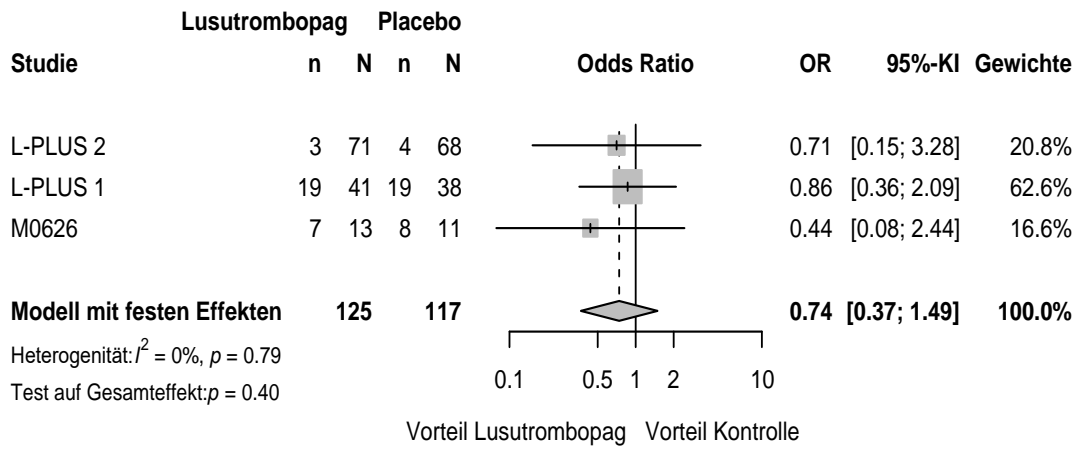
18 Schwere UE_OR Gender - Female



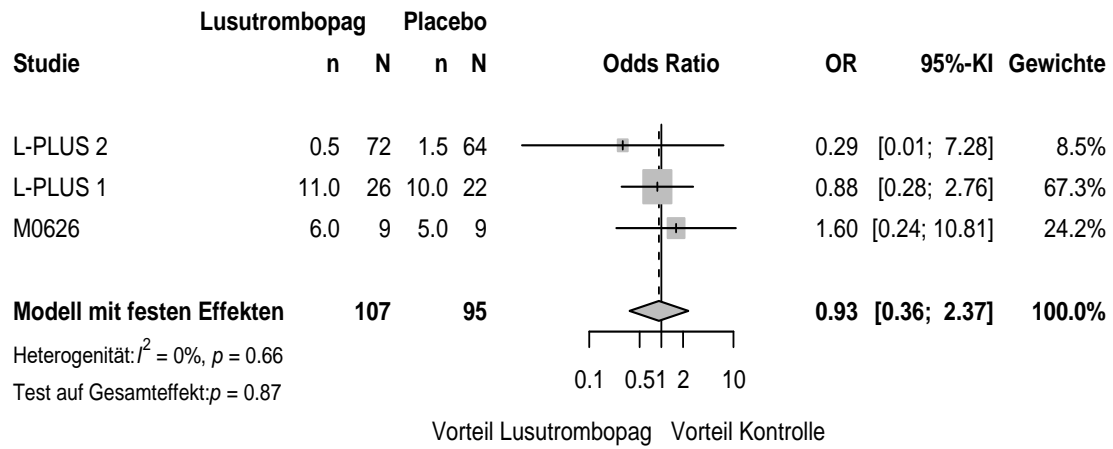
19 Schwere UE_OR Baseline platelet count (*10⁴/uL) - < 3.5



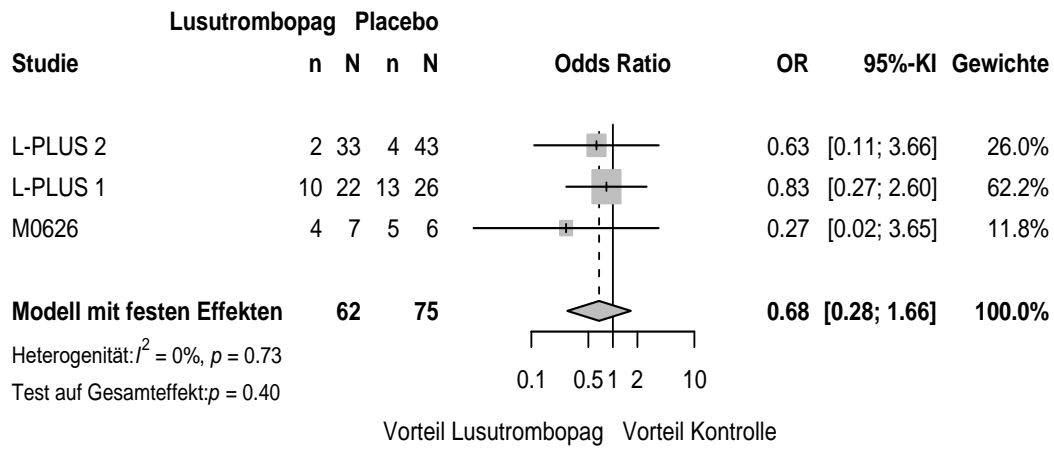
20 Schwere UE_OR Baseline platelet count (*10⁴/uL) - >= 3.5



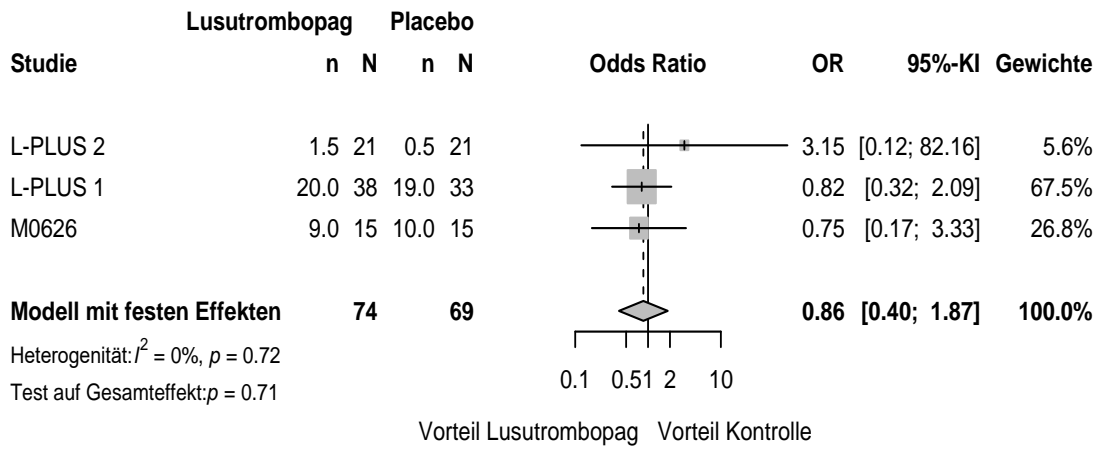
21 Schwere UE_OR Child-Pugh class - A



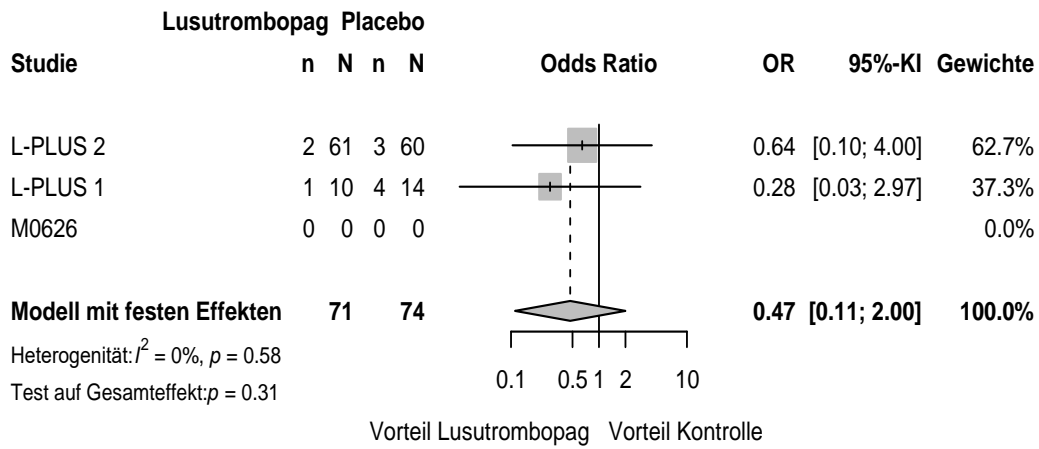
22 Schwere UE_OR Child-Pugh class - B



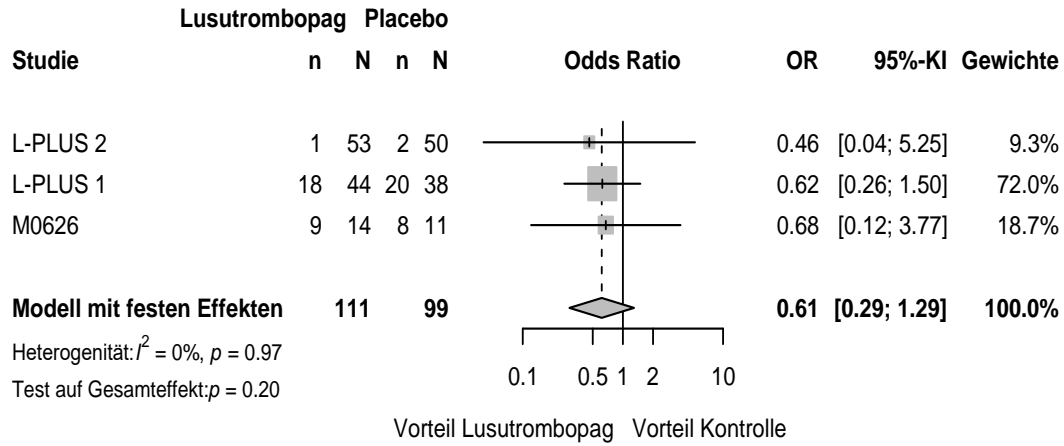
23 Schwere UE_OR Invasive procedure liver-related



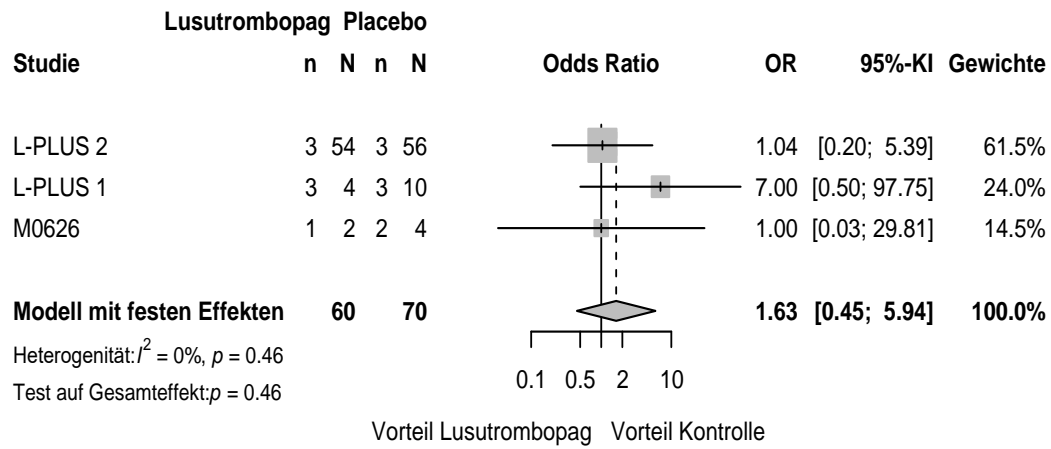
24 Schwere UE_OR Invasive procedure gi-related



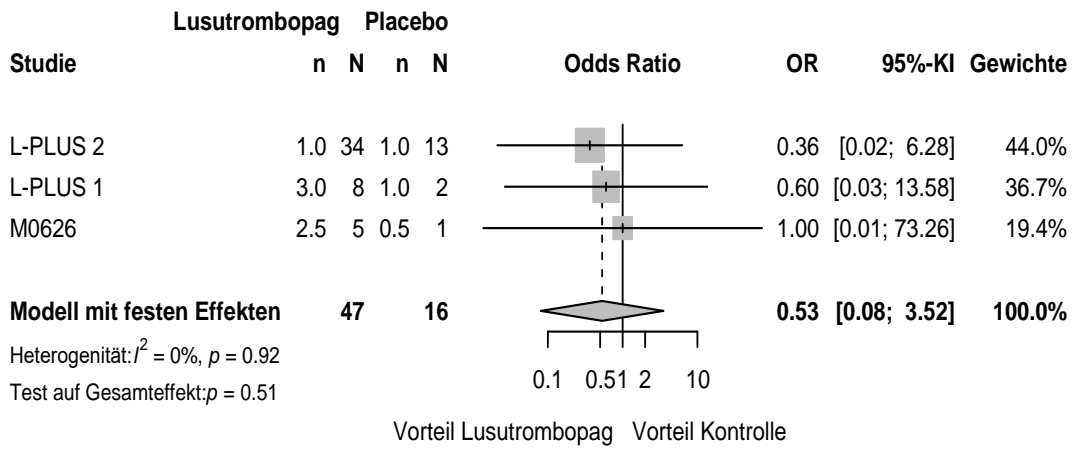
25 Schwere UE_OR Baseline body weight (kg) - < 75



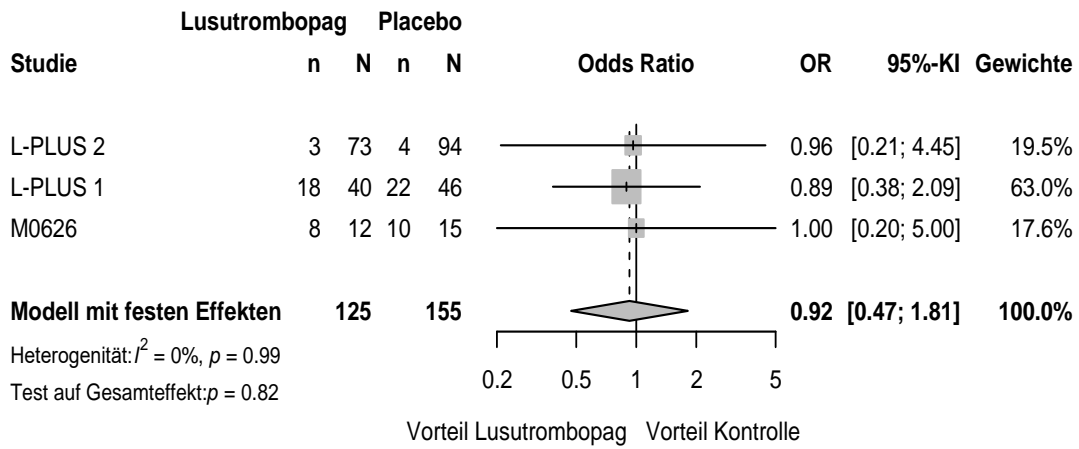
26 Schwere UE_OR Baseline body weight (kg) - >= 75



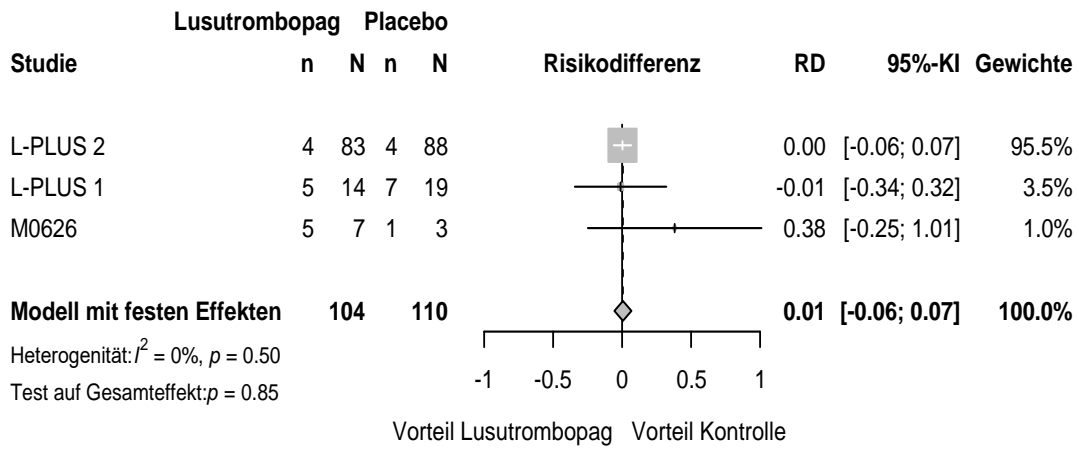
27 Schwere UE_OR Treatment duration (days) - < 7



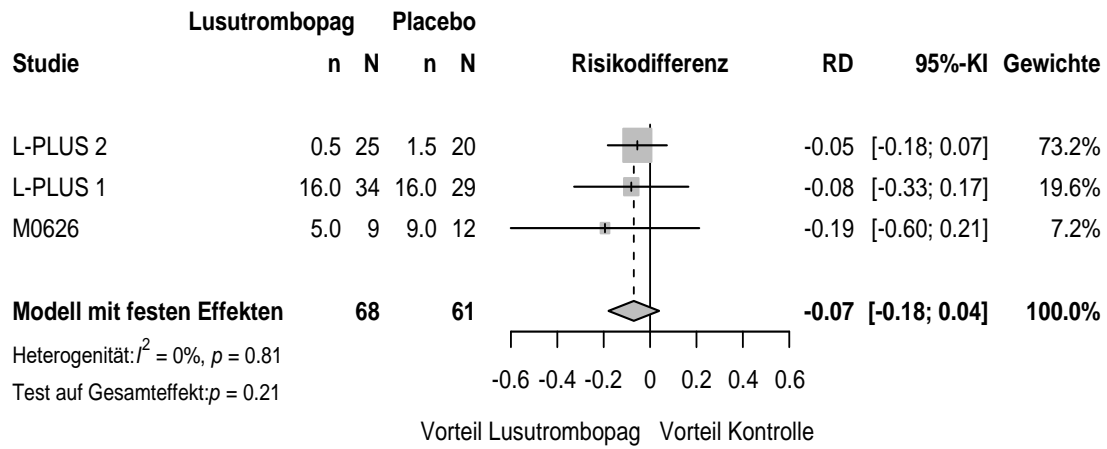
28 Schwere UE_OR Treatment duration (days) -7



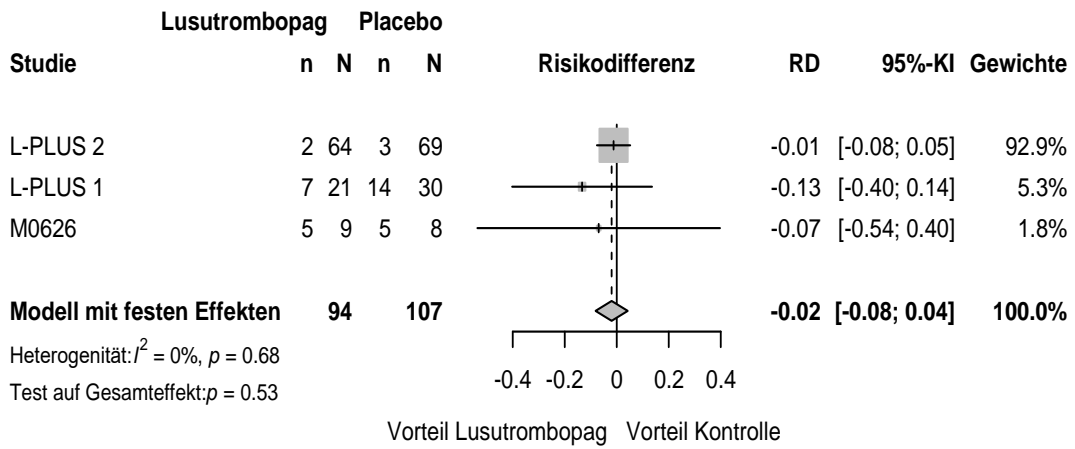
29 Schwere UE_RD Age (years) - < 65



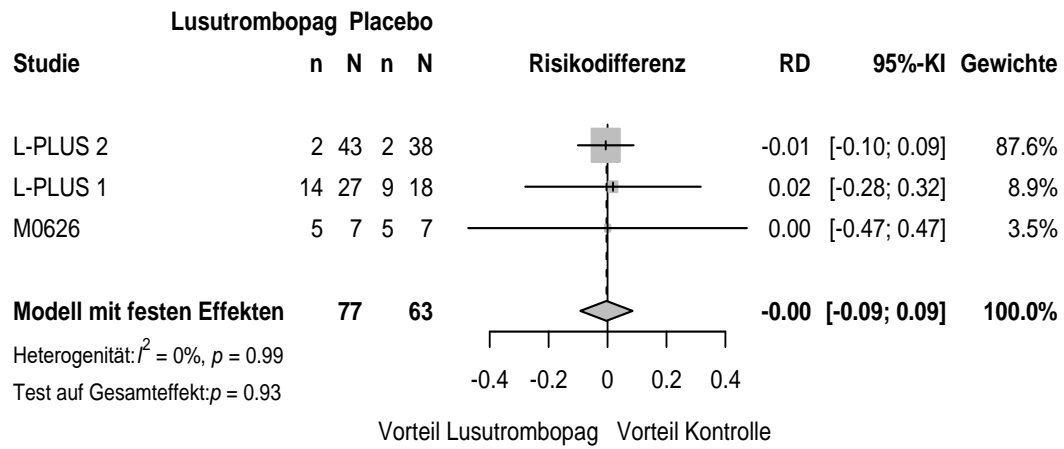
30 Schwere UE_RD Age (years) - >=65



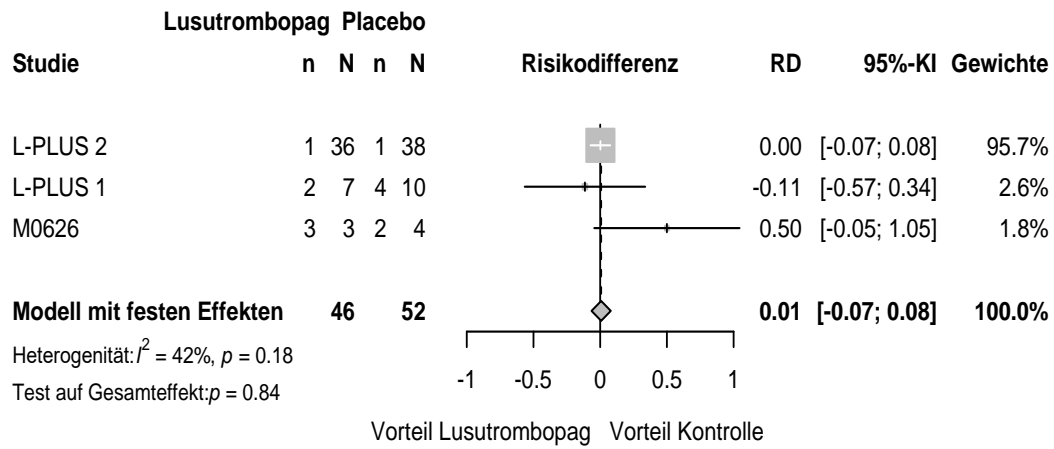
31 Schwere UE_RD Gender - Male



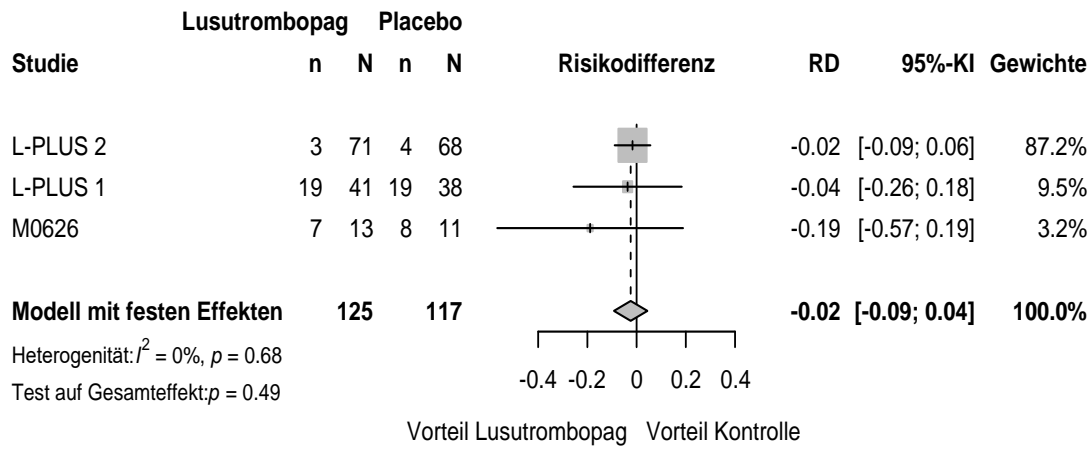
32 Schwere UE_RD Gender - Female



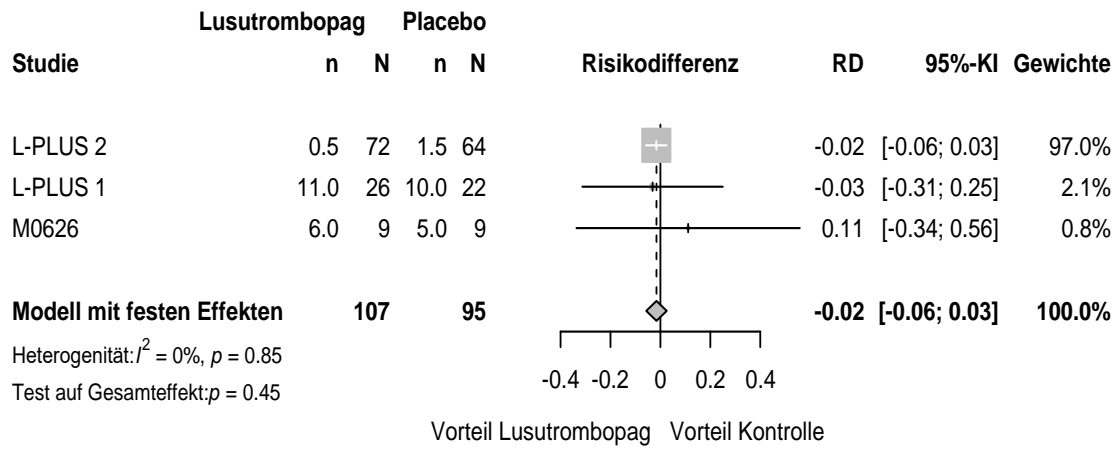
33 Schwere UE_RD Baseline platelet count (*10⁴/uL) - < 3.5



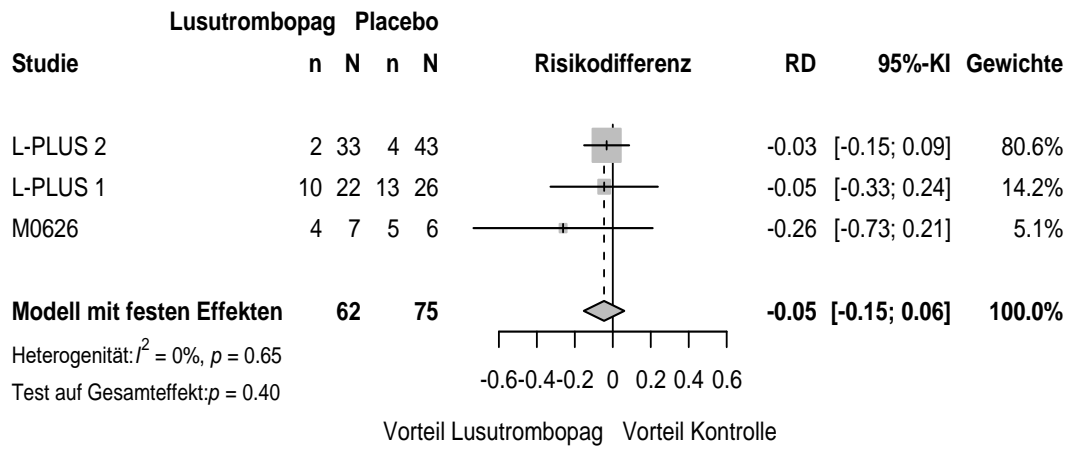
34 Schwere UE_RD Baseline platelet count ($\cdot 10^4/uL$) - ≥ 3.5



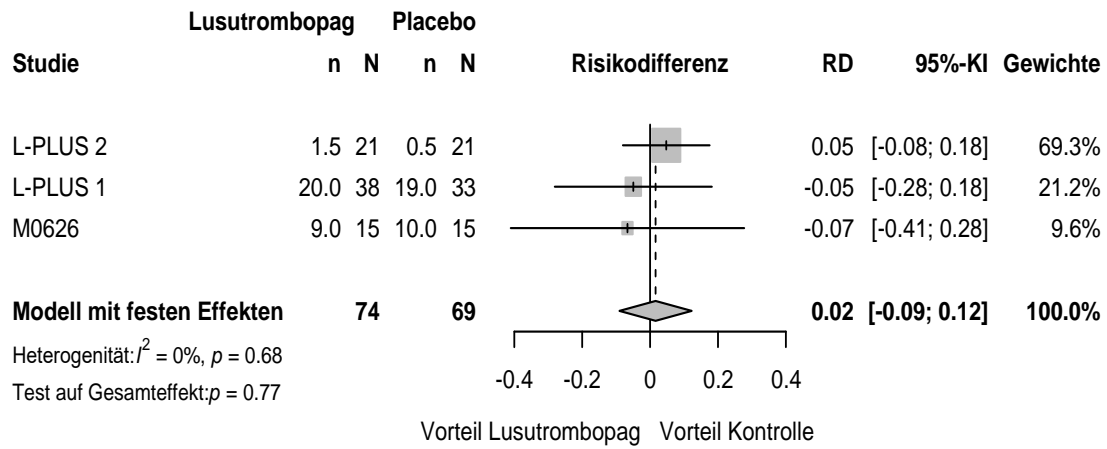
35 Schwere UE_RD Child-Pugh class - A



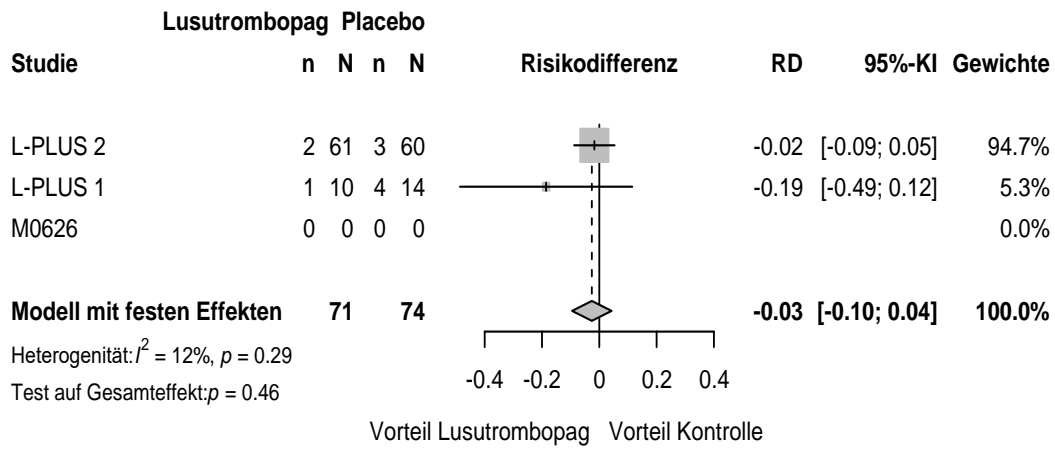
36 Schwere UE_RD Child-Pugh class - B



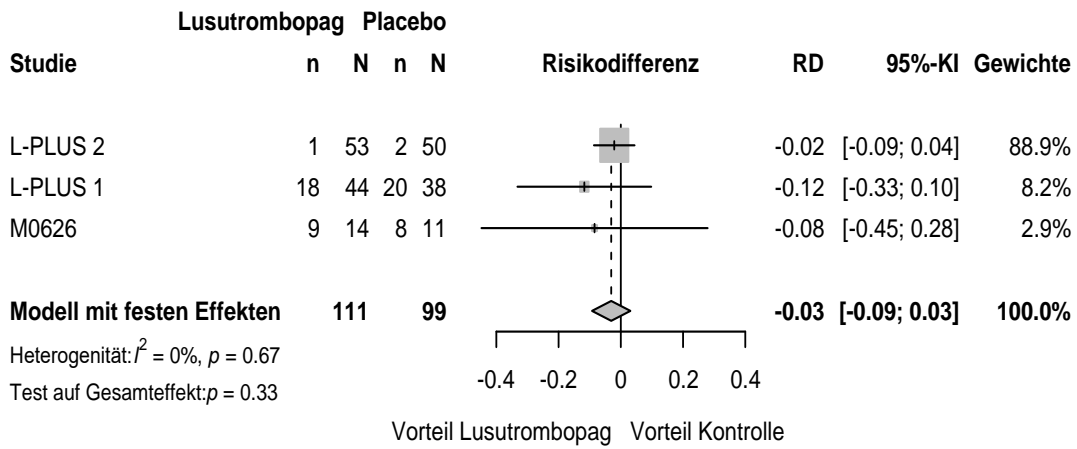
37 Schwere UE_RD Invasive procedure liver-related



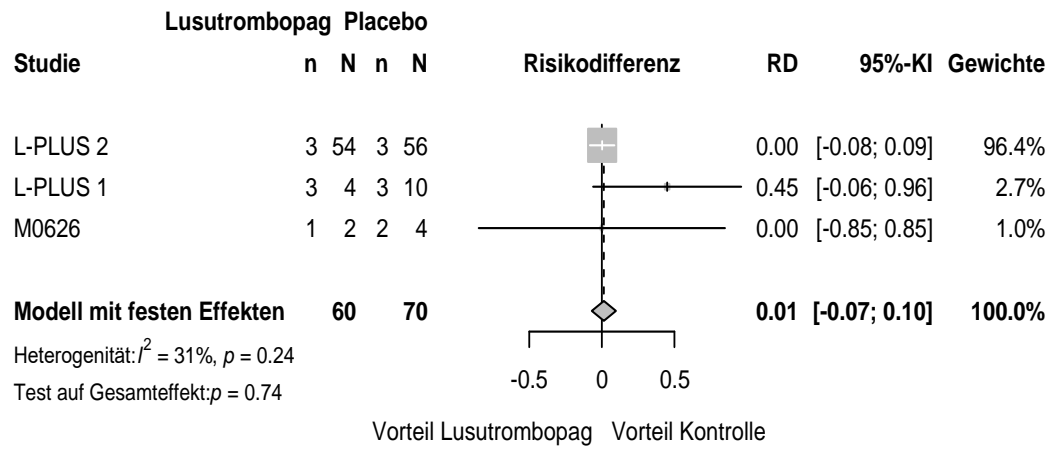
38 Schwere UE_RD Invasive procedure gi-related



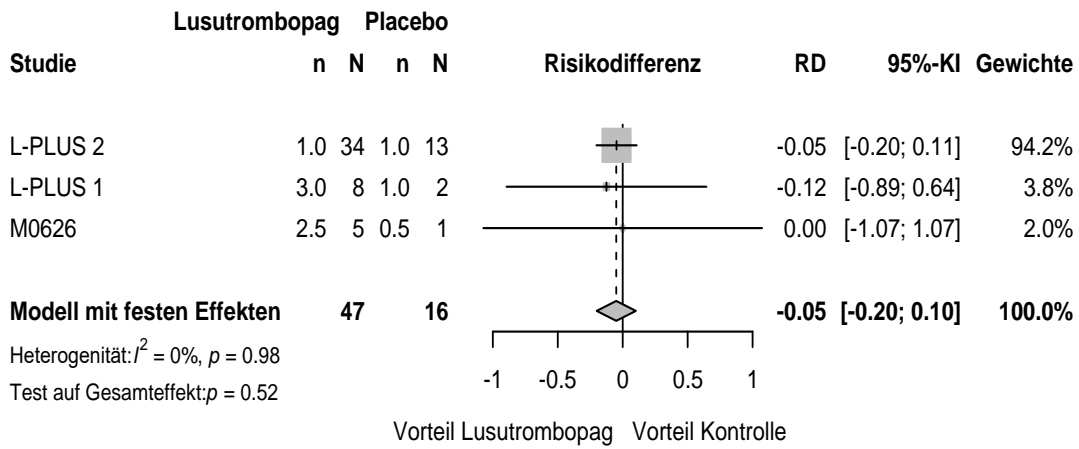
39 Schwere UE_RD Baseline body weight (kg) - < 75



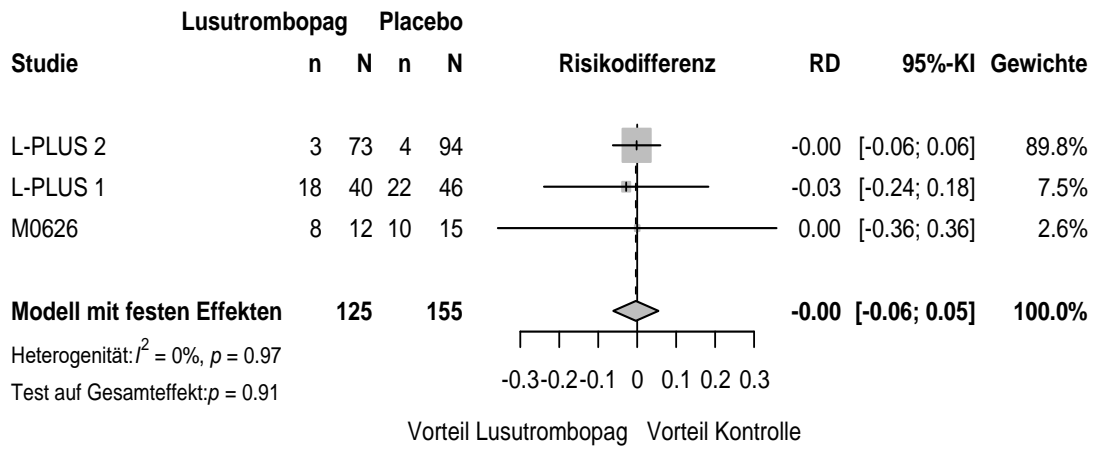
40 Schwere UE_RD Baseline body weight (kg) - >= 75



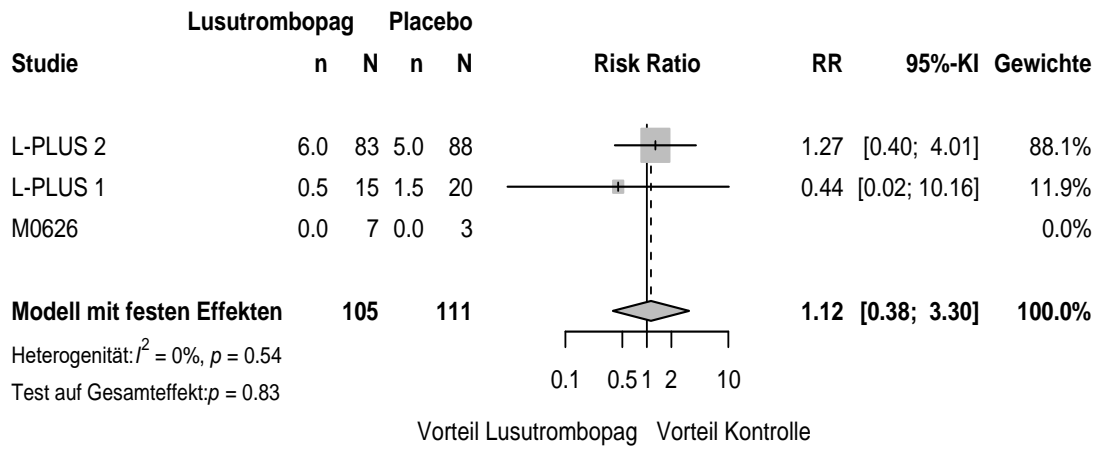
41 Schwere UE_RD Treatment duration (days) - < 7



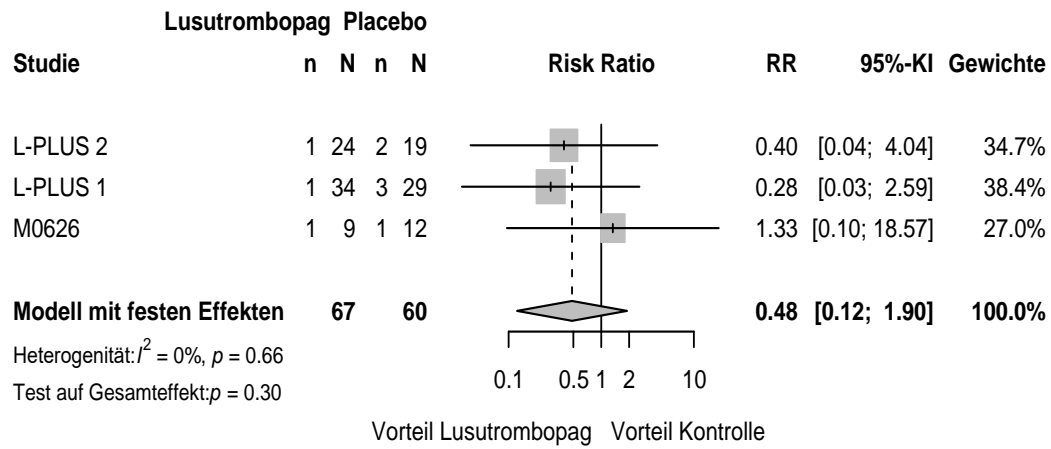
42 Schwere UE_RD Treatment duration (days) -7



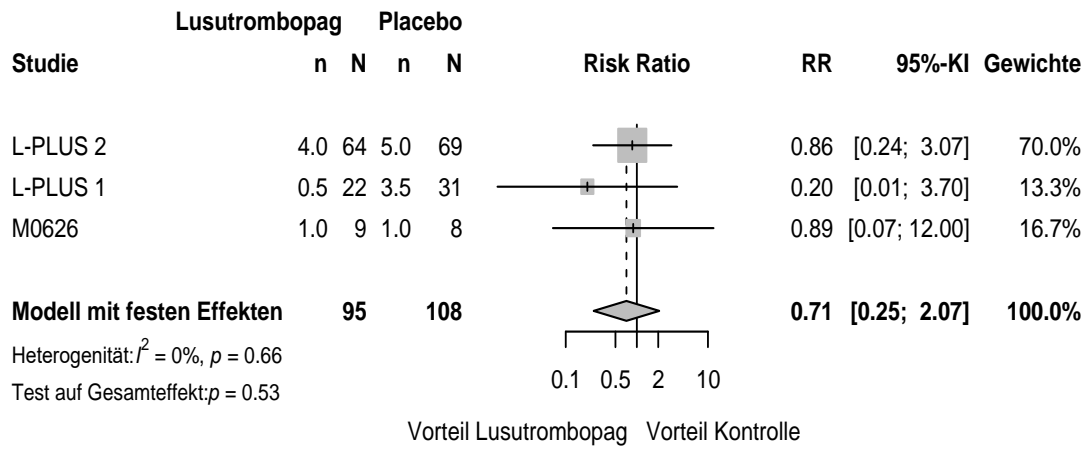
43 SUE_RR Age (years) - < 65



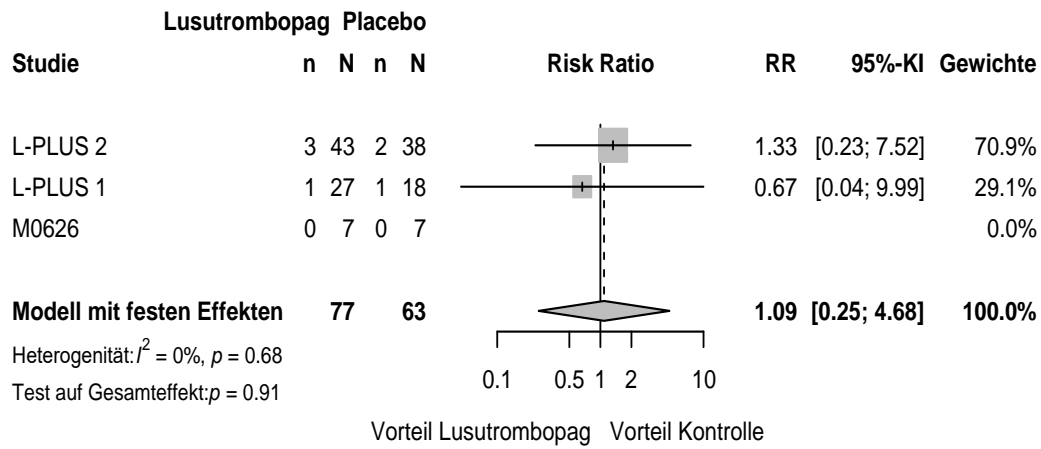
44 SUE_RR Age (years) - >=65



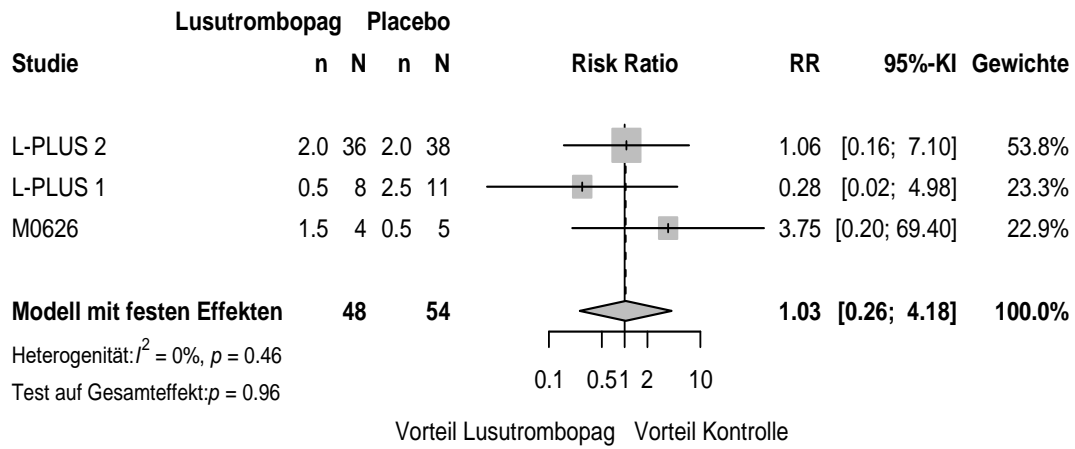
45 SUE_RR Gender - Male



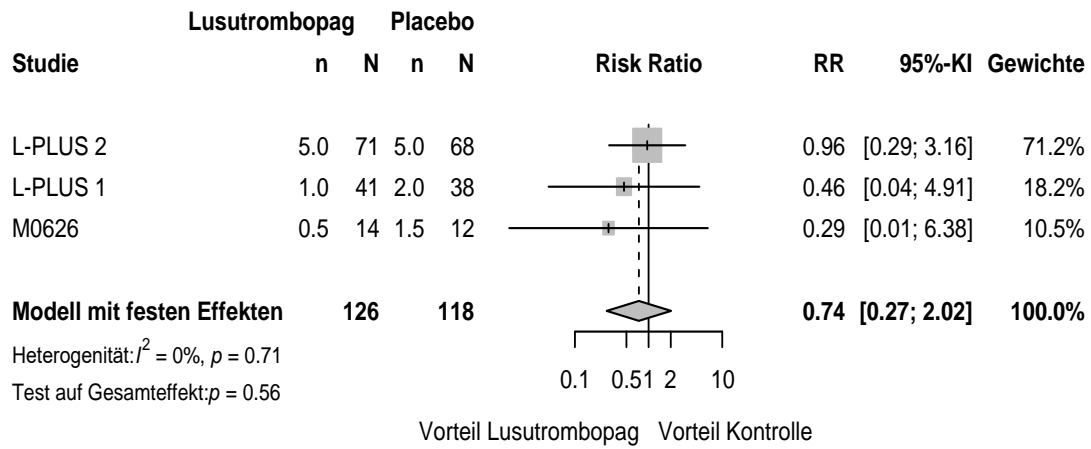
46 SUE_RR Gender - Female



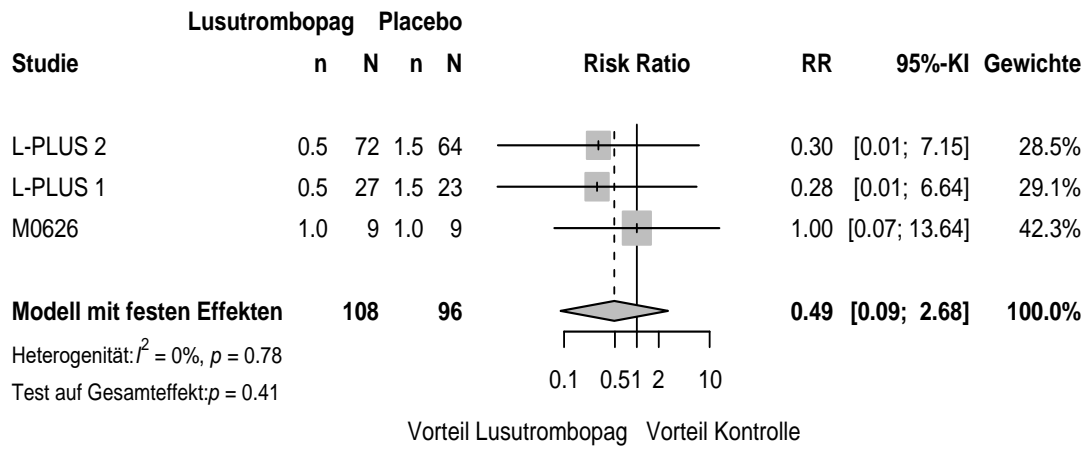
47 SUE_RR Baseline platelet count ($\cdot 10^4/uL$) - < 3.5



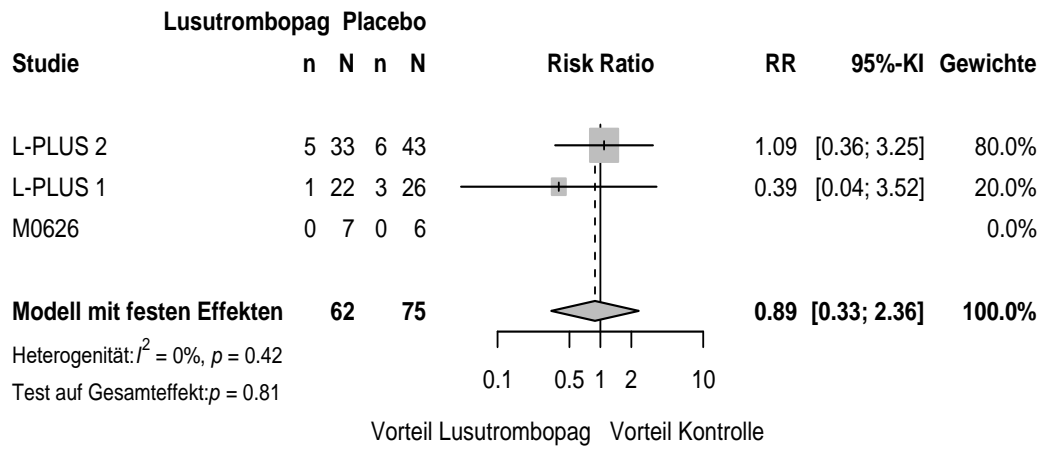
48 SUE_RR Baseline platelet count ($\cdot 10^4/\mu\text{L}$) - ≥ 3.5



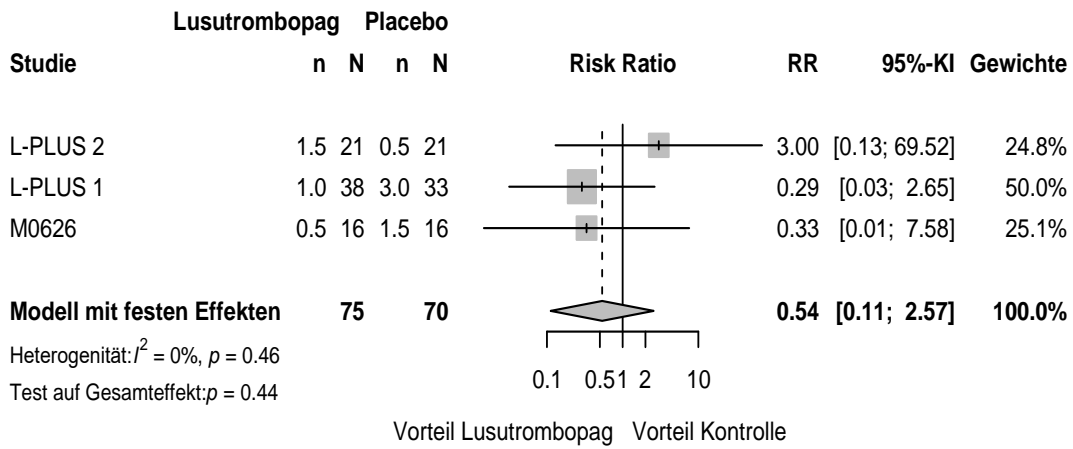
49 SUE_RR Child-Pugh class - A



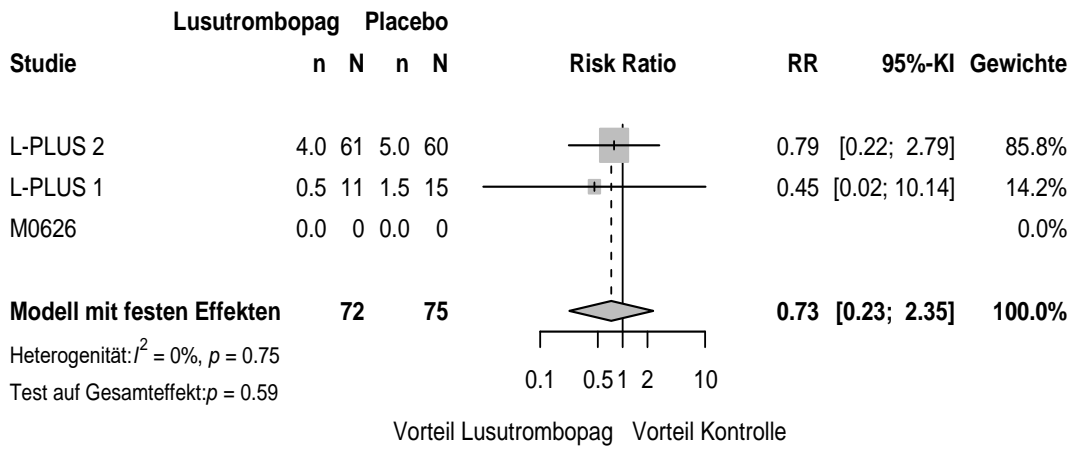
50 SUE_RR Child-Pugh class - B



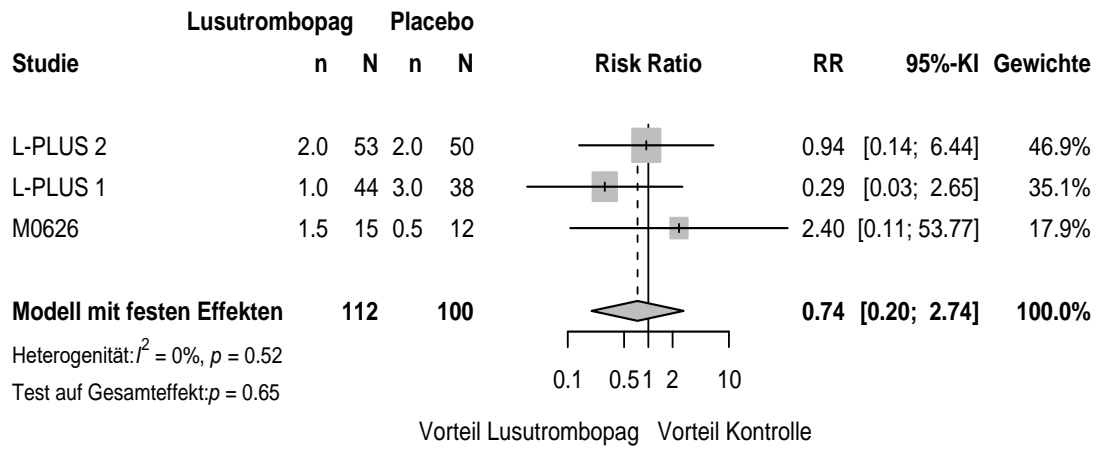
51 SUE_RR Invasive procedure liver-related



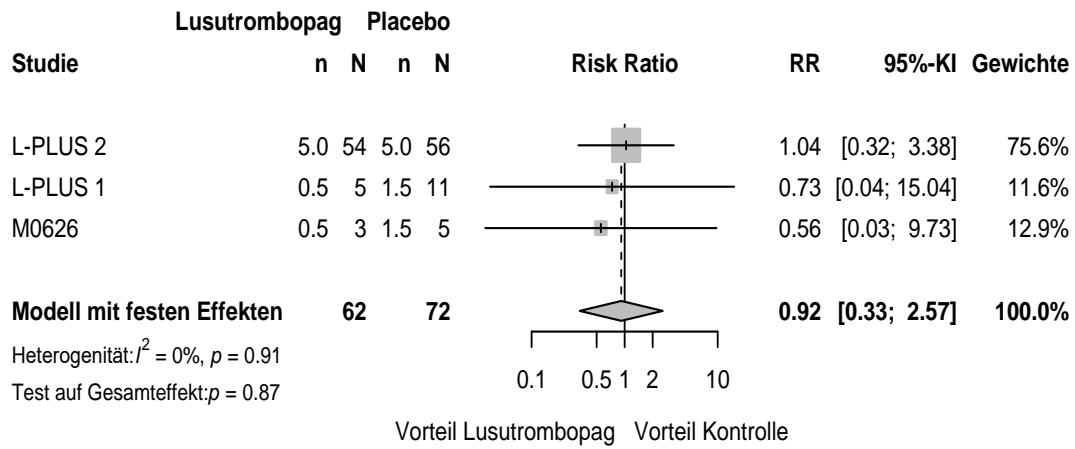
52 SUE_RR Invasive procedure gi-related



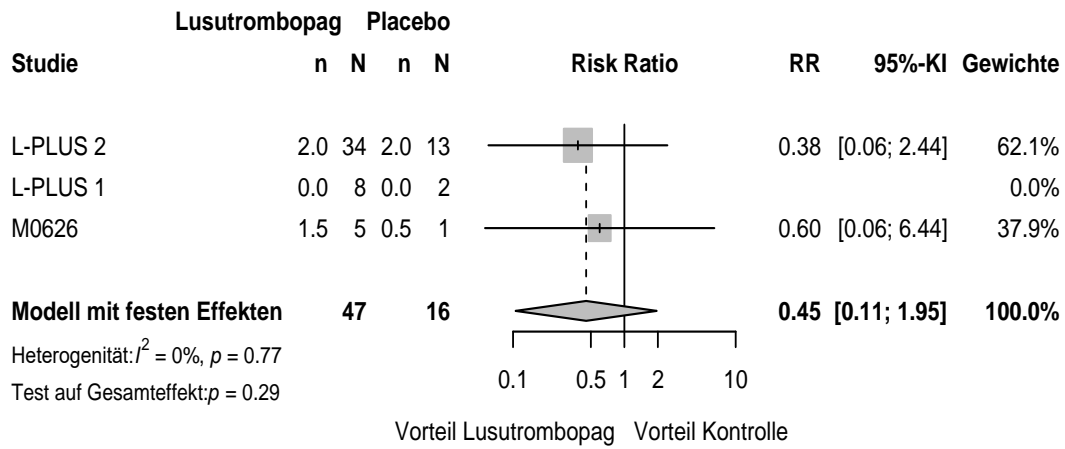
53 SUE_RR Baseline body weight (kg) - < 75



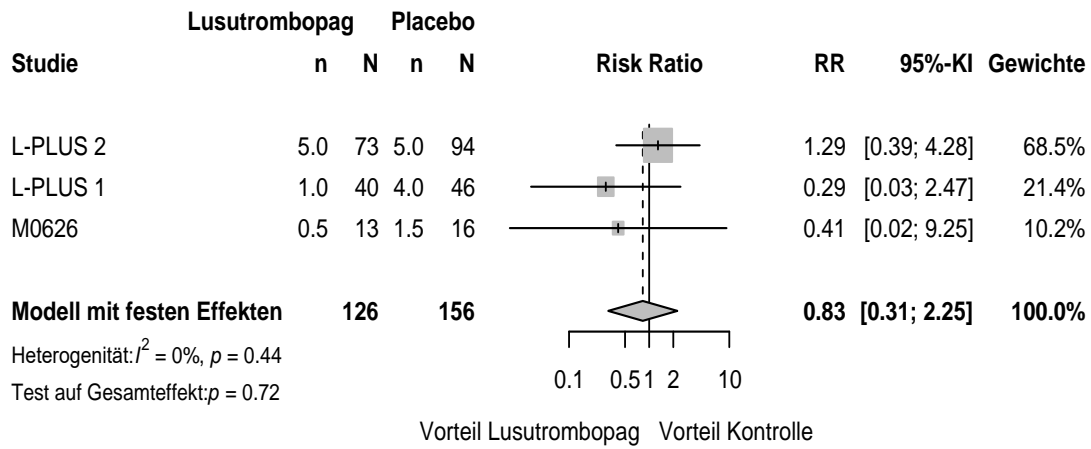
54 SUE_RR Baseline body weight (kg) - >= 75



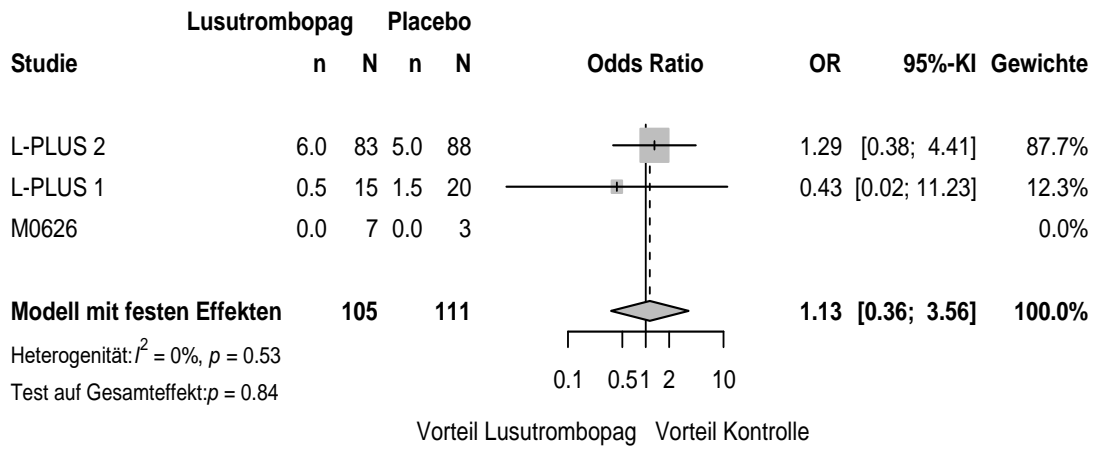
55 SUE_RR Treatment duration (days) - < 7



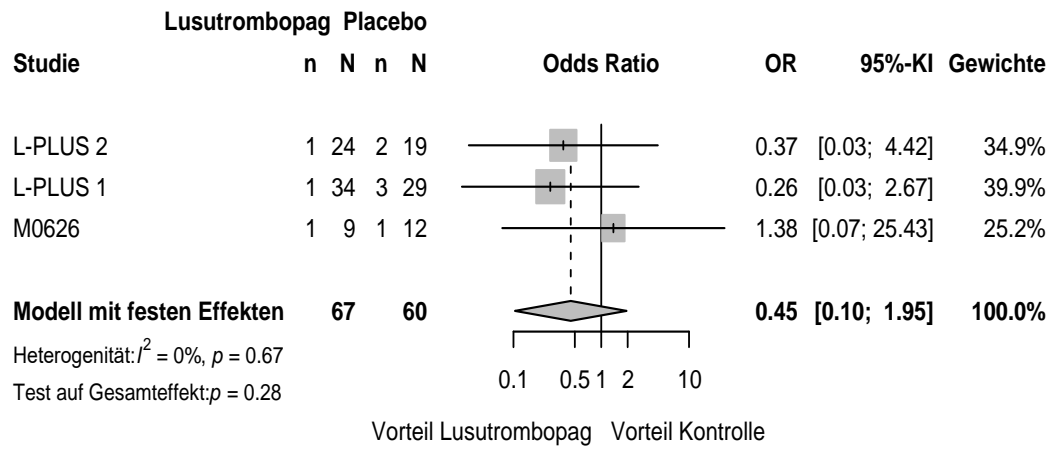
56 SUE_RR Treatment duration (days) -7



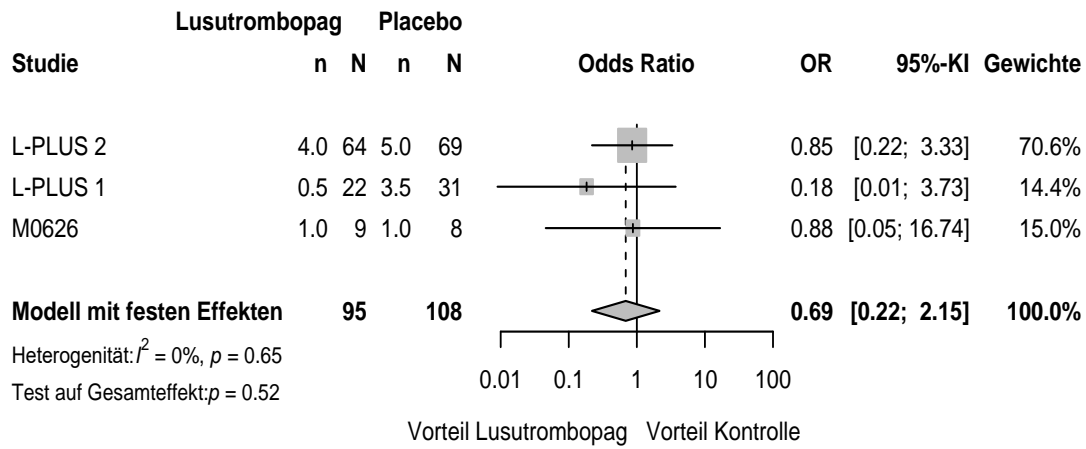
57 SUE_OR Age (years) - < 65



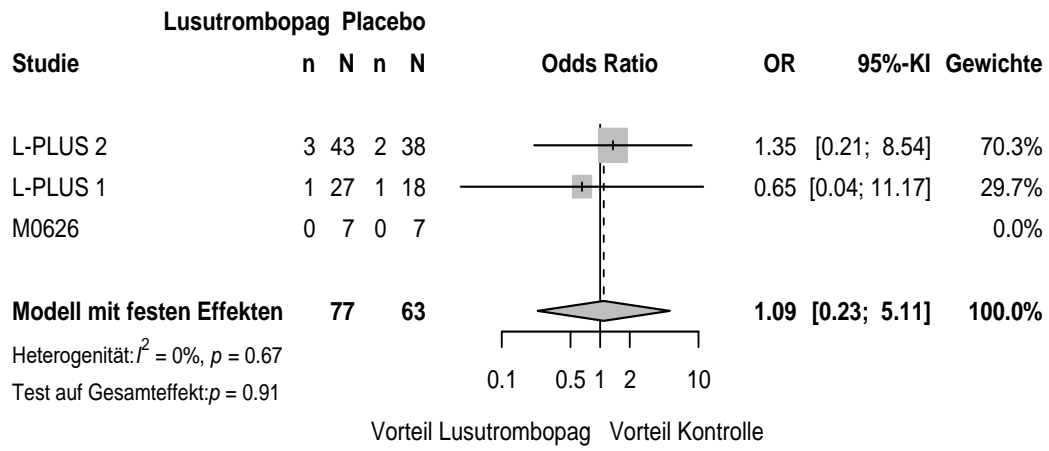
58 SUE_OR Age (years) - >=65



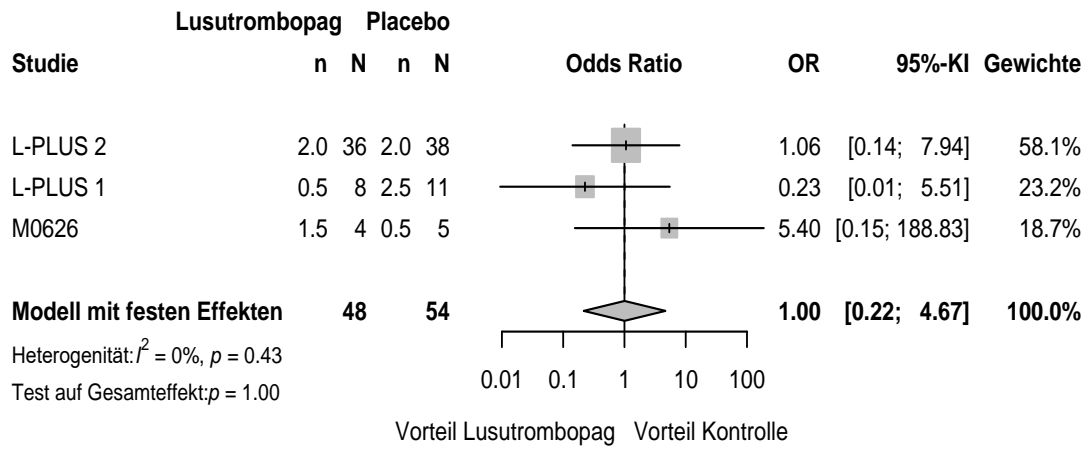
59 SUE_OR Gender - Male



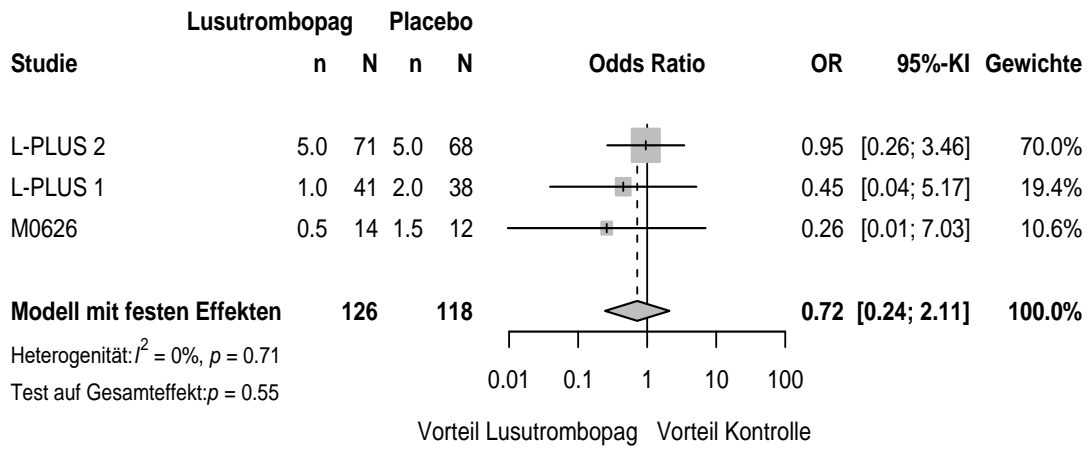
60 SUE_OR Gender - Female



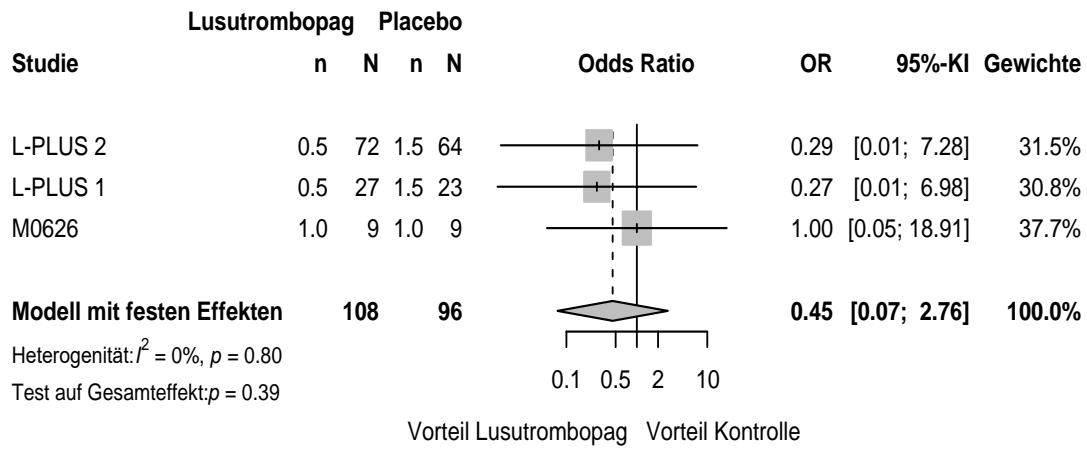
61 SUE_OR Baseline platelet count ($\cdot 10^4/uL$) - < 3.5



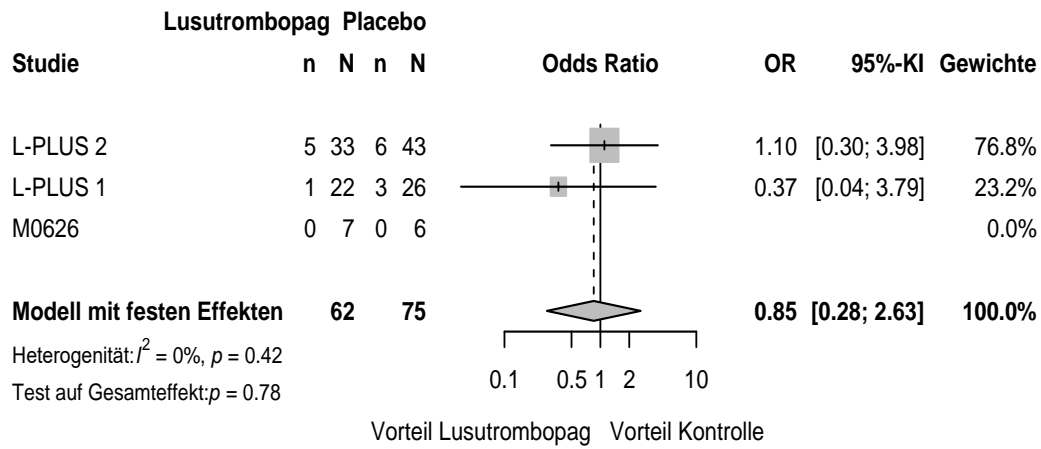
62 SUE_OR Baseline platelet count ($\cdot 10^4/uL$) - ≥ 3.5



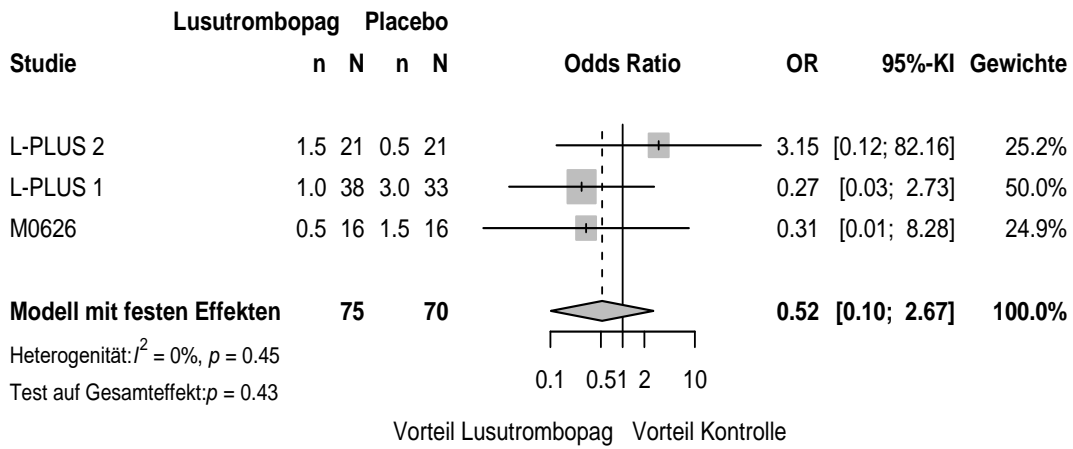
63 SUE_OR Child-Pugh class - A



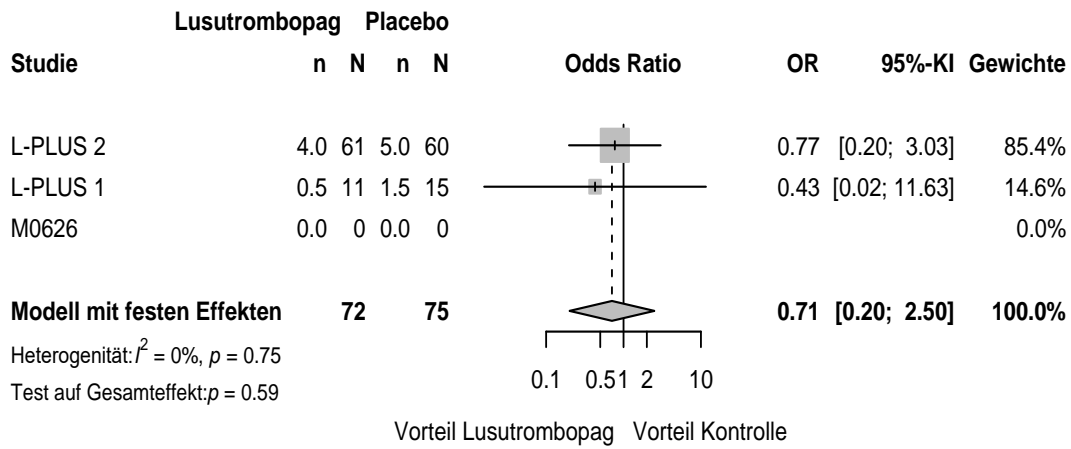
64 SUE_OR Child-Pugh class - B



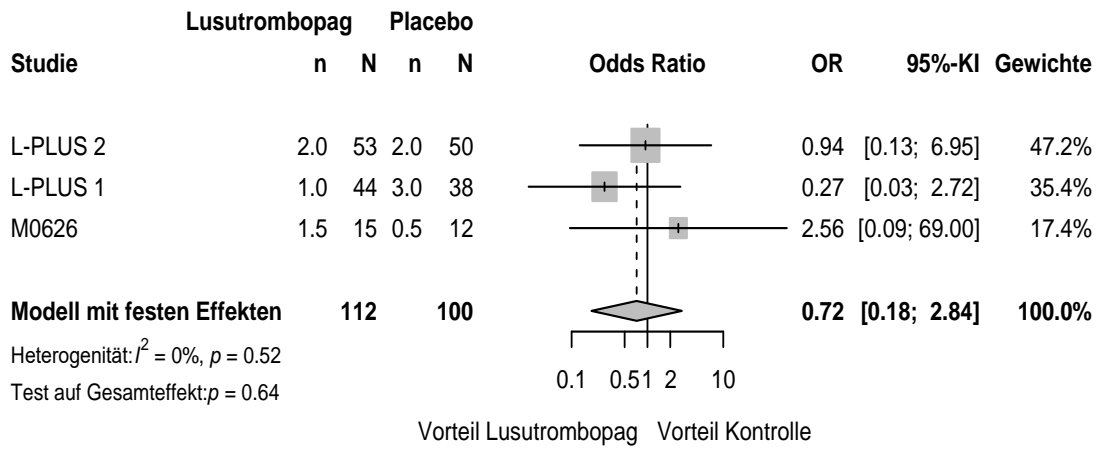
65 SUE_OR Invasive procedure liver-related



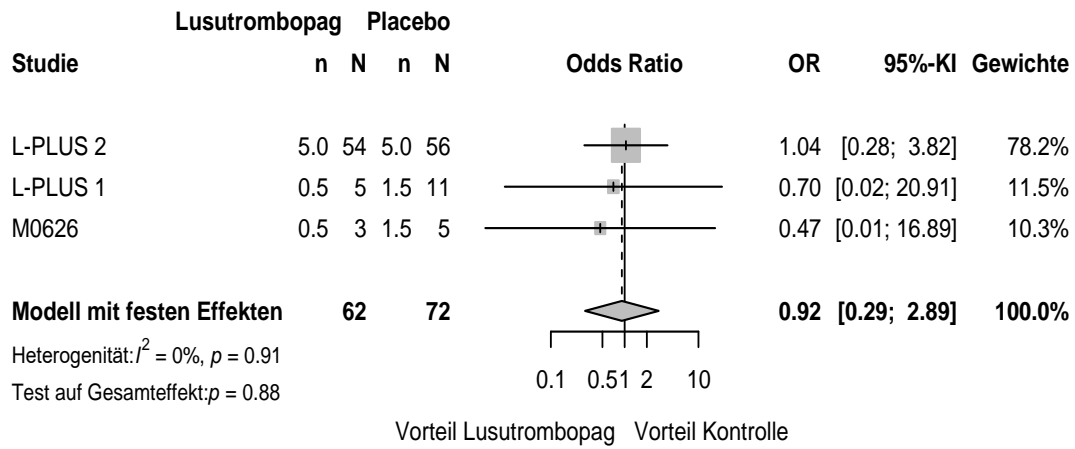
66 SUE_OR Invasive procedure gi-related



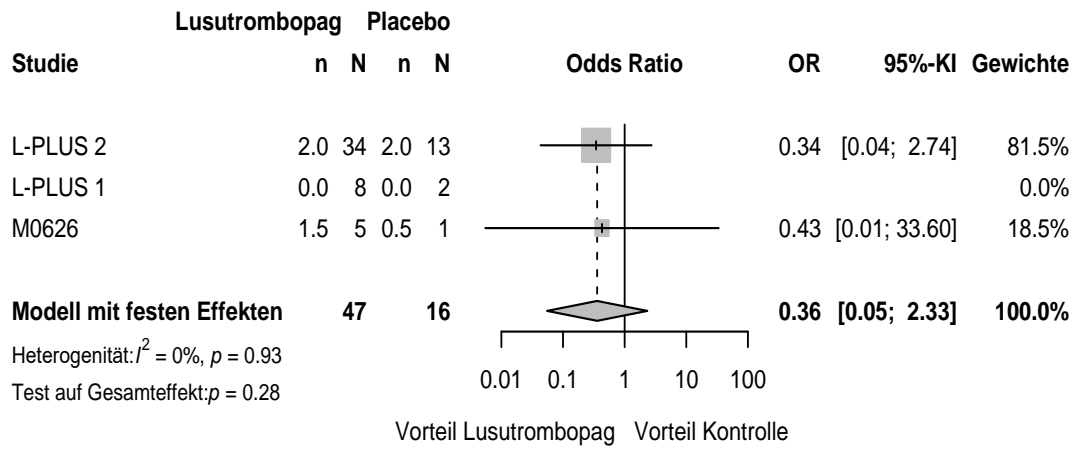
67 SUE_OR Baseline body weight (kg) - < 75



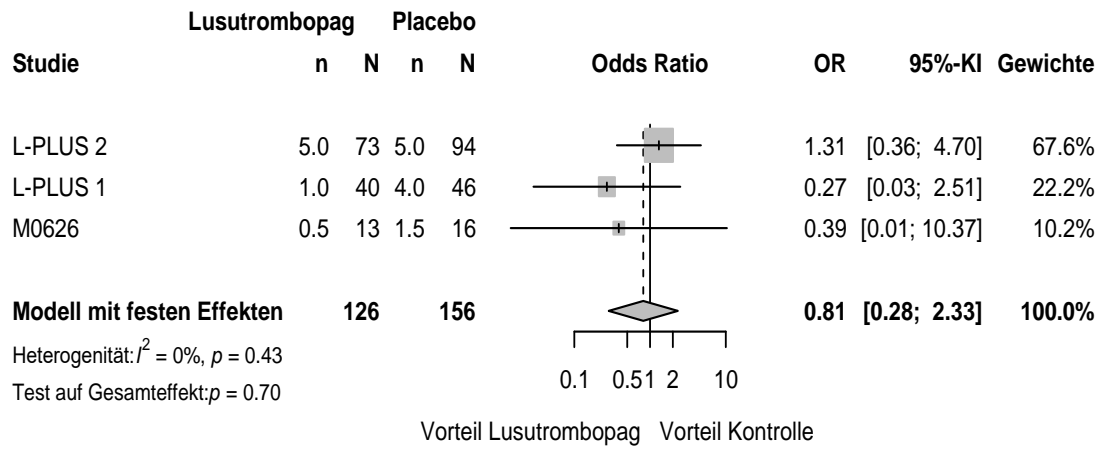
68 SUE_OR Baseline body weight (kg) - >= 75



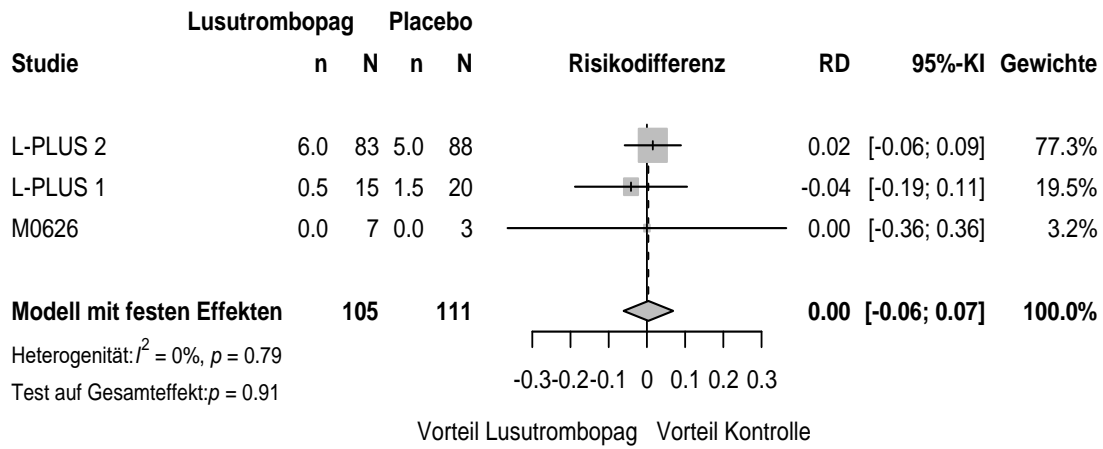
69 SUE_OR Treatment duration (days) - < 7



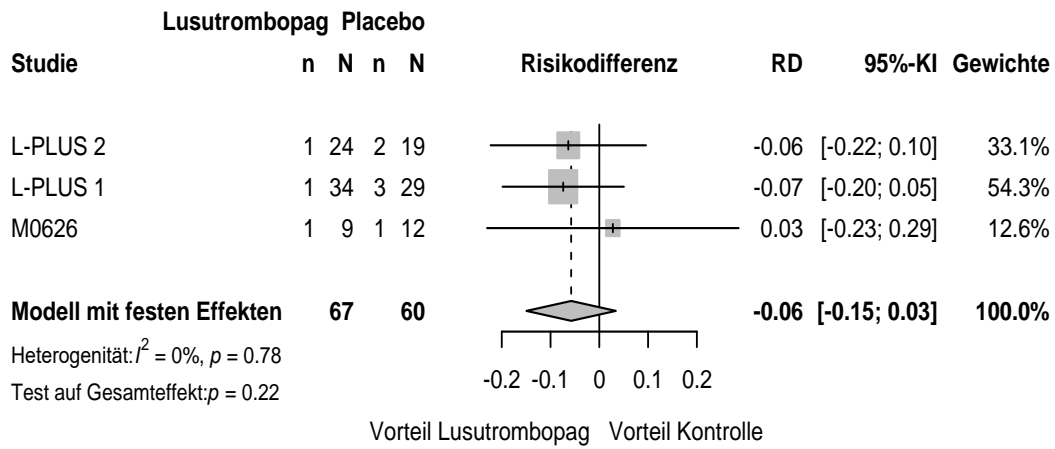
70 SUE_OR Treatment duration (days) -7



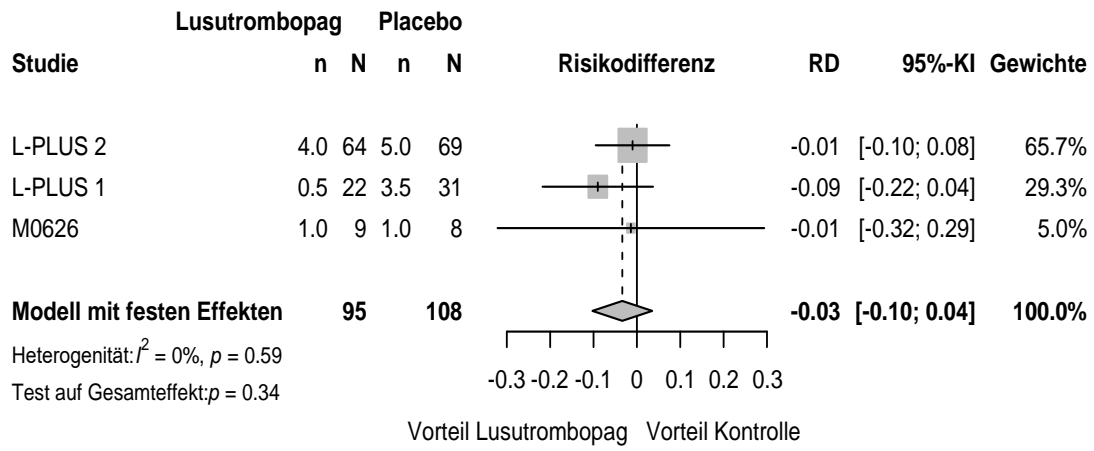
71 SUE_RD Age (years) - < 65



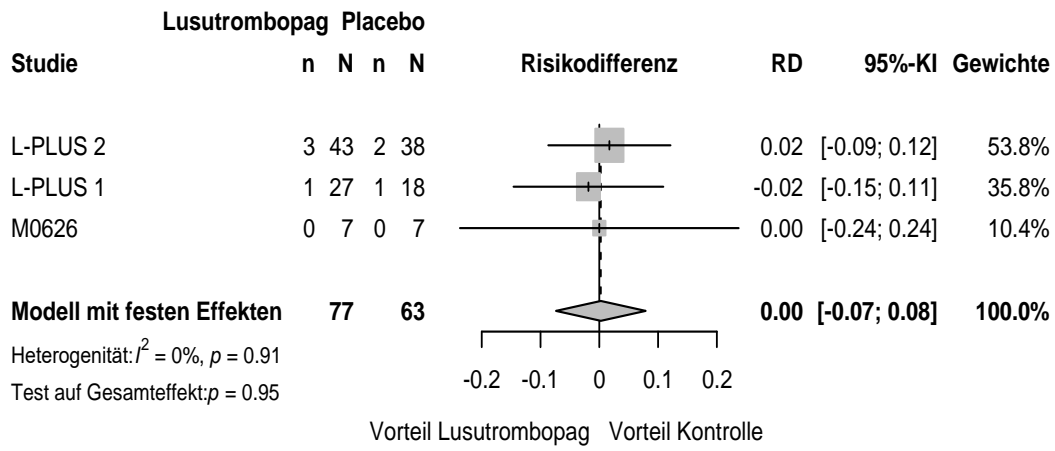
72 SUE_RD Age (years) - >=65



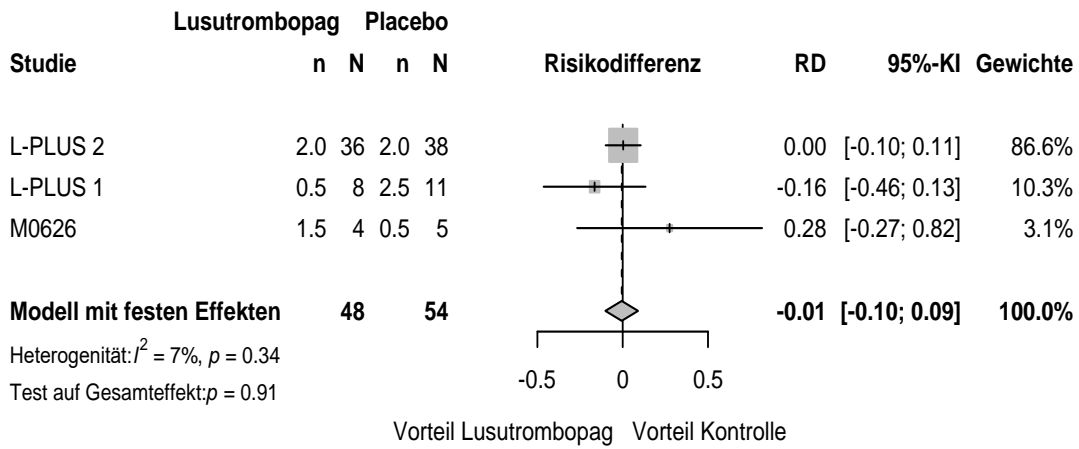
73 SUE_RD Gender - Male



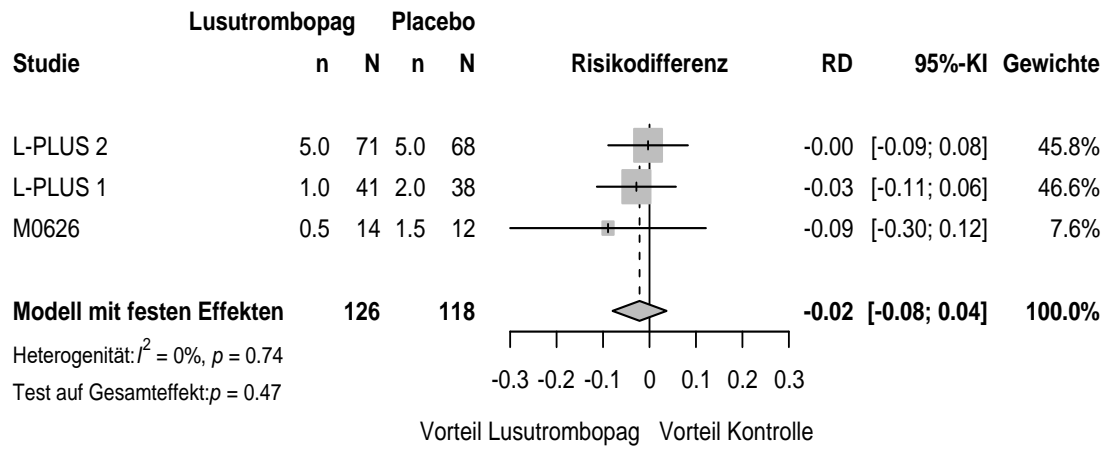
74 SUE_RD Gender - Female



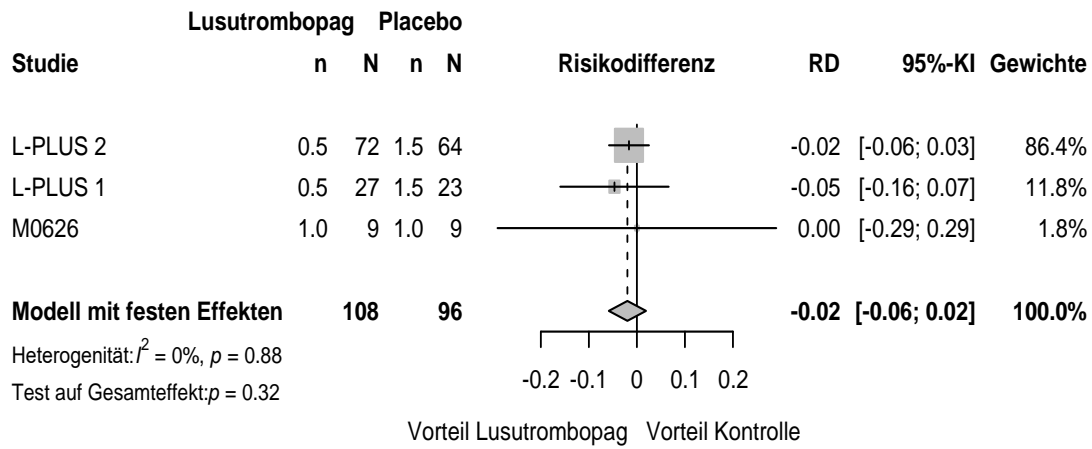
75 SUE_RD Baseline platelet count ($\cdot 10^4/\mu\text{L}$) - < 3.5



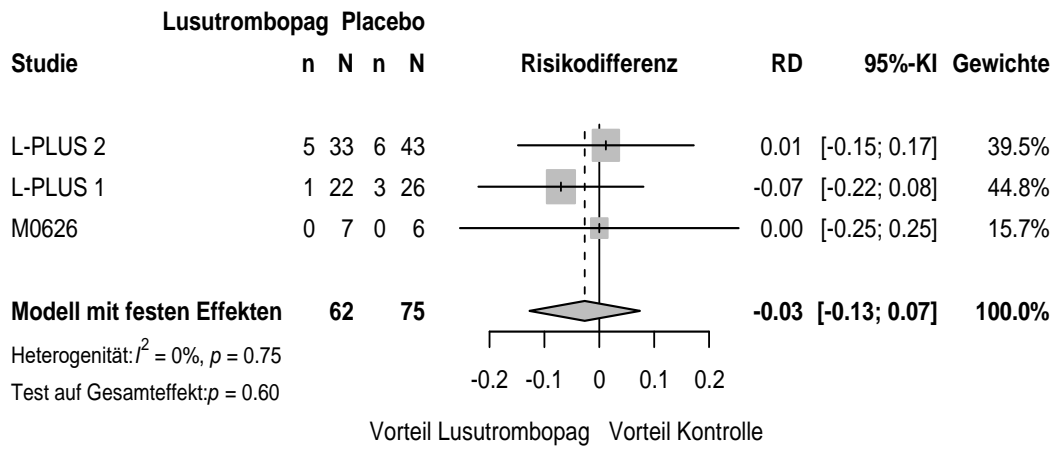
76 SUE_RD Baseline platelet count (*10⁴/uL) - >= 3.5



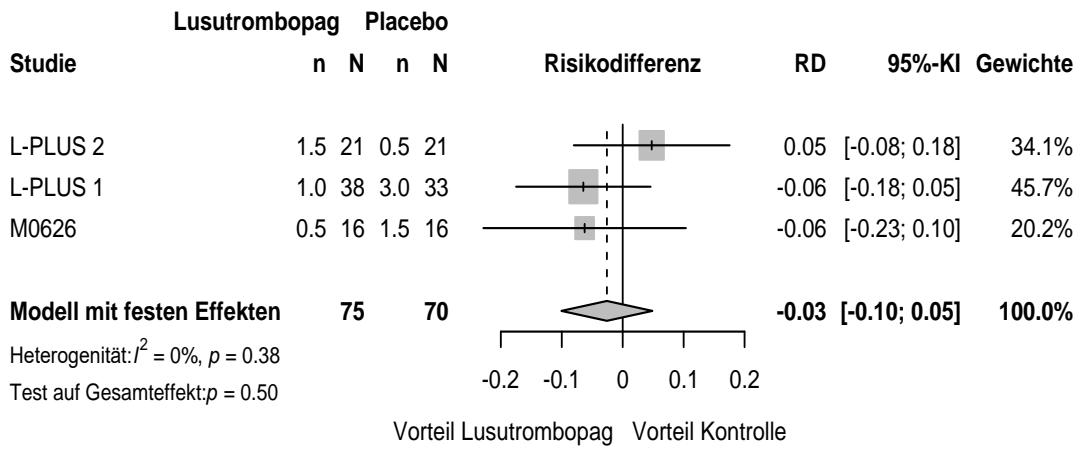
77 SUE_RD Child-Pugh class - A



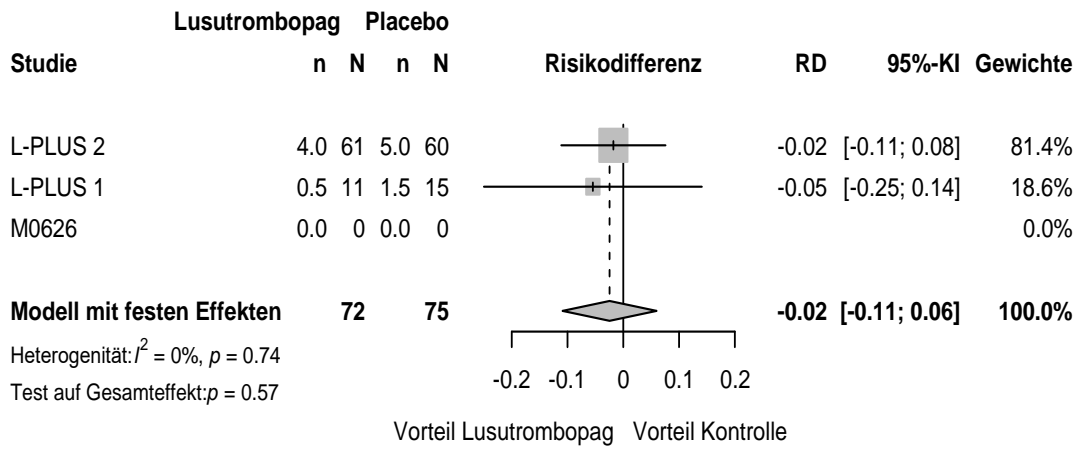
78 SUE_RD Child-Pugh class - B



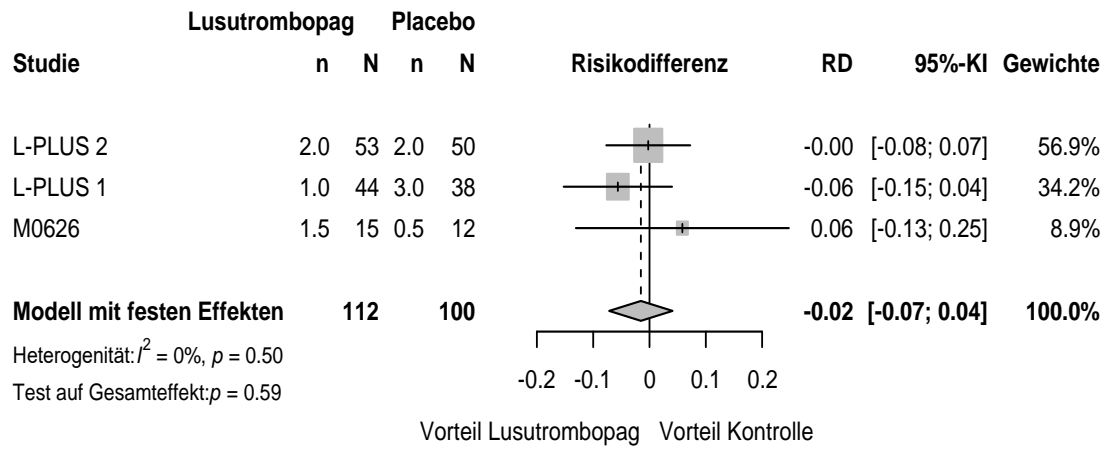
79 SUE_RD Invasive procedure liver-related



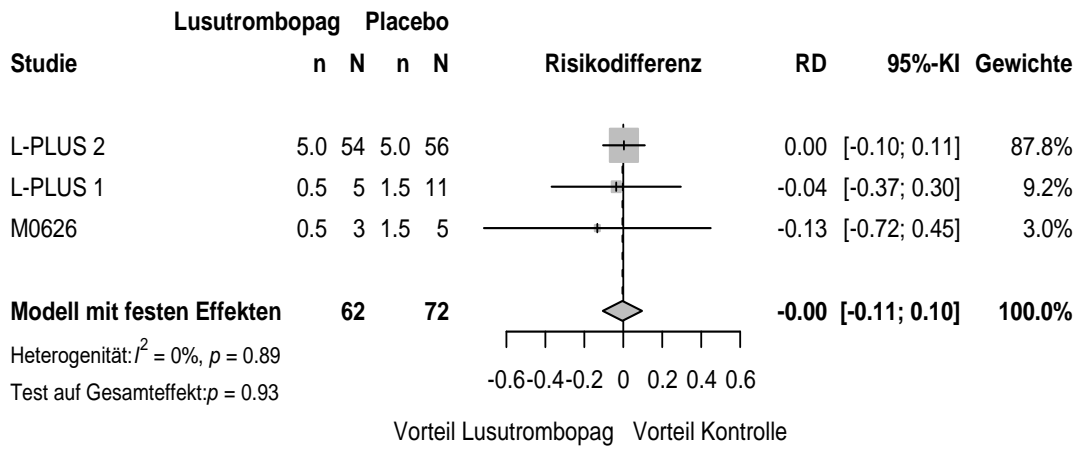
80 SUE_RD Invasive procedure gi-related



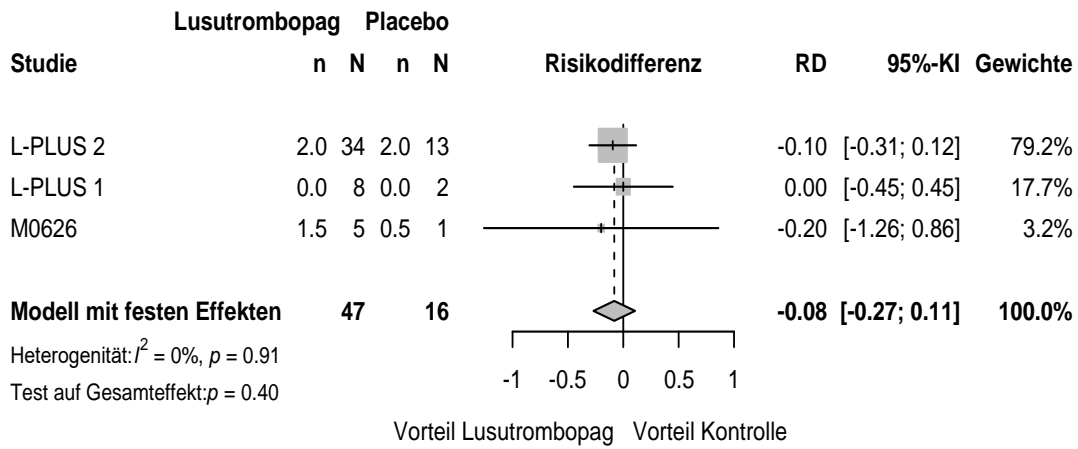
81 SUE_RD Baseline body weight (kg) - < 75



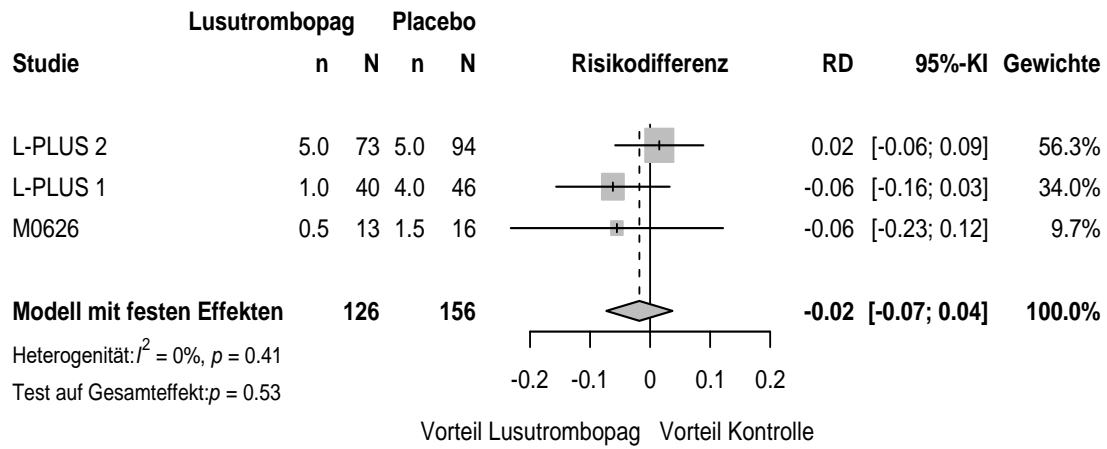
82 SUE_RD Baseline body weight (kg) - >= 75



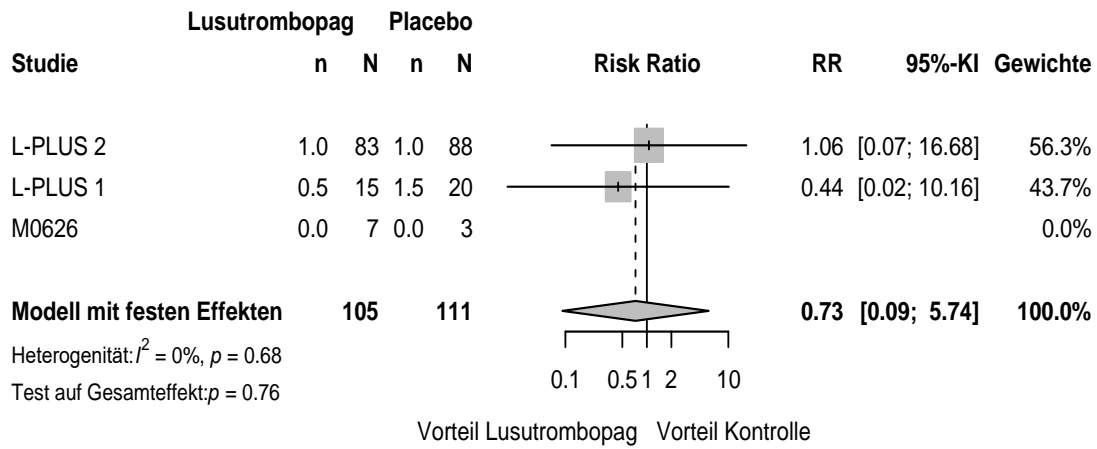
83 SUE_RD Treatment duration (days) - < 7



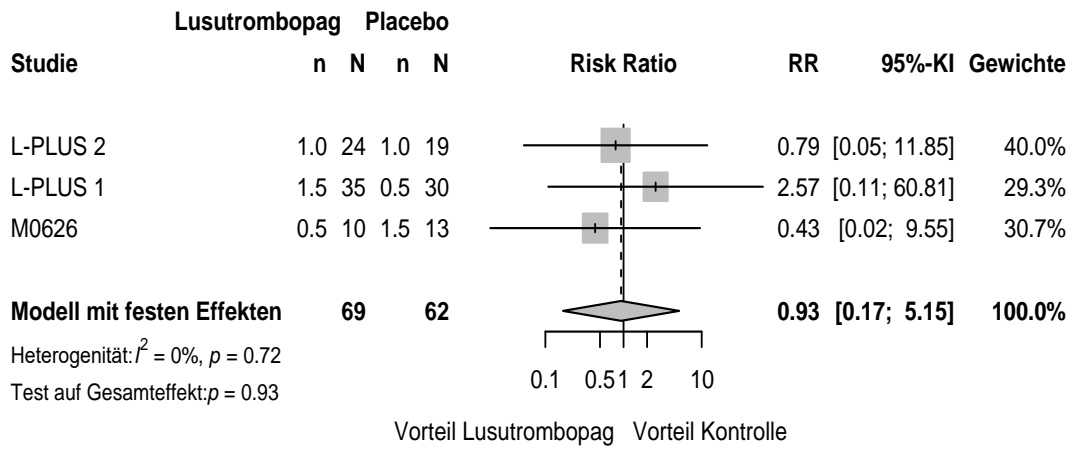
84 SUE_RD Treatment duration (days) -7



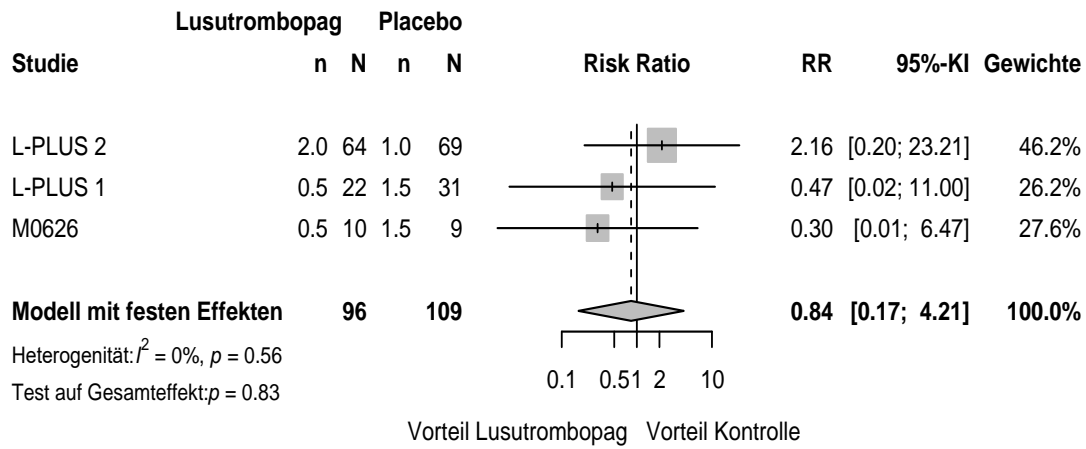
85 Thrombose/Thromboembolie (Gesamtrate)_RR Age (years) - < 65



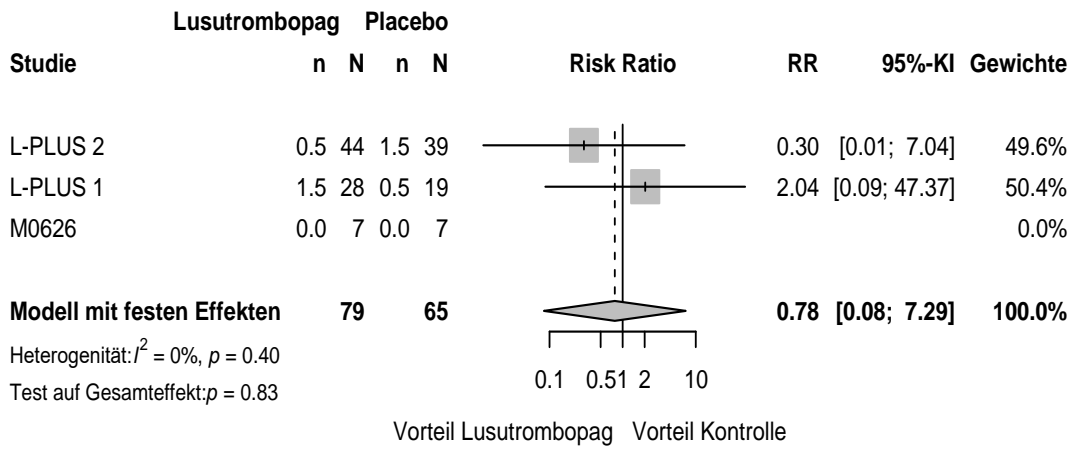
86 Thrombose/Thromboembolie (Gesamtrate)_RR Age (years) - >=65



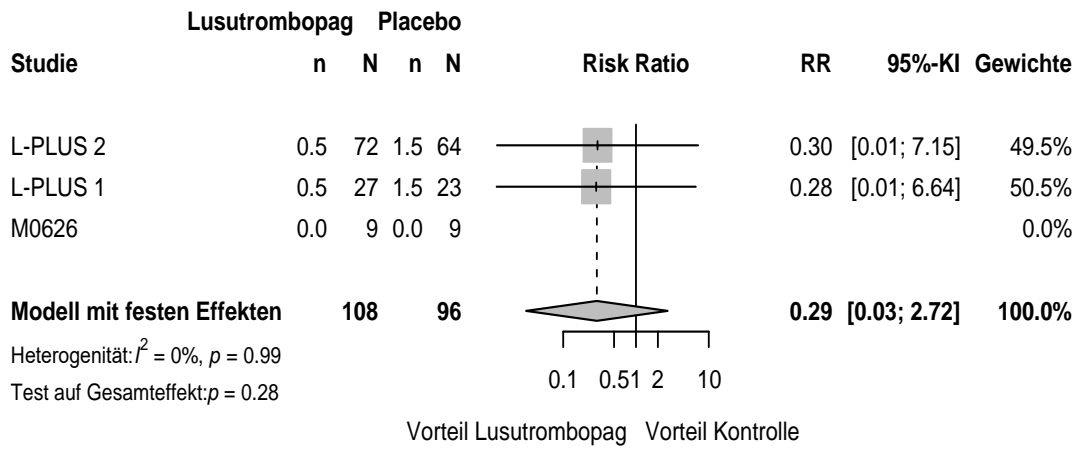
87 Thrombose/Thromboembolie (Gesamtrate)_RR Gender - Male



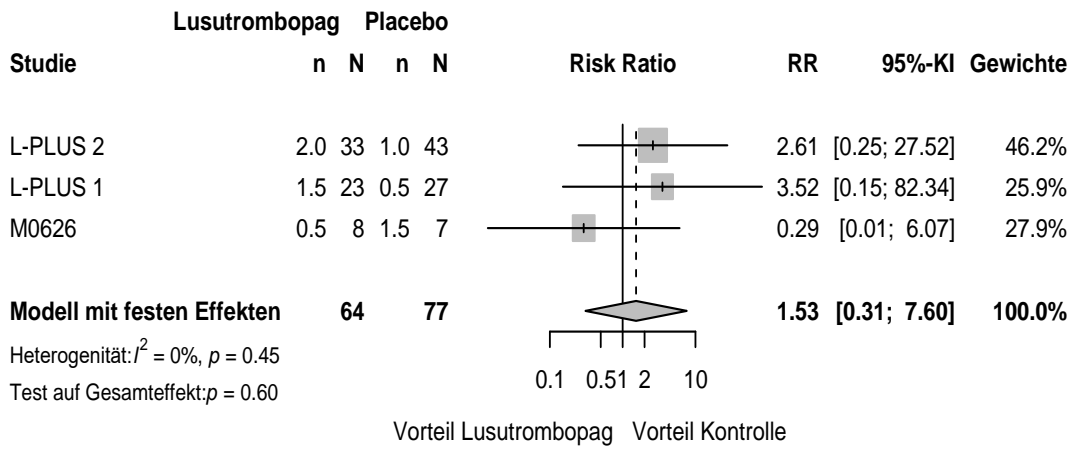
88 Thrombose/Thromboembolie (Gesamtrate)_RR Gender - Female



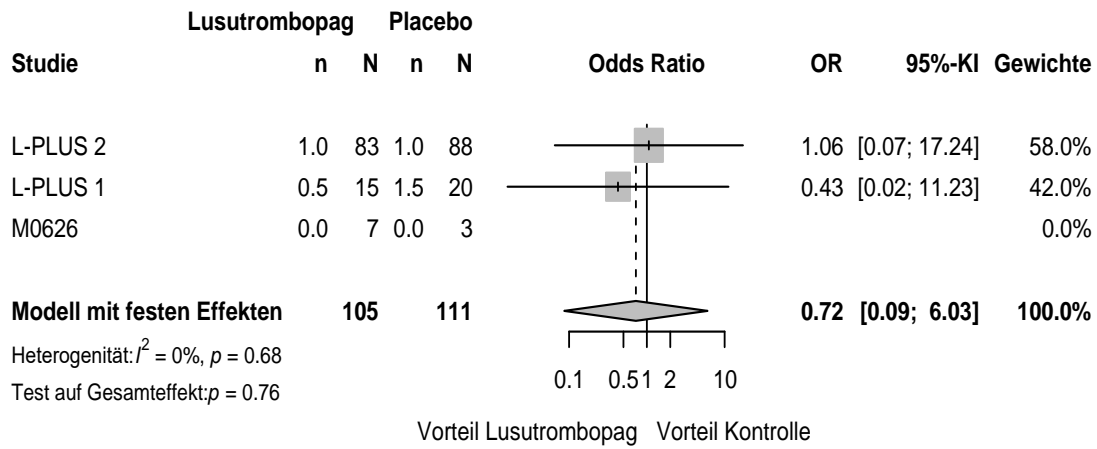
89 Thrombose/Thromboembolie (Gesamtrate)_RR Child-Pugh class - A



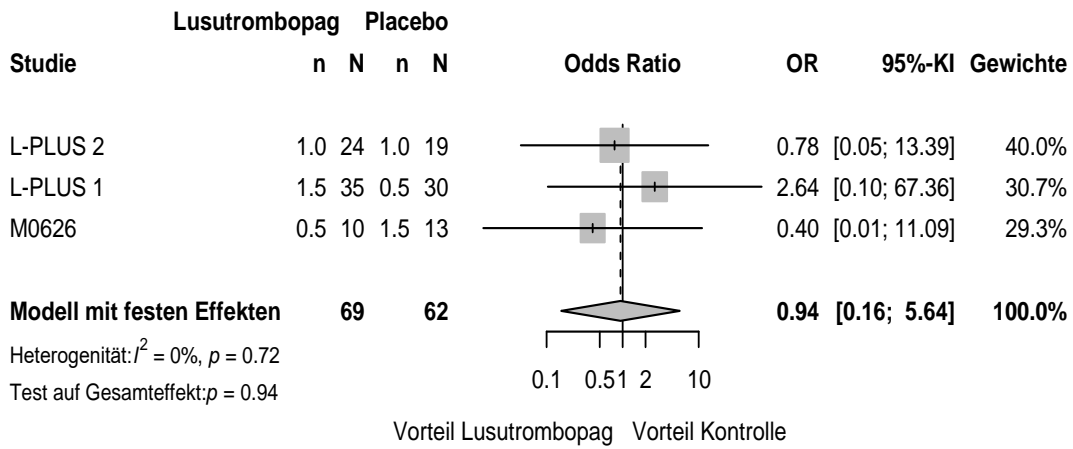
90 Thrombose/Thromboembolie (Gesamtrate)_RR Child-Pugh class - B



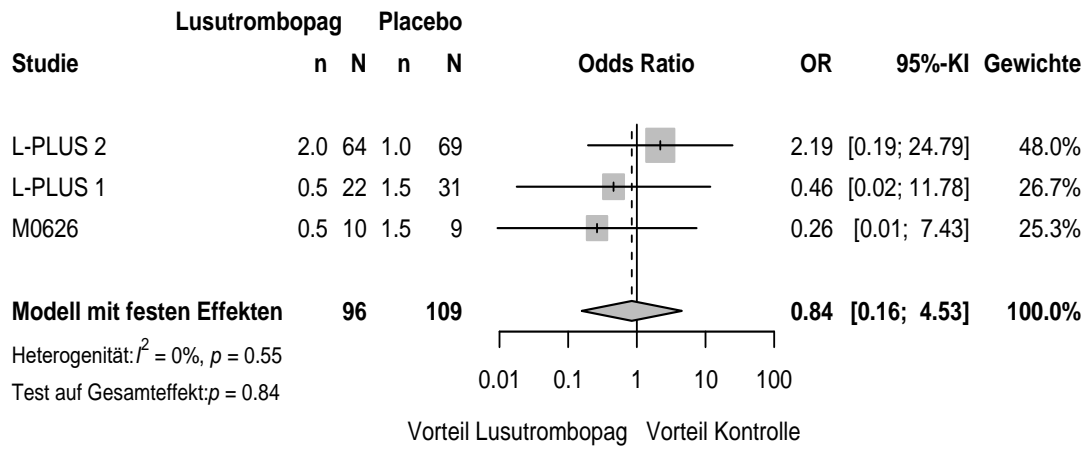
91 Thrombose/Thromboembolie (Gesamtrate)_OR Age (years) - < 65



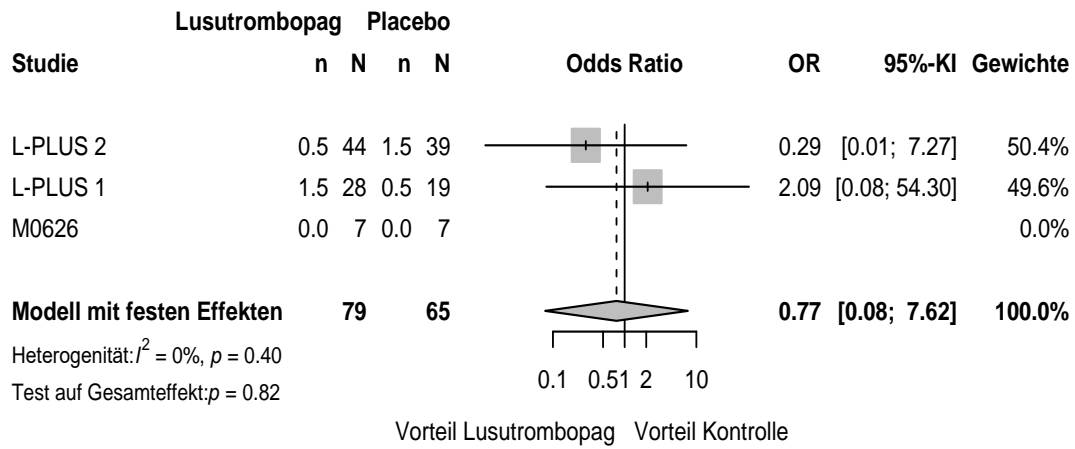
92 Thrombose/Thromboembolie (Gesamtrate)_OR Age (years) - >=65



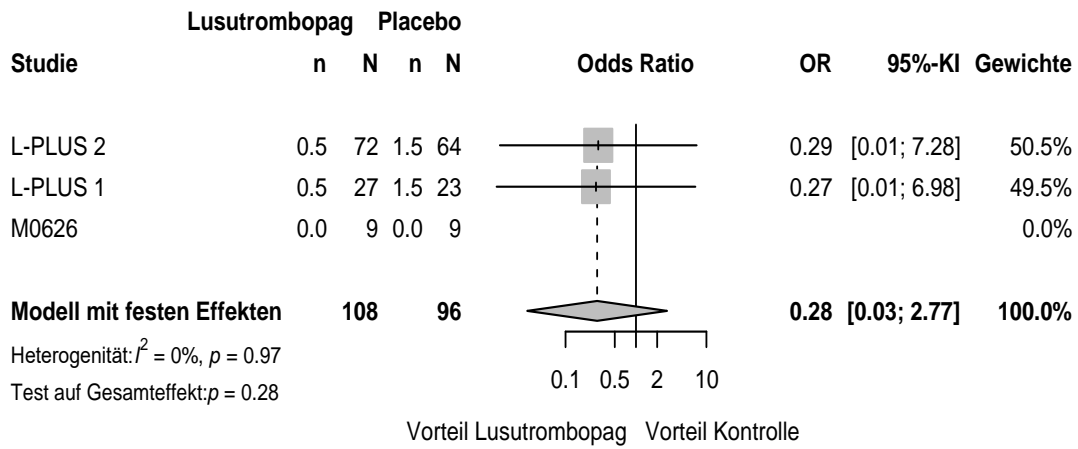
93 Thrombose/Thromboembolie (Gesamtrate)_OR Gender - Male



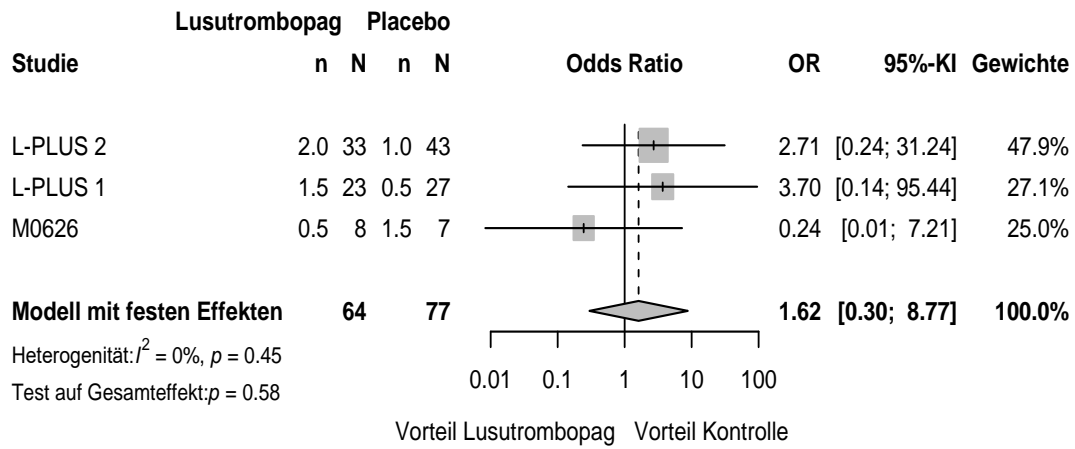
94 Thrombose/Thromboembolie (Gesamtrate)_OR Gender - Female



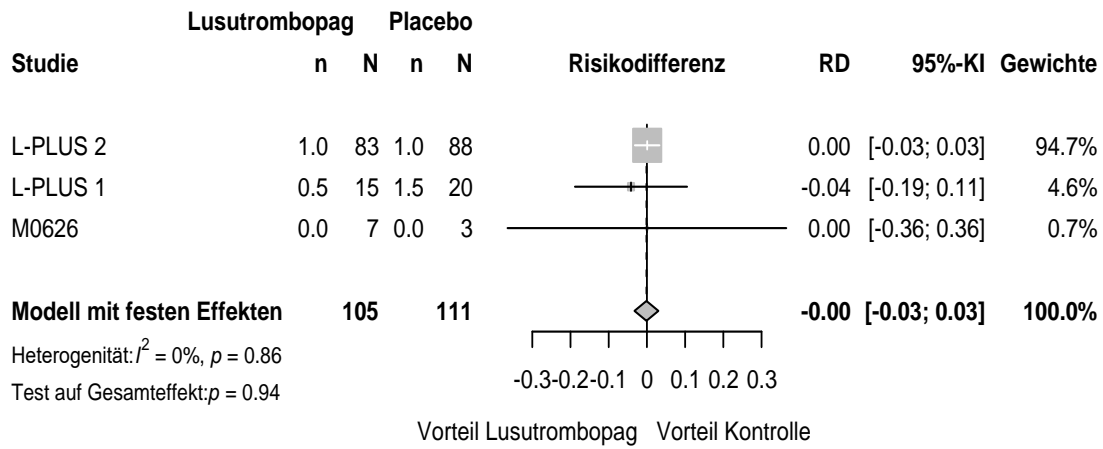
95 Thrombose/Thromboembolie (Gesamtrate)_OR Child-Pugh class - A



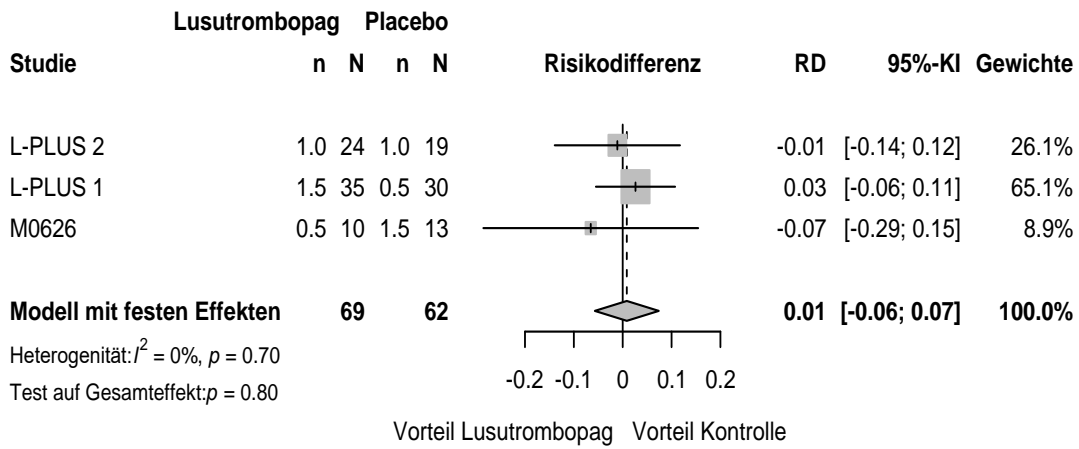
96 Thrombose/Thromboembolie (Gesamtrate)_OR Child-Pugh class - B



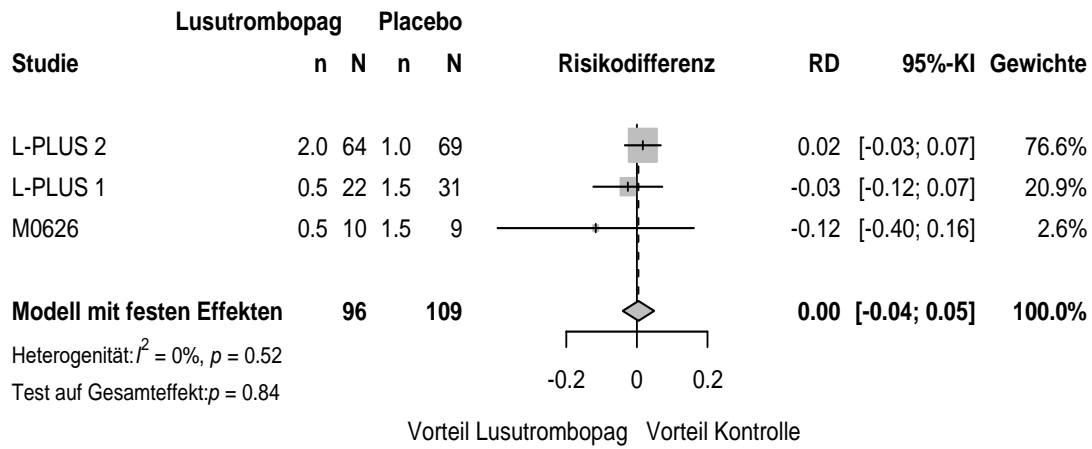
97 Thrombose/Thromboembolie (Gesamtrate)_RD Age (years) - < 65



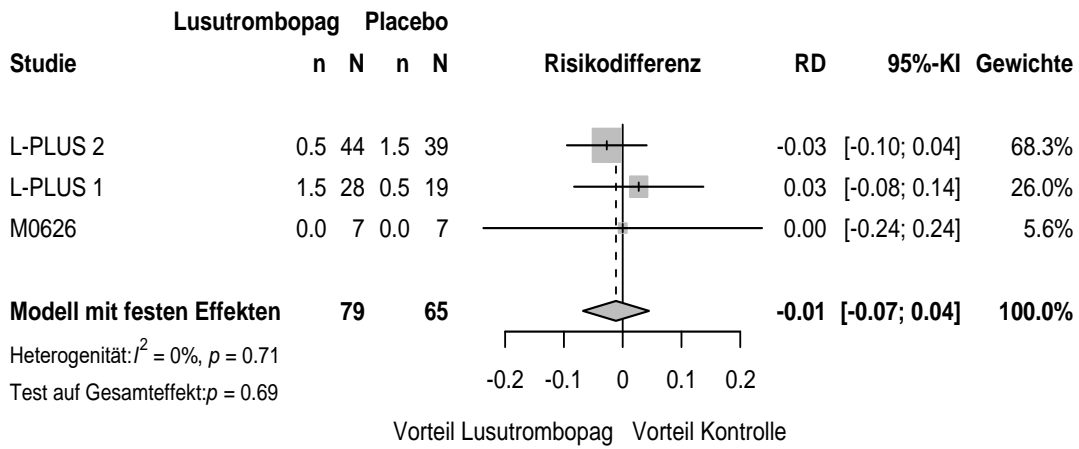
98 Thrombose/Thromboembolie (Gesamtrate)_RD Age (years) - >=65



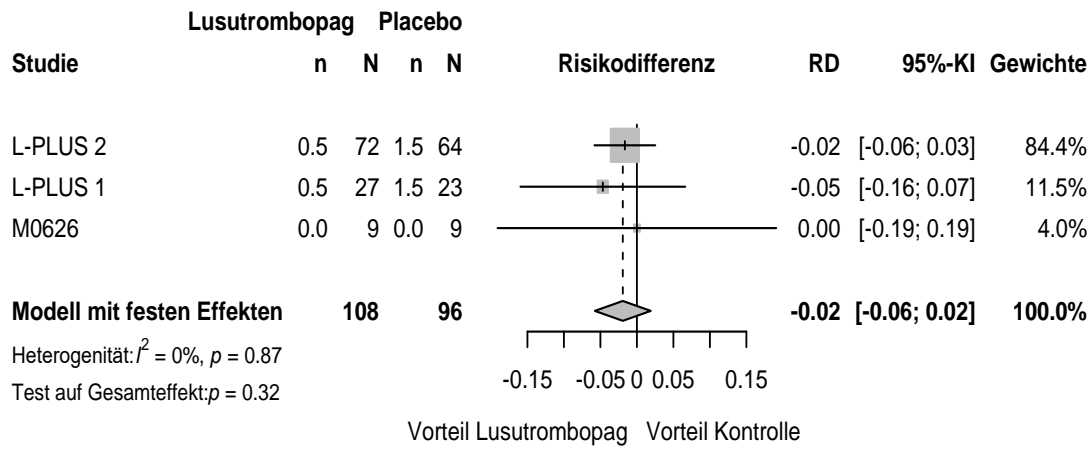
99 Thrombose/Thromboembolie (Gesamtrate)_RD Gender - Male



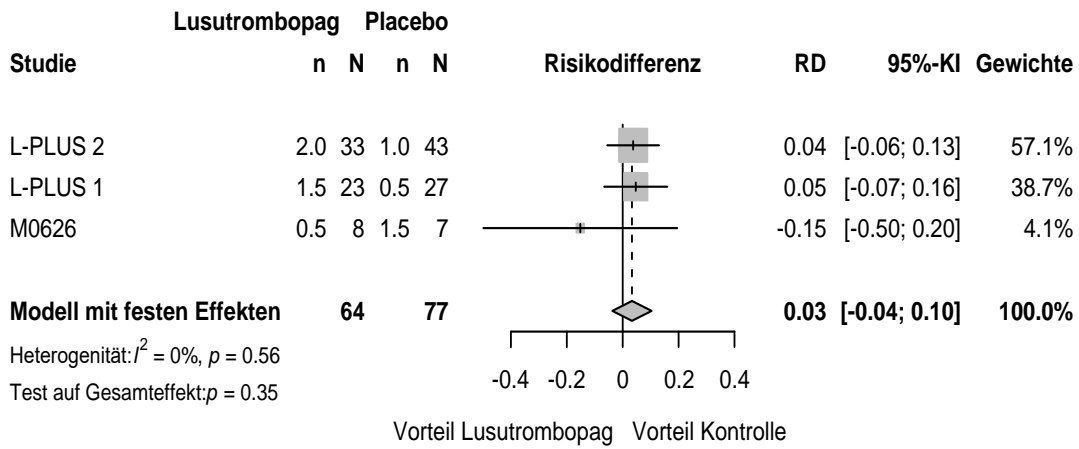
100 Thrombose/Thromboembolie (Gesamtrate)_RD Gender - Female



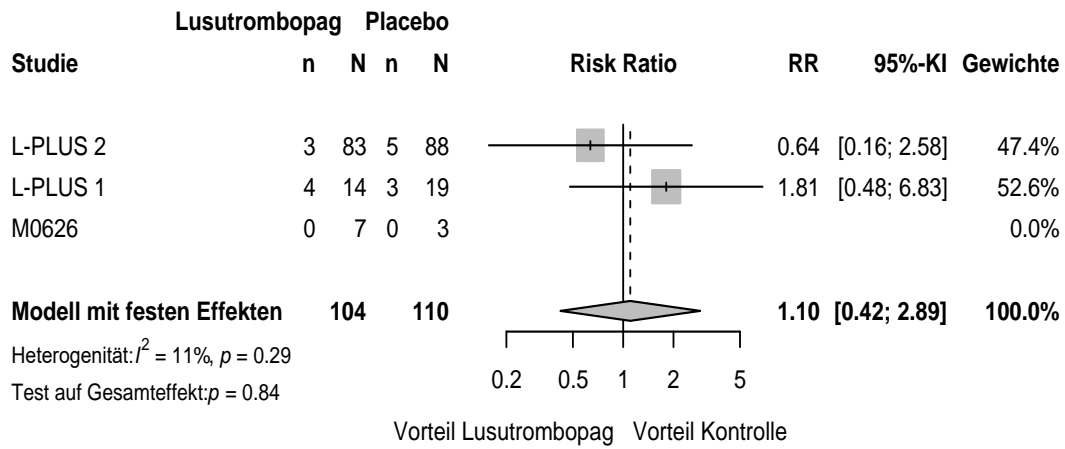
101 Thrombose/Thromboembolie (Gesamtrate)_RD Child-Pugh class - A



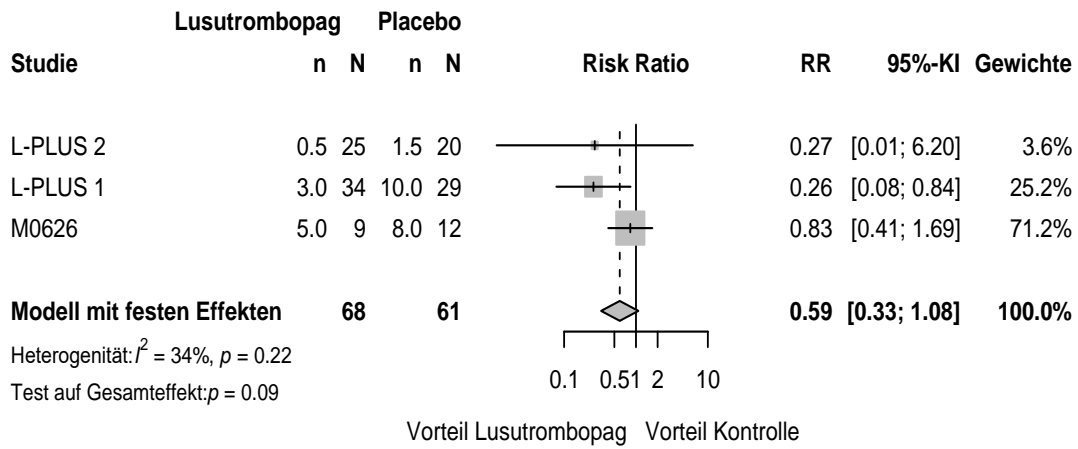
102 Thrombose/Thromboembolie (Gesamtrate)_RD Child-Pugh class - B



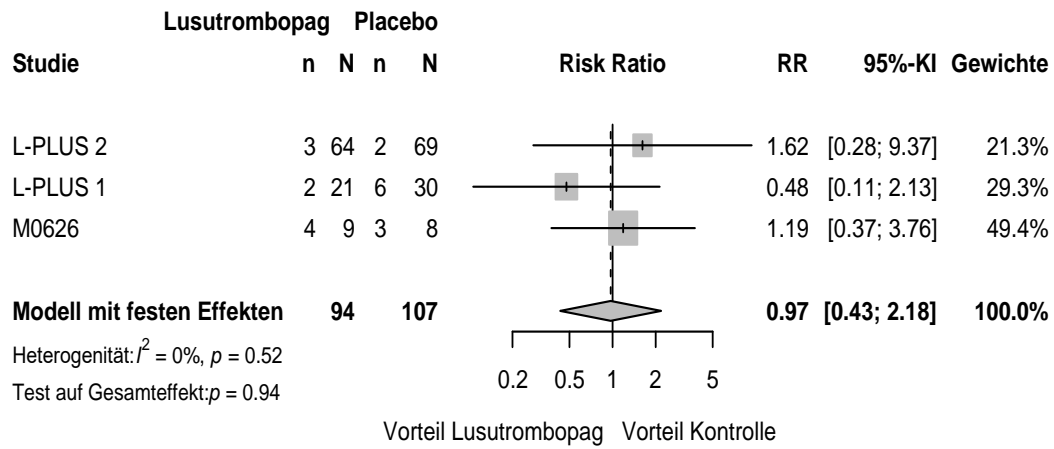
103 Blutungen (Gesamtrate)_RR Age (years) - < 65



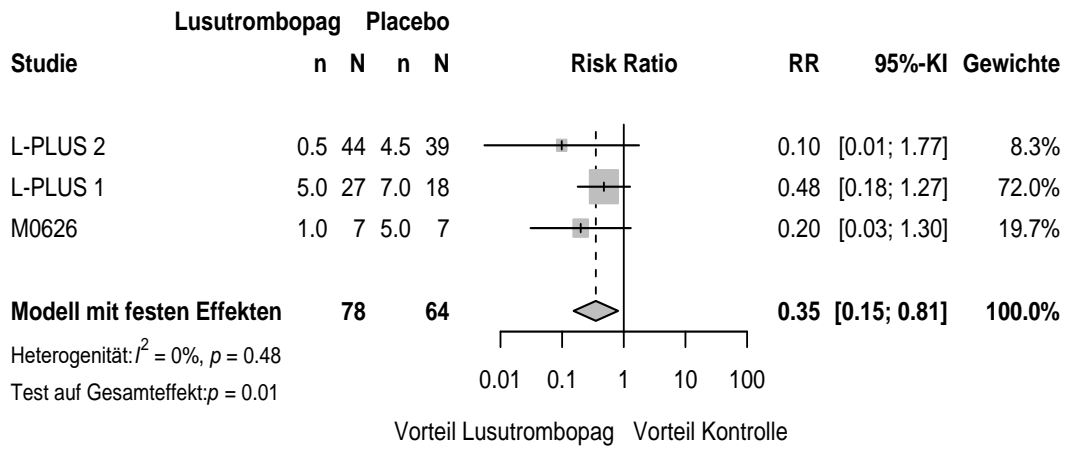
104 Blutungen (Gesamtrate)_RR Age (years) - >=65



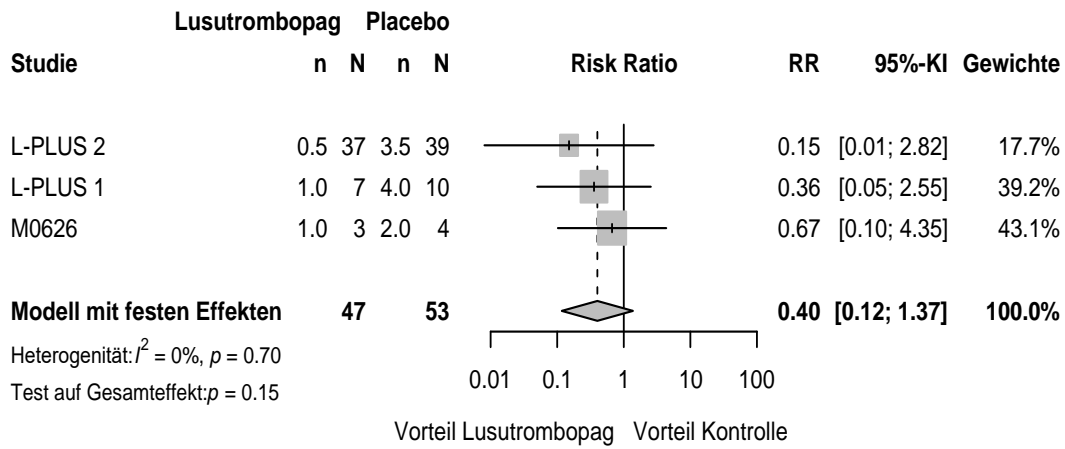
105 Blutungen (Gesamtrate)_RR Gender - Male



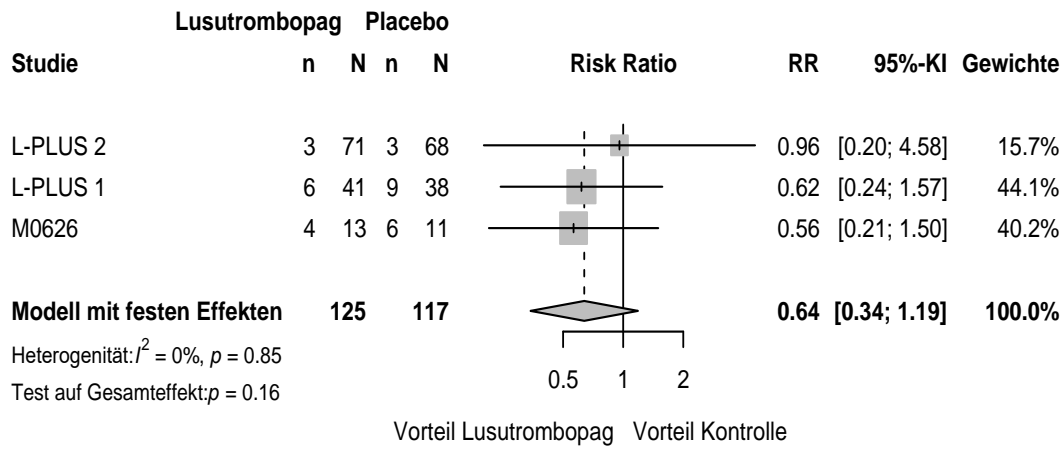
106 Blutungen (Gesamtrate)_RR Gender - Female



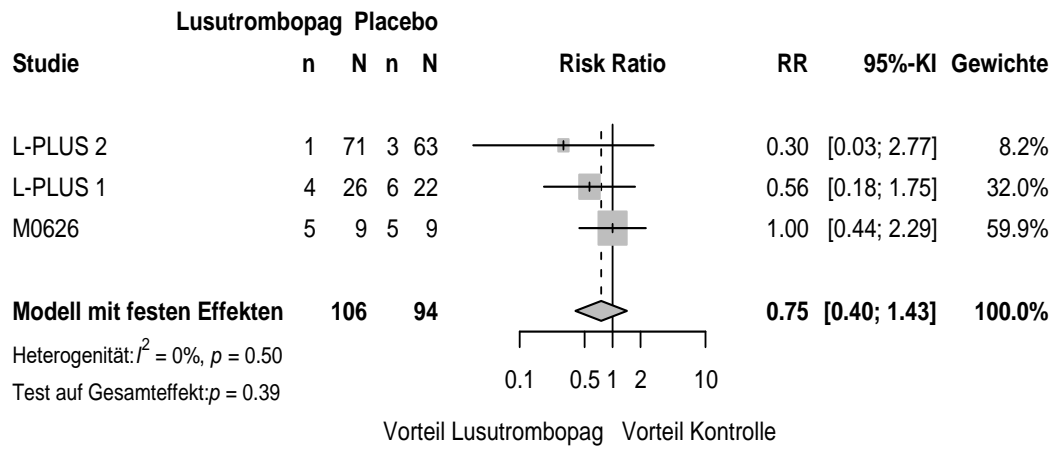
107 Blutungen (Gesamtrate)_RR Baseline platelet count ($\cdot 10^4/uL$) - < 3.5



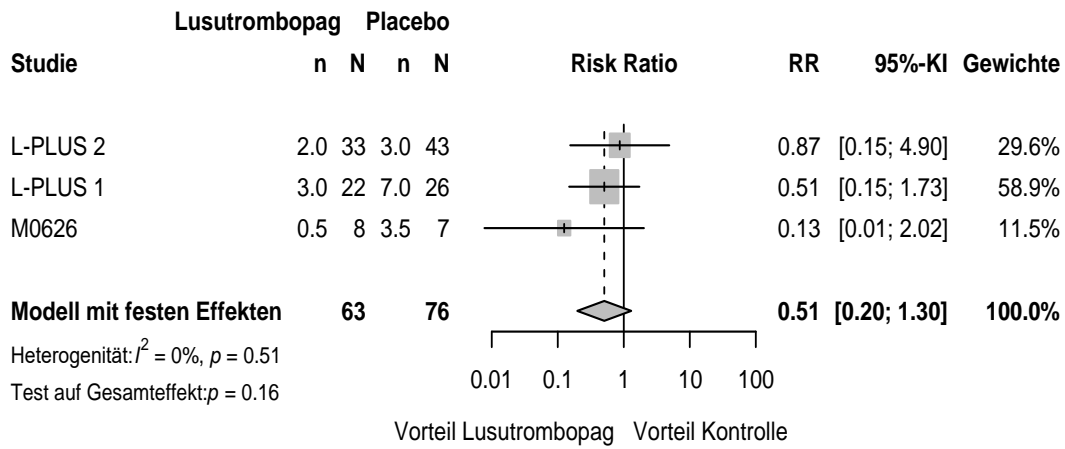
108 Blutungen (Gesamtrate)_RR Baseline platelet count (*10⁴/uL) - >= 3.5



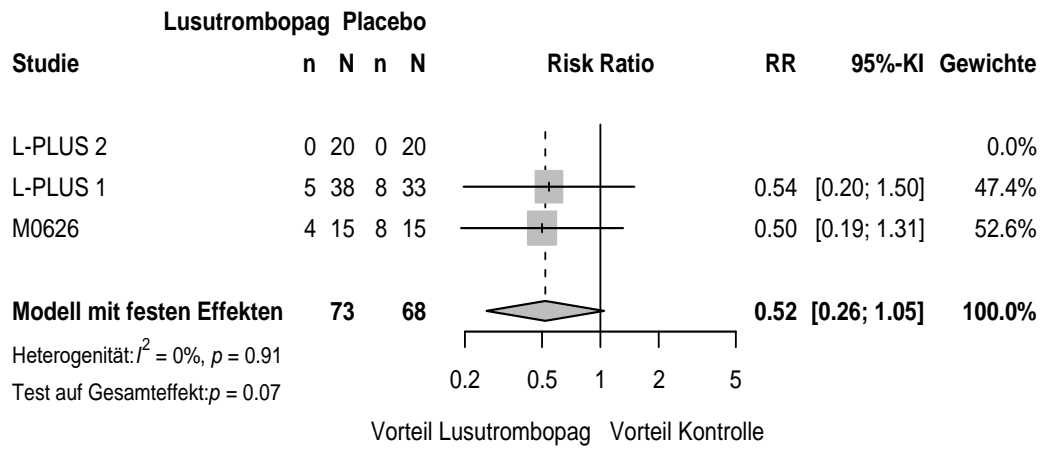
109 Blutungen (Gesamtrate)_RR Child-Pugh class - A



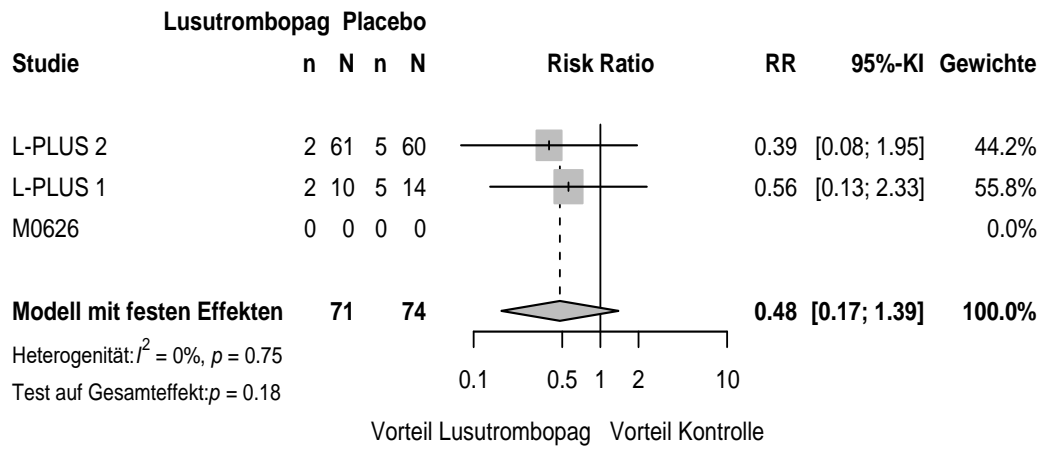
110 Blutungen (Gesamtrate)_RR Child-Pugh class - B



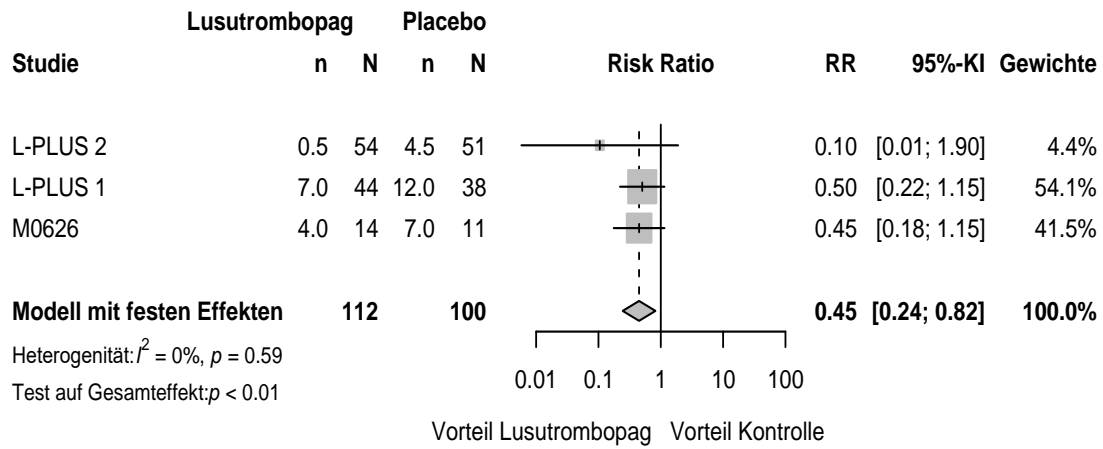
111 Blutungen (Gesamtrate)_RR Invasive procedure liver-related



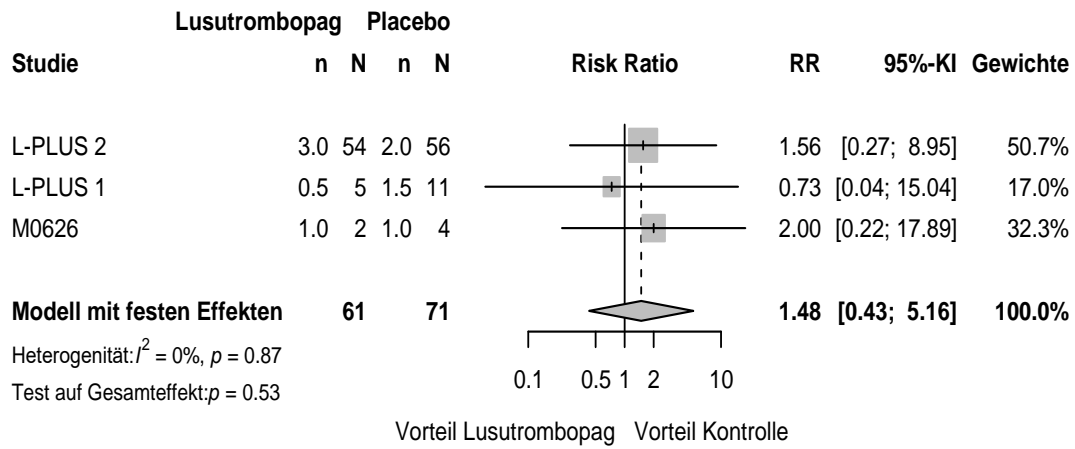
112 Blutungen (Gesamtrate)_RR Invasive procedure gi-related



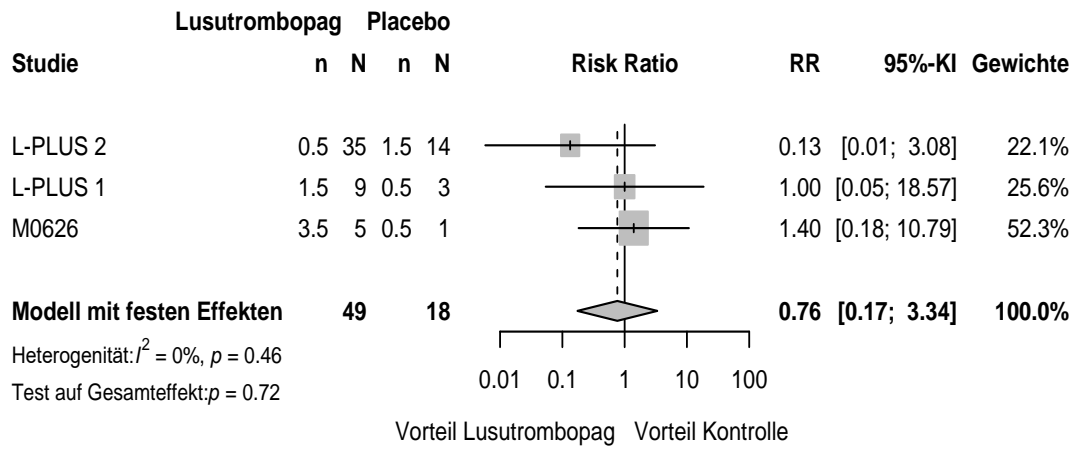
113 Blutungen (Gesamtrate)_RR Baseline body weight (kg) - < 75



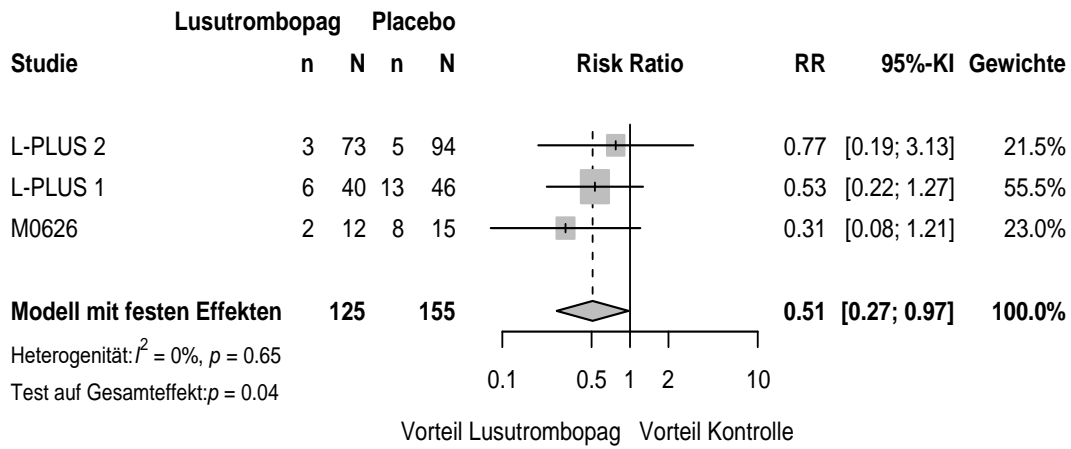
114 Blutungen (Gesamtrate)_RR Baseline body weight (kg) - >= 75



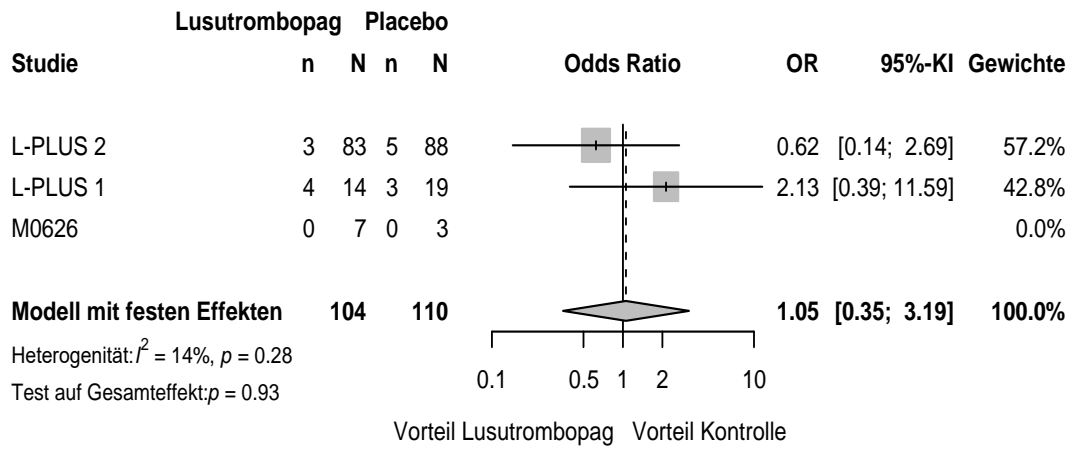
115 Blutungen (Gesamtrate)_RR Treatment duration (days) - < 7



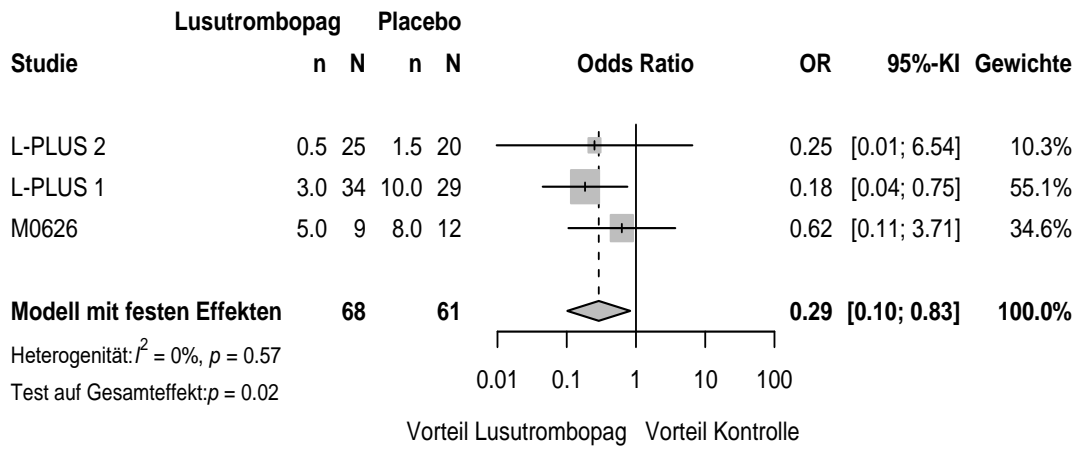
116 Blutungen (Gesamtrate)_RR Treatment duration (days) -7



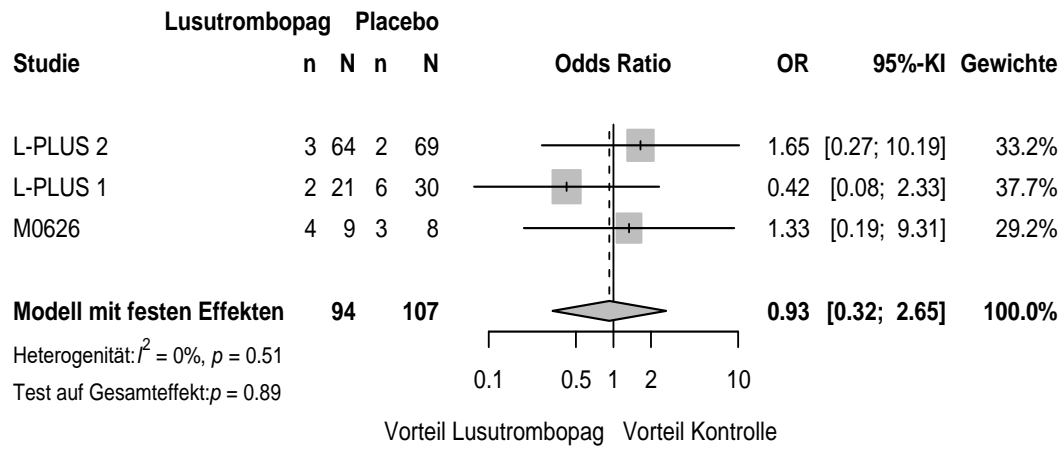
117 Blutungen (Gesamtrate)_OR Age (years) - < 65



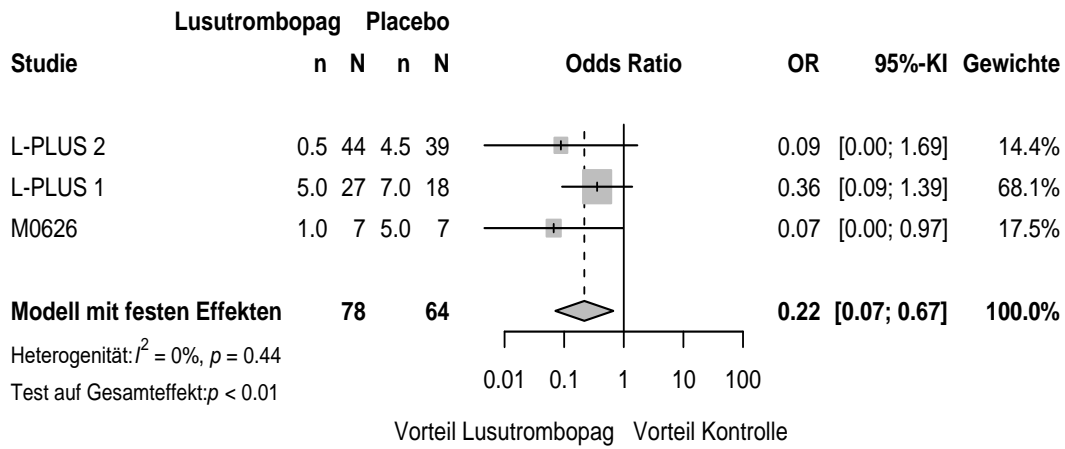
118 Blutungen (Gesamtrate)_OR Age (years) - >=65



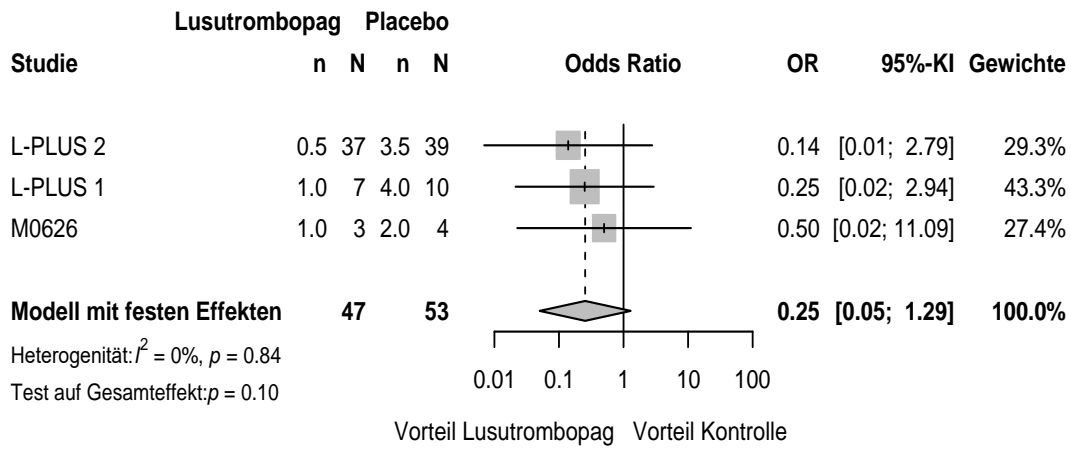
119 Blutungen (Gesamtrate)_OR Gender - Male



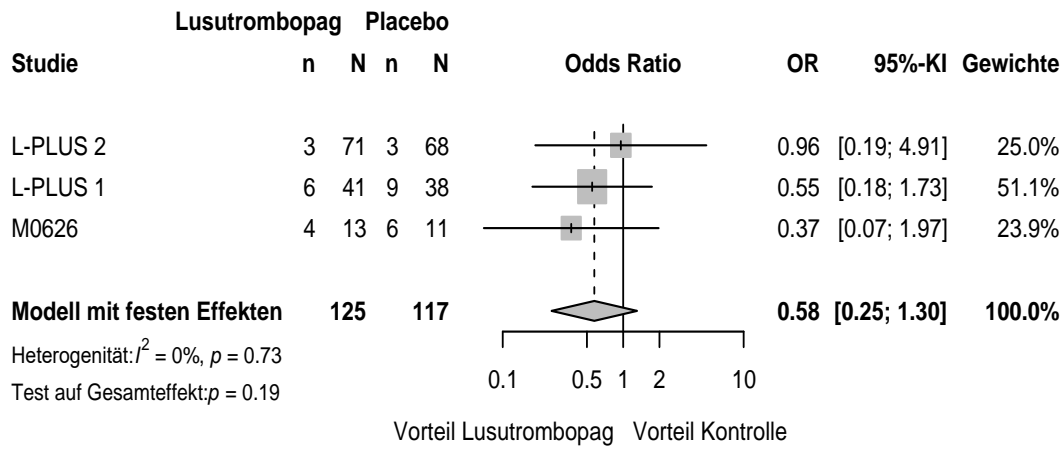
120 Blutungen (Gesamtrate)_OR Gender - Female



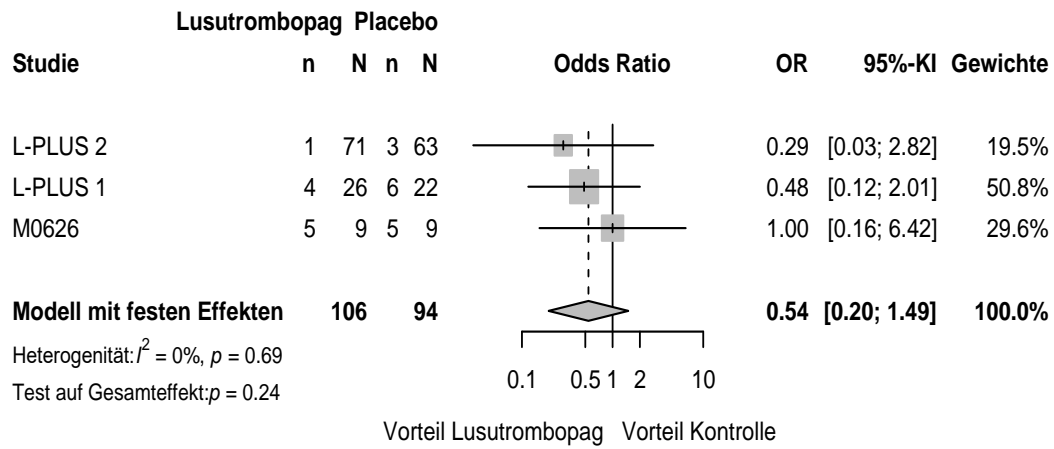
121 Blutungen (Gesamtrate)_OR Baseline platelet count ($\cdot 10^4/uL$) - < 3.5



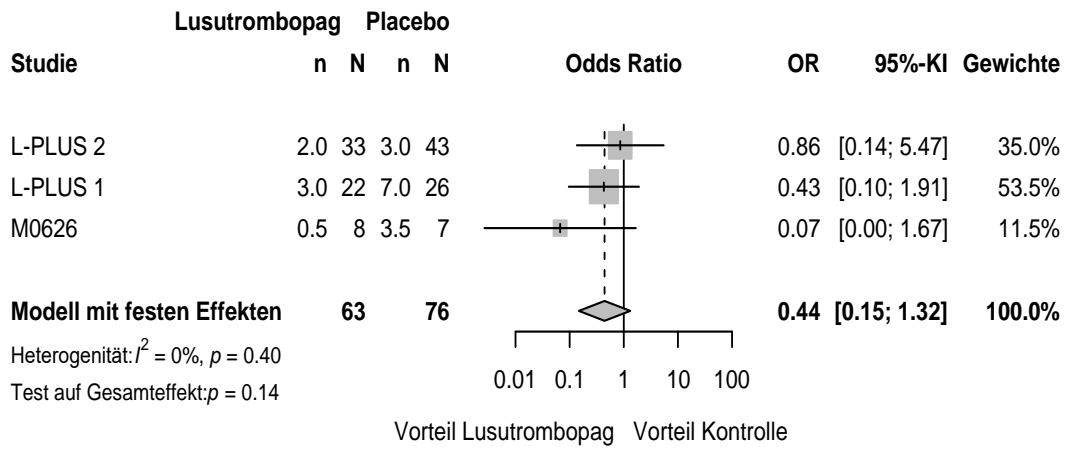
122 Blutungen (Gesamtrate)_OR Baseline platelet count ($\cdot 10^4/uL$) - ≥ 3.5



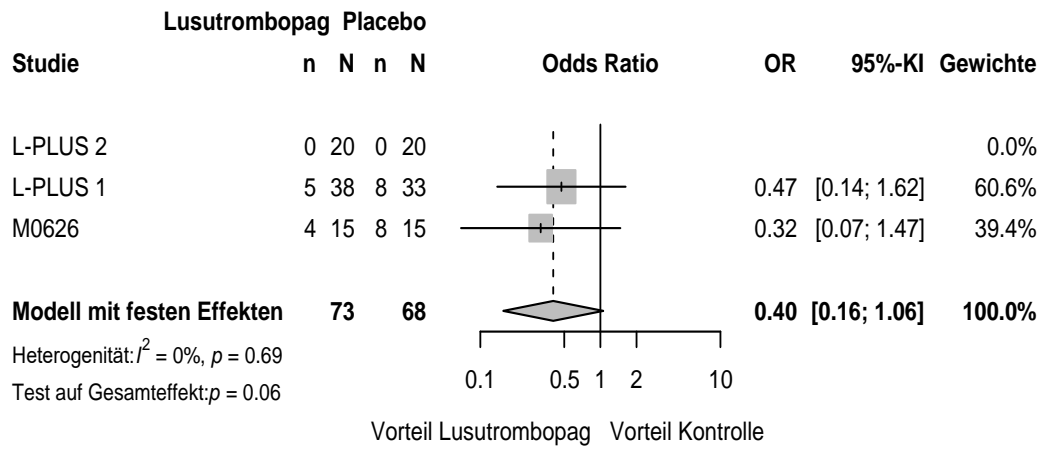
123 Blutungen (Gesamtrate)_OR Child-Pugh class - A



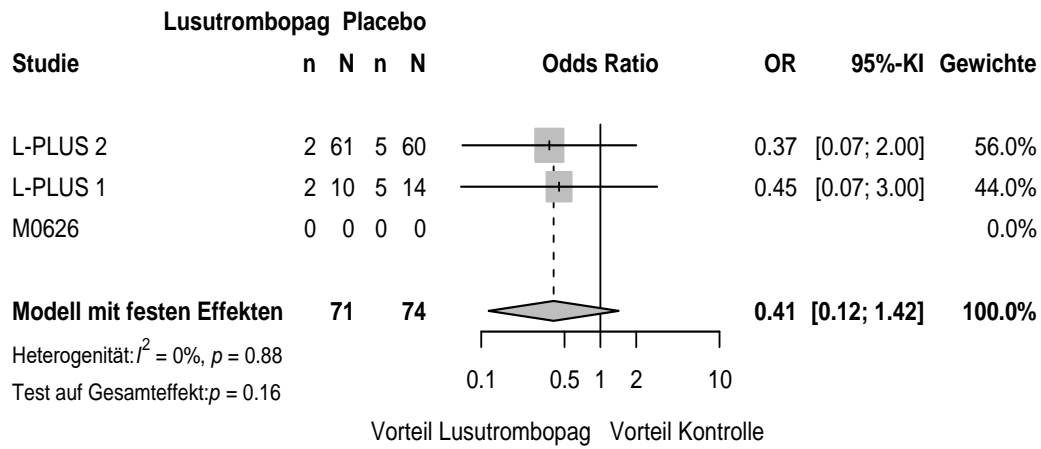
124 Blutungen (Gesamtrate)_OR Child-Pugh class - B



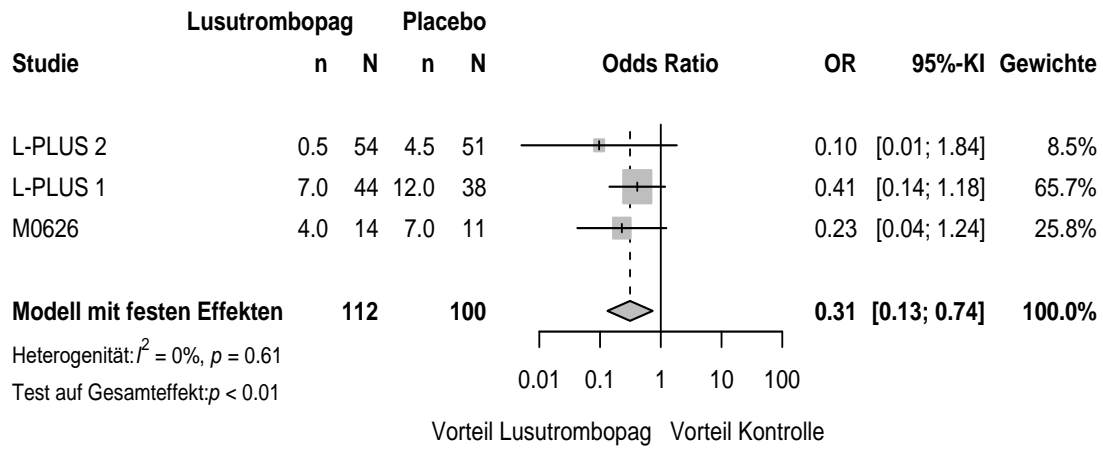
125 Blutungen (Gesamtrate)_OR Invasive procedure liver-related



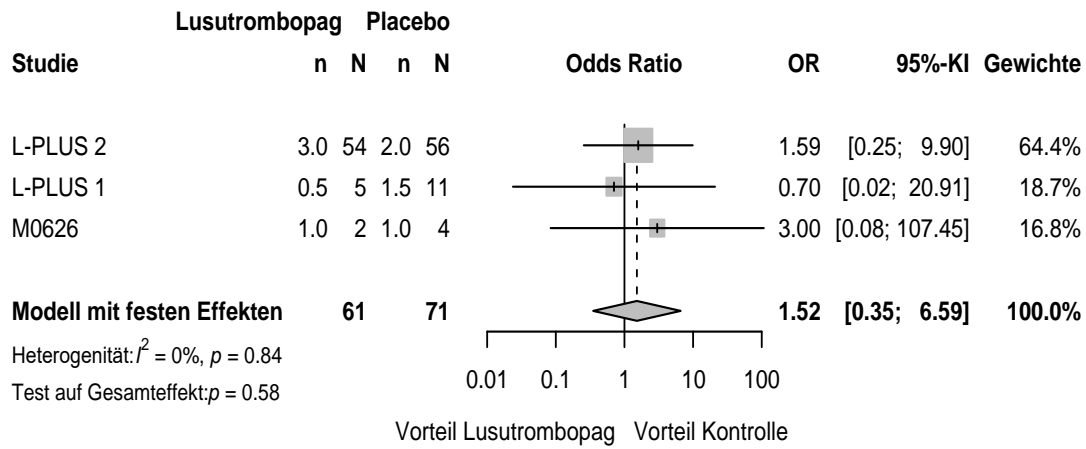
126 Blutungen (Gesamtrate)_OR Invasive procedure gi-related



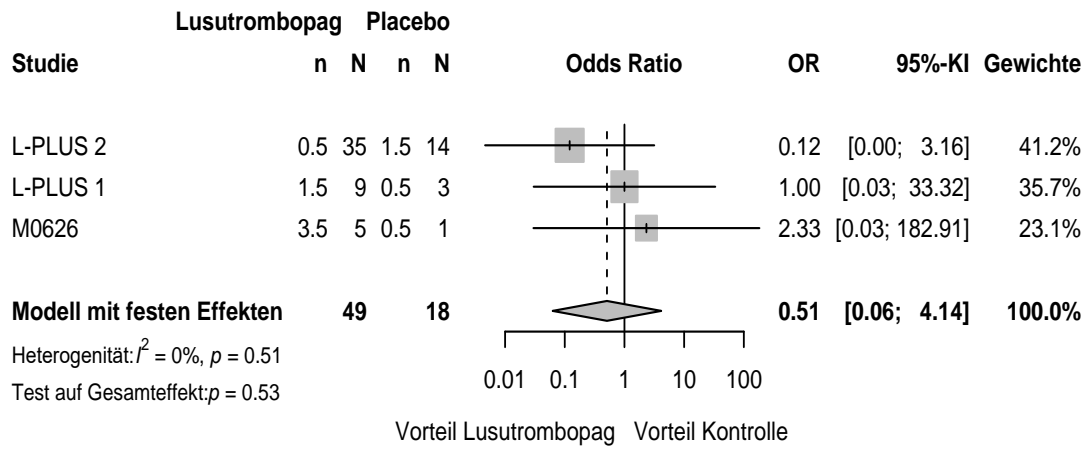
127 Blutungen (Gesamtrate)_OR Baseline body weight (kg) - < 75



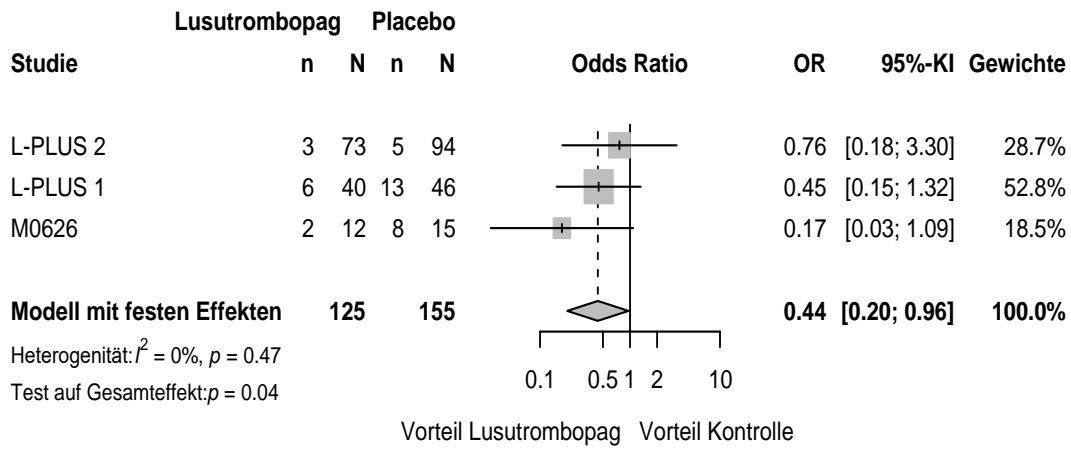
128 Blutungen (Gesamtrate)_OR Baseline body weight (kg) - >= 75



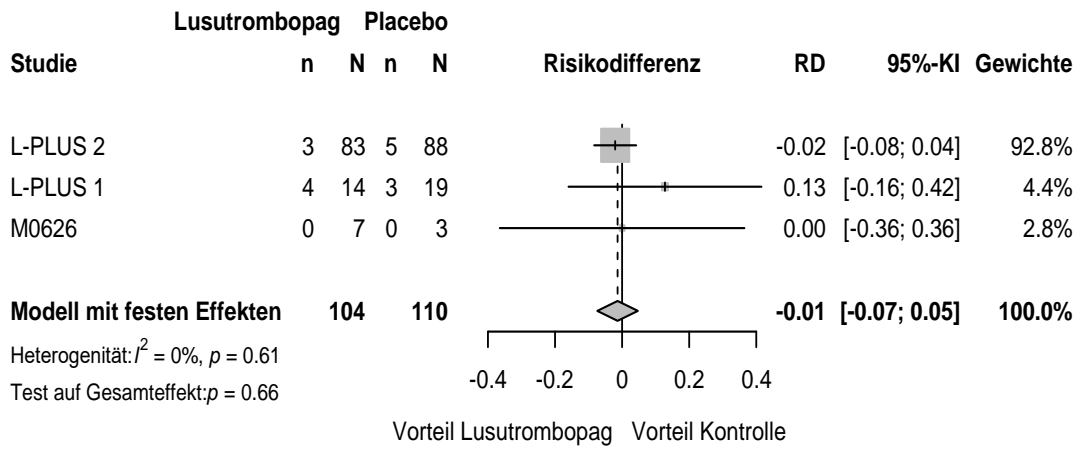
129 Blutungen (Gesamtrate)_OR Treatment duration (days) - < 7



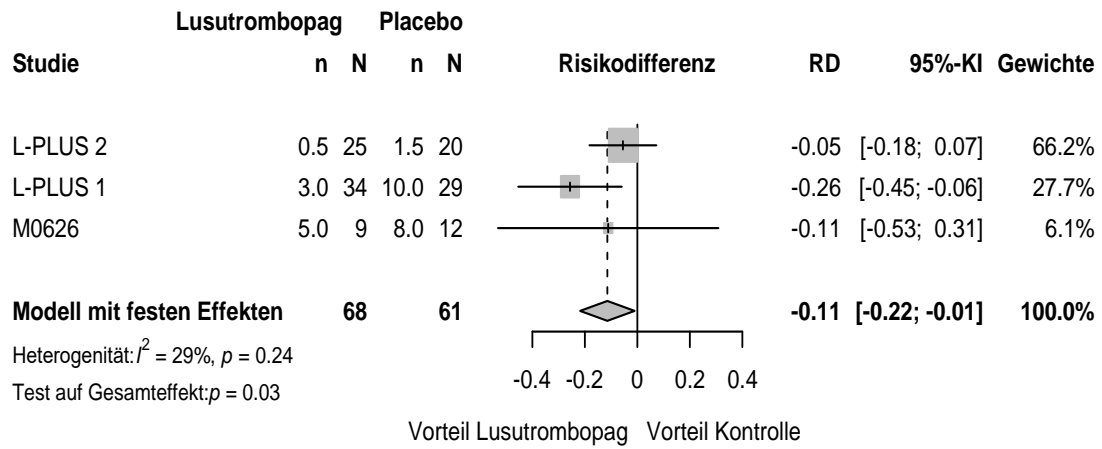
130 Blutungen (Gesamtrate)_OR Treatment duration (days) -7



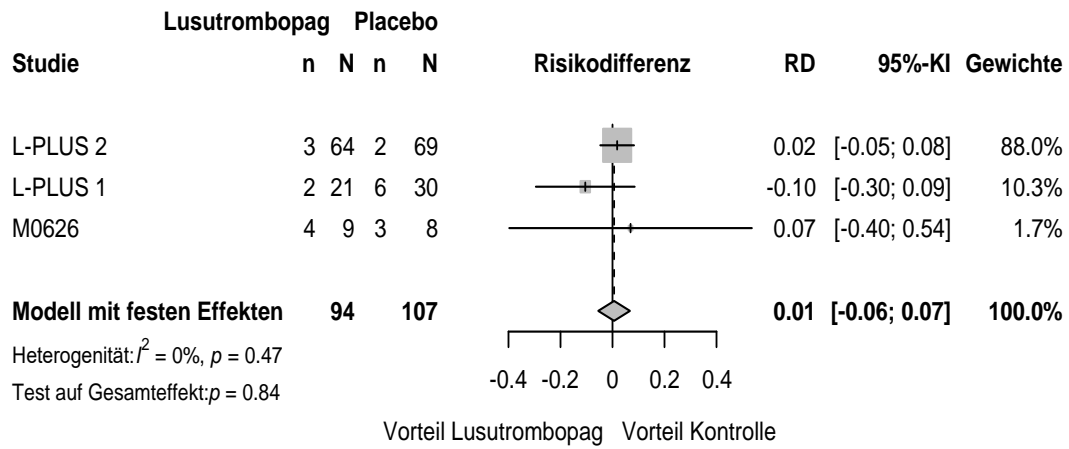
131 Blutungen (Gesamtrate)_RD Age (years) - < 65



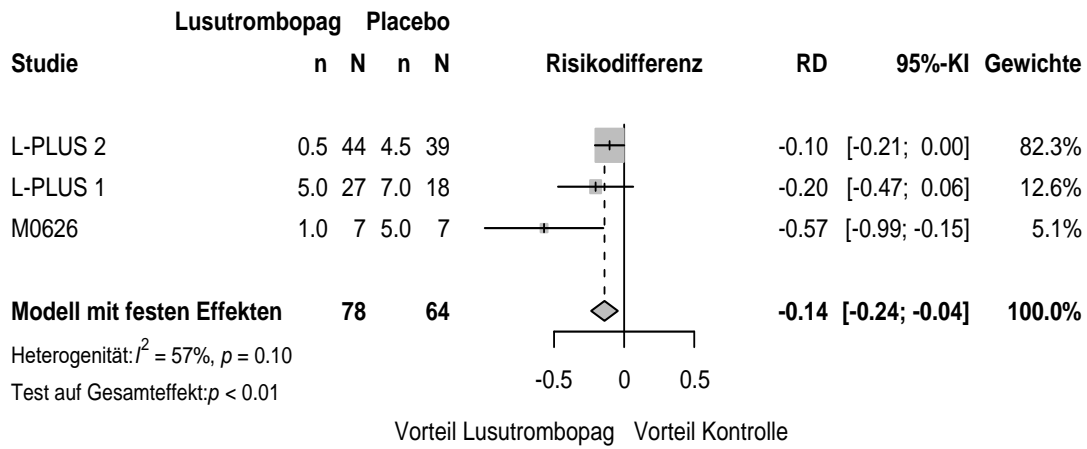
132 Blutungen (Gesamtrate)_RD Age (years) - >=65



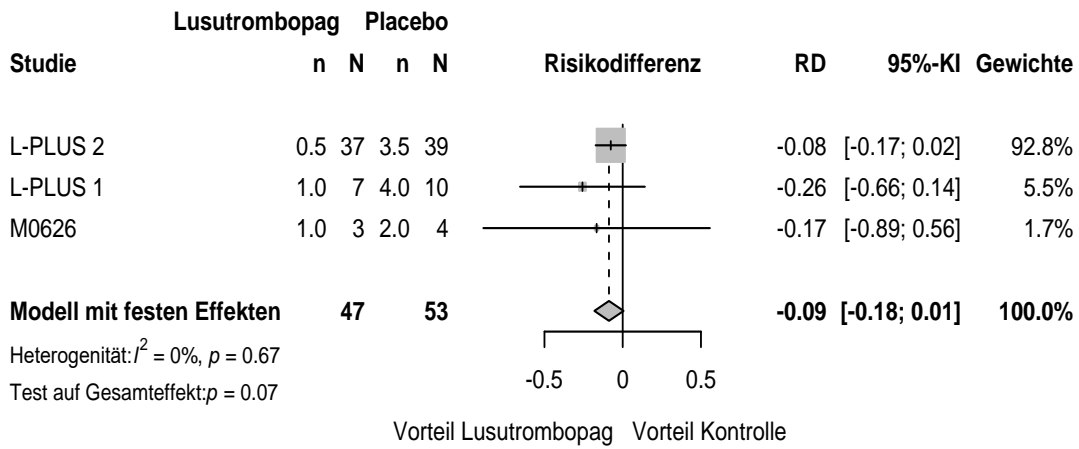
133 Blutungen (Gesamtrate)_RD Gender - Male



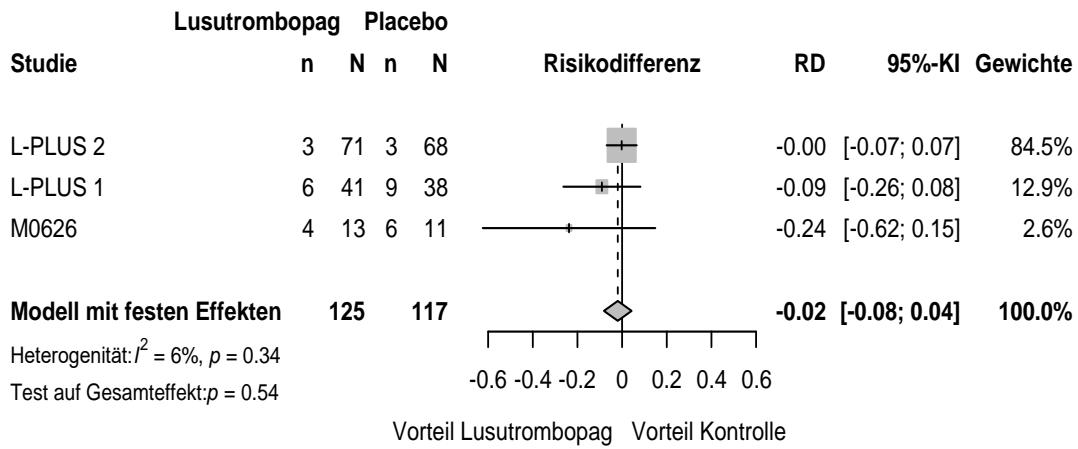
134 Blutungen (Gesamtrate)_RD Gender - Female



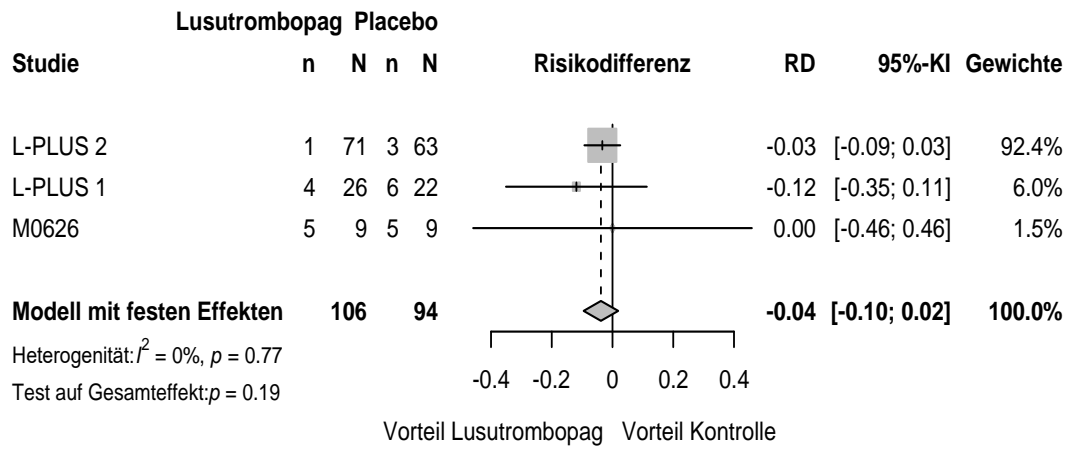
135 Blutungen (Gesamtrate)_RD Baseline platelet count (*10⁴/uL) - < 3.5



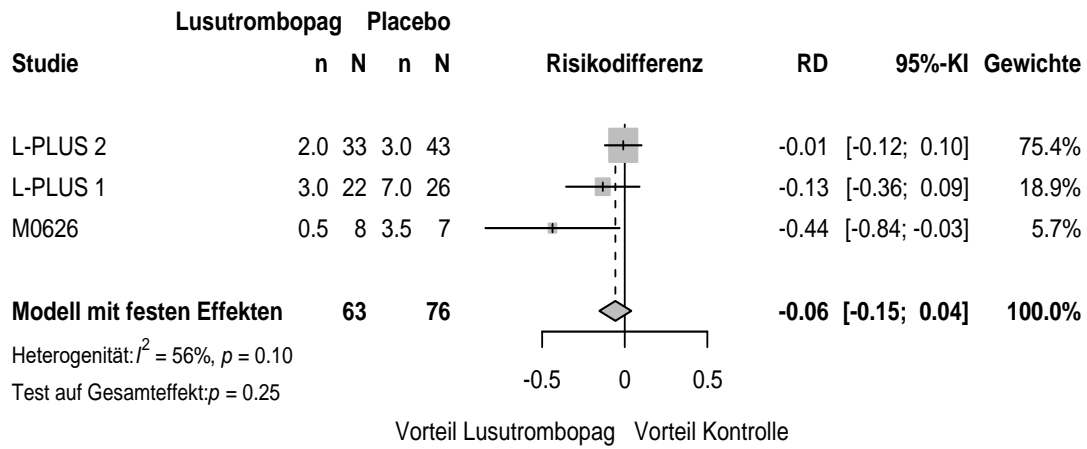
136 Blutungen (Gesamtrate)_RD Baseline platelet count (*10⁴/uL) - >= 3.5



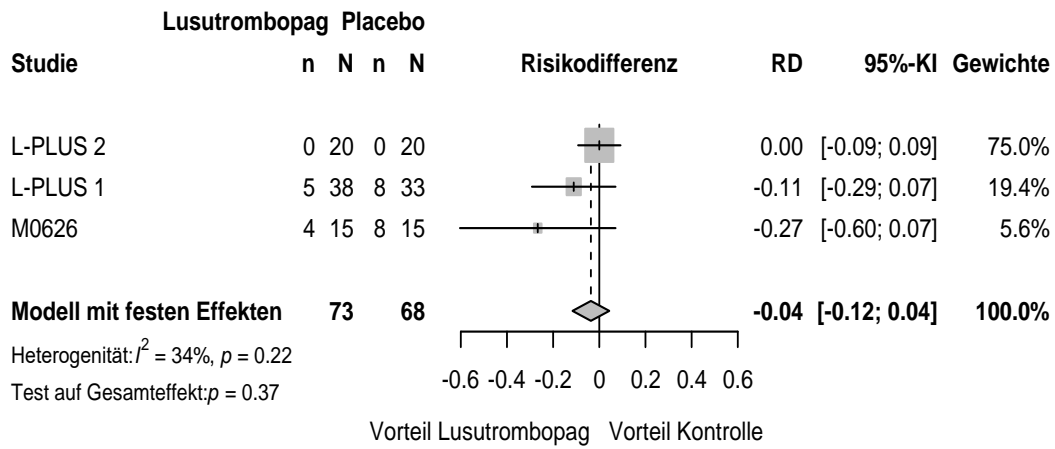
137 Blutungen (Gesamtrate)_RD Child-Pugh class - A



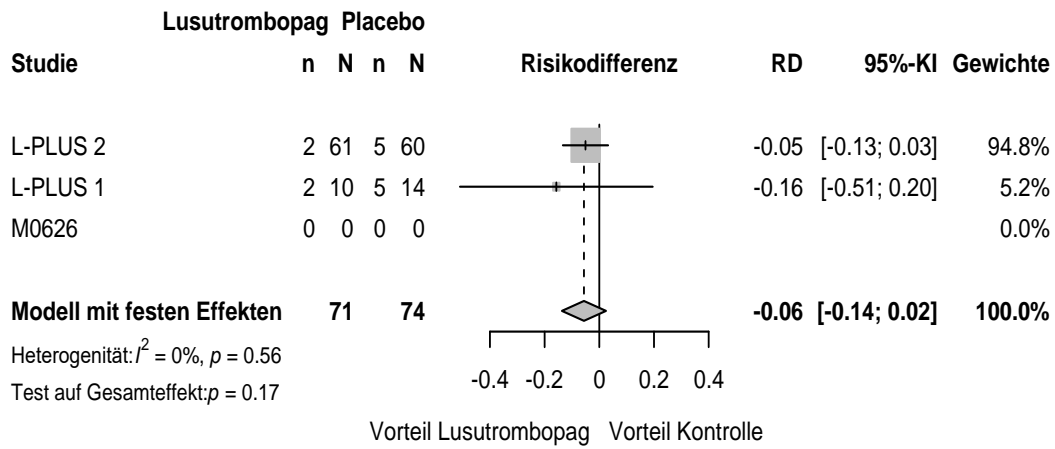
138 Blutungen (Gesamtrate)_RD Child-Pugh class - B



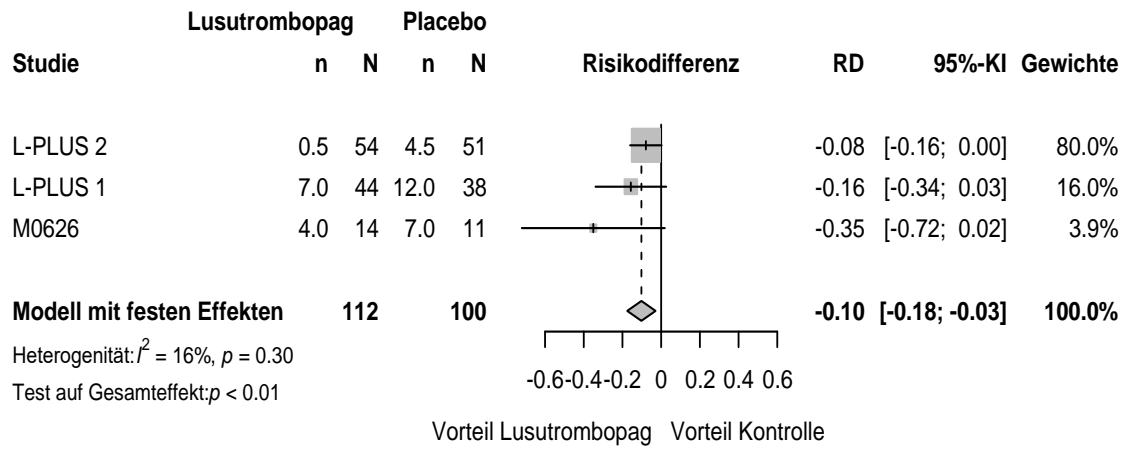
139 Blutungen (Gesamtrate)_RD Invasive procedure liver-related



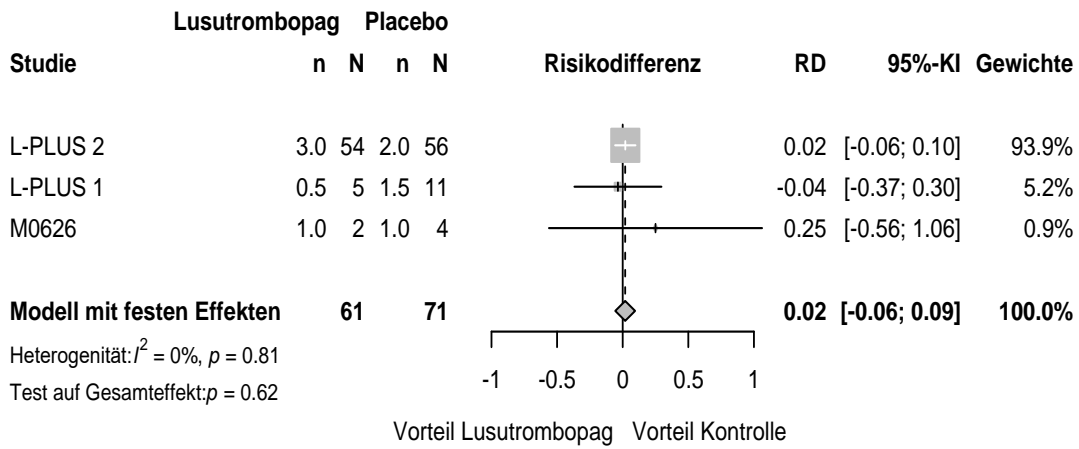
140 Blutungen (Gesamtrate)_RD Invasive procedure gi-related



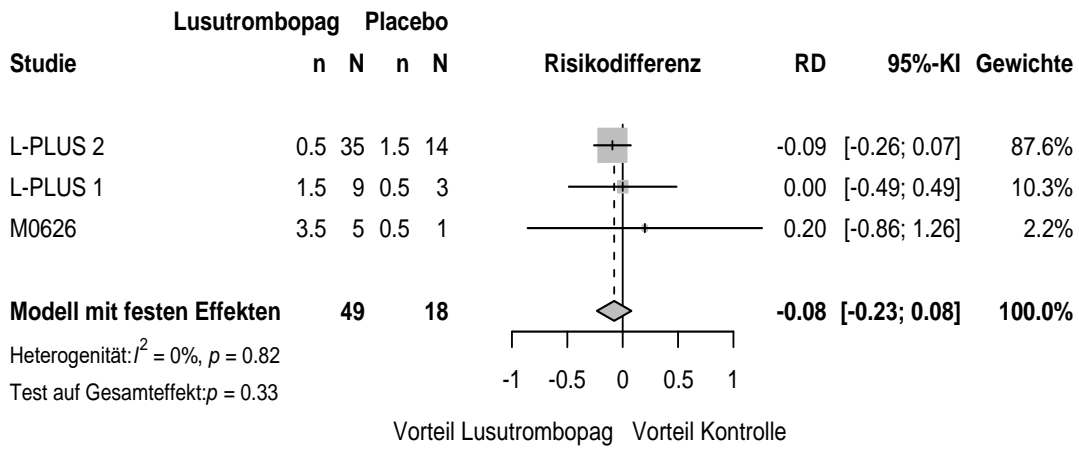
141 Blutungen (Gesamtrate)_RD Baseline body weight (kg) - < 75



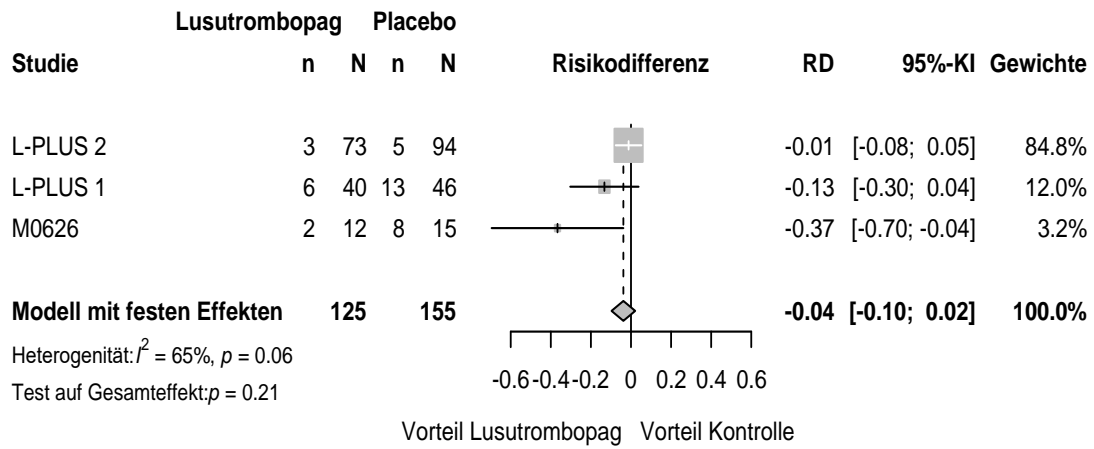
142 Blutungen (Gesamtrate)_RD Baseline body weight (kg) - >= 75



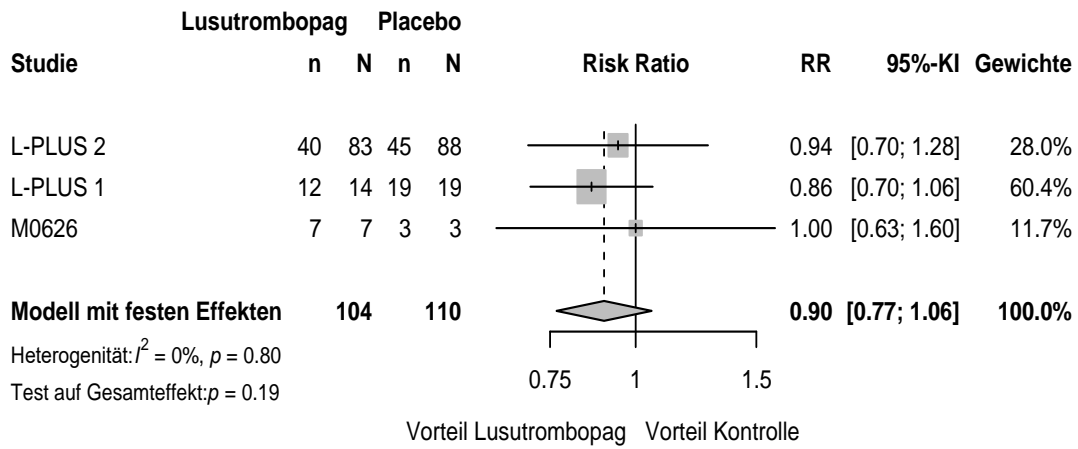
143 Blutungen (Gesamtrate)_RD Treatment duration (days) - < 7



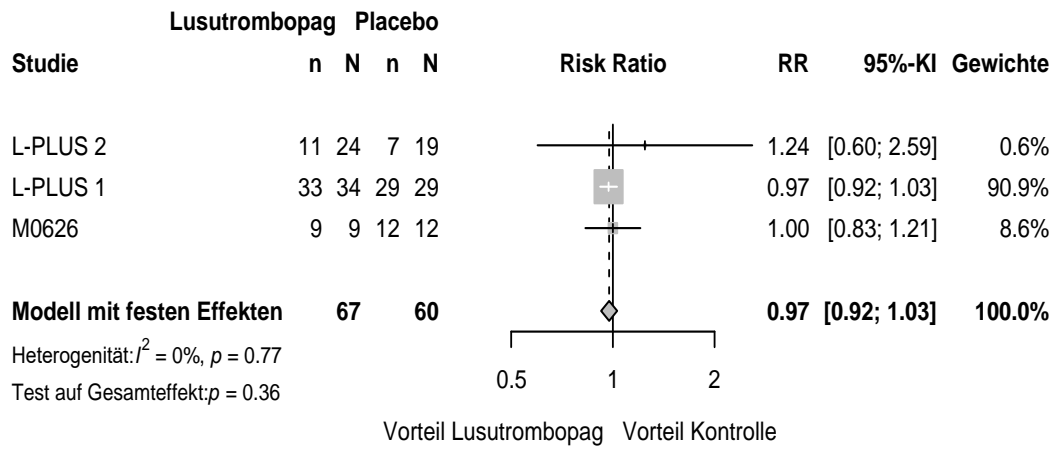
144 Blutungen (Gesamtrate)_RD Treatment duration (days) -7



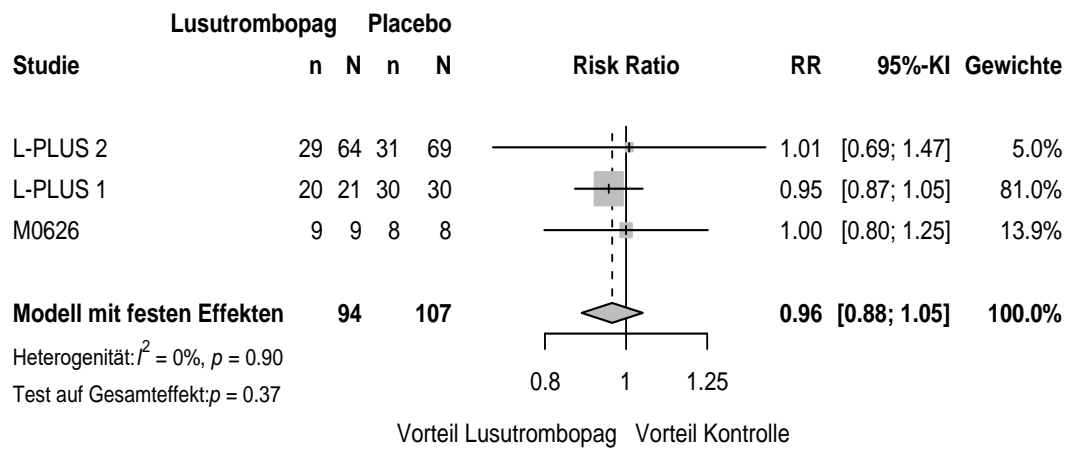
145 Unerwünschte Ereignisse (UE)_RR Age (years) - < 65



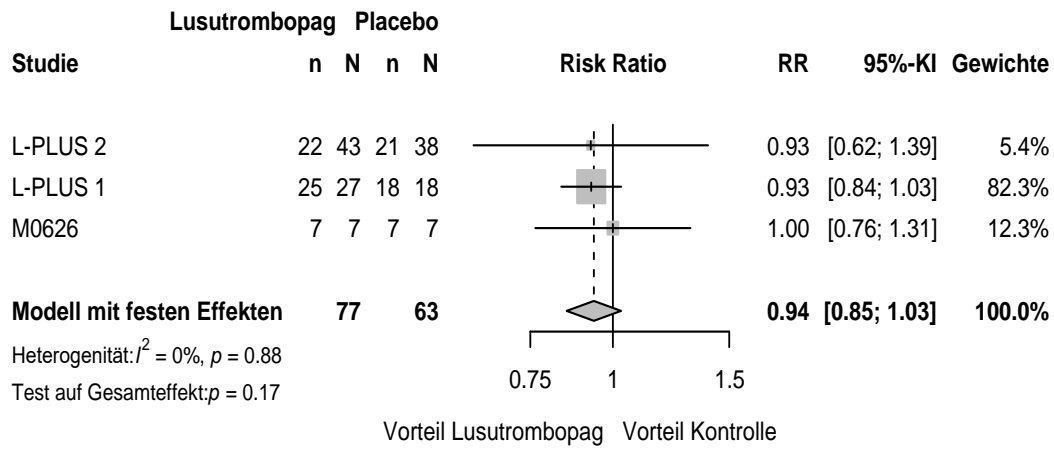
146 Unerwünschte Ereignisse (UE)_RR Age (years) - >=65



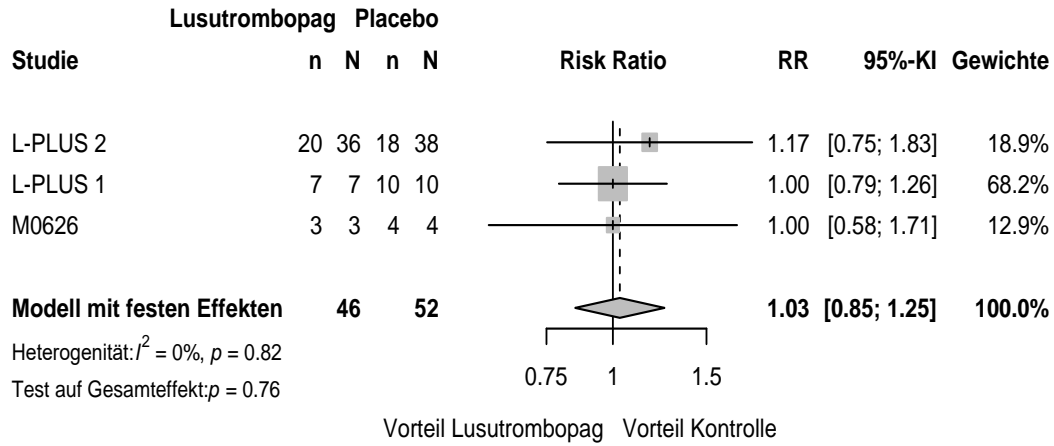
147 Unerwünschte Ereignisse (UE)_RR Gender - Male



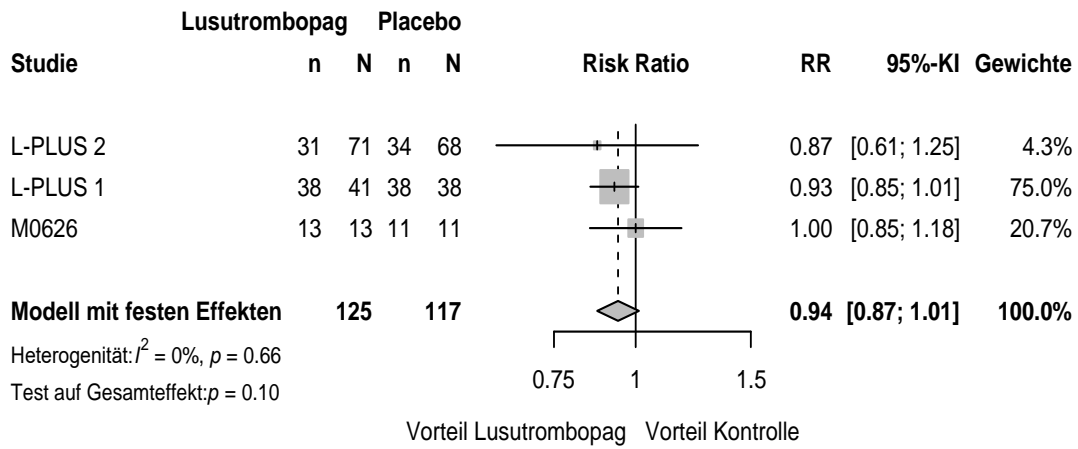
148 Unerwünschte Ereignisse (UE)_RR Gender - Female



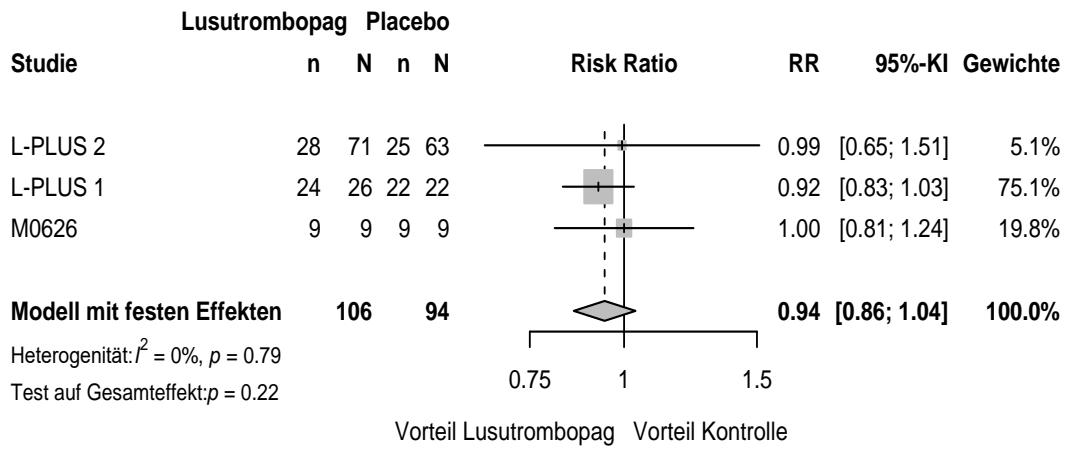
149 Unerwünschte Ereignisse (UE)_RR Baseline platelet count (*10⁴/uL) - < 3.5



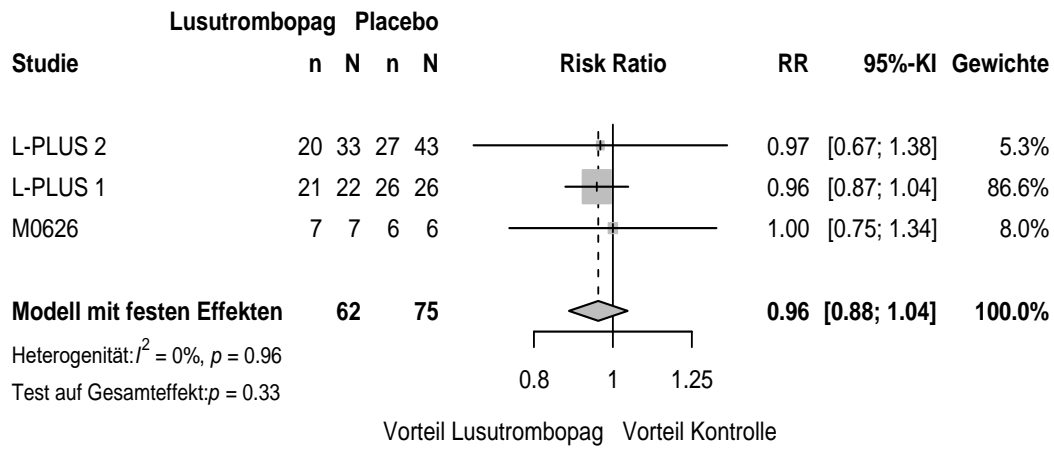
150 Unerwünschte Ereignisse (UE)_RR Baseline platelet count (*10⁴/uL) - >= 3.5



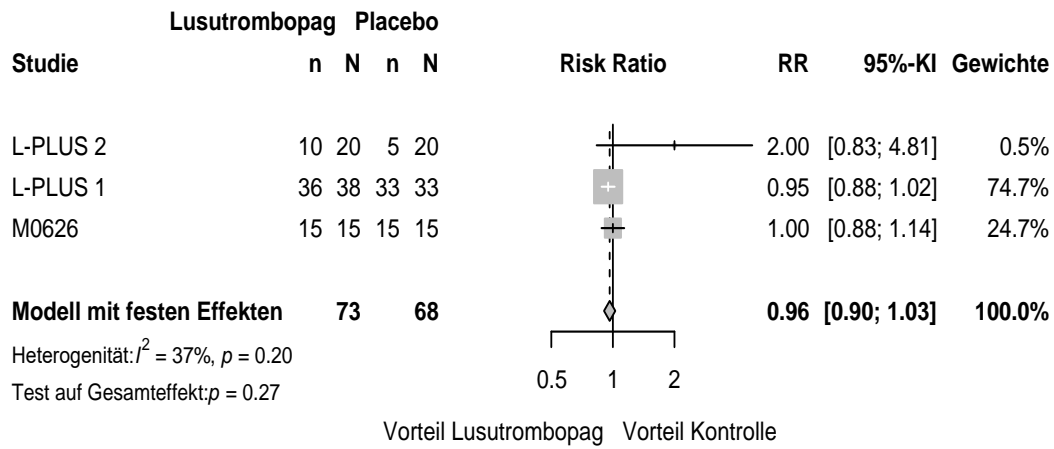
151 Unerwünschte Ereignisse (UE)_RR Child-Pugh class - A



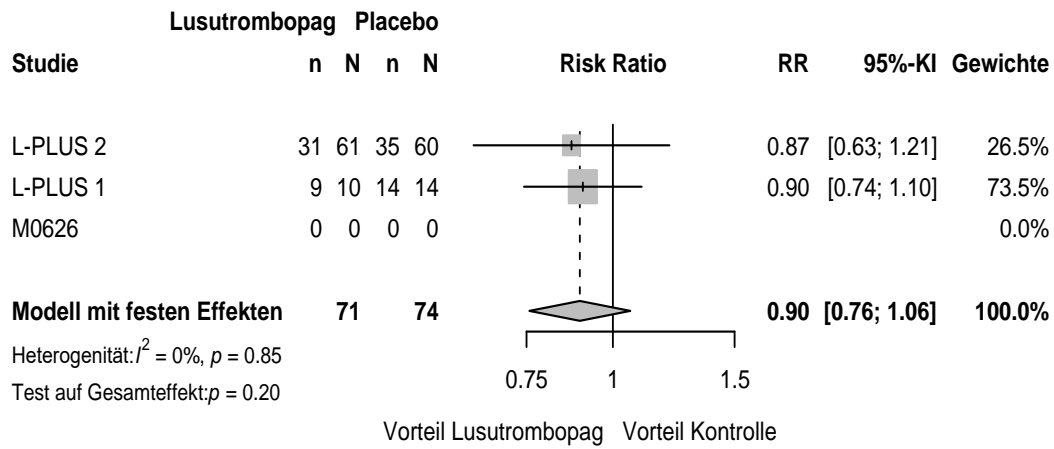
152 Unerwünschte Ereignisse (UE)_RR Child-Pugh class - B



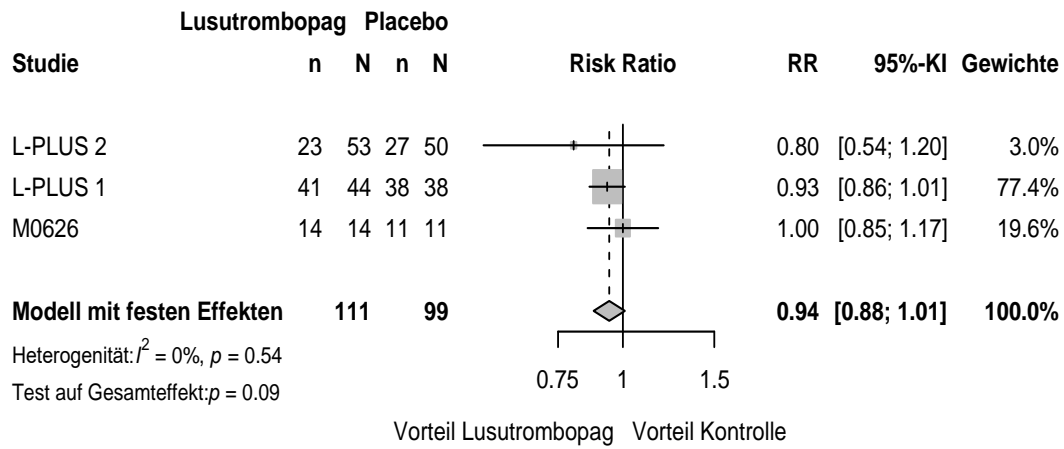
153 Unerwünschte Ereignisse (UE)_RR Invasive procedure liver-related



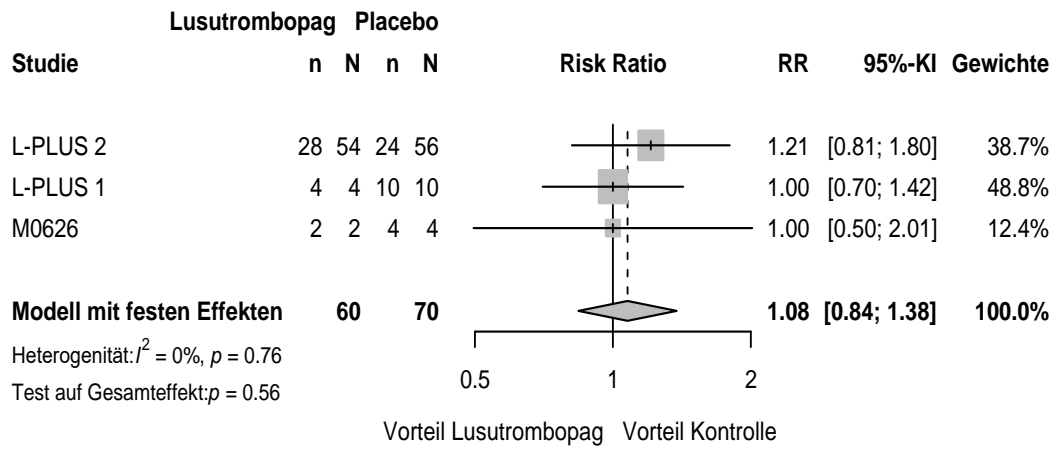
154 Unerwünschte Ereignisse (UE)_RR Invasive procedure gi-related



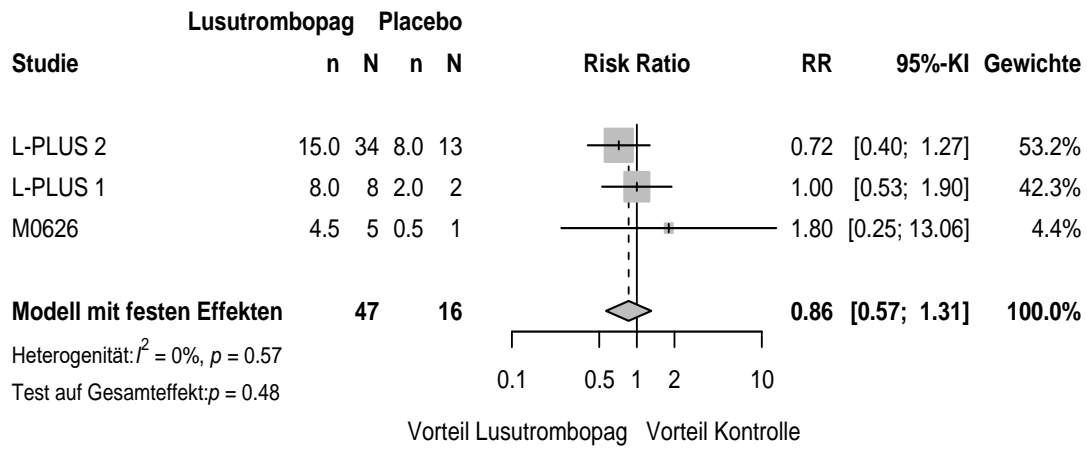
155 Unerwünschte Ereignisse (UE)_RR Baseline body weight (kg) - < 75



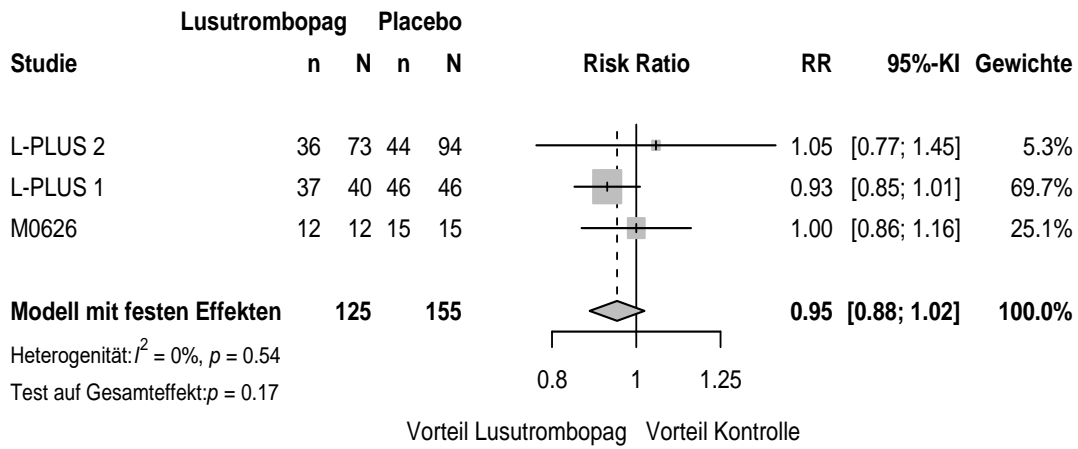
156 Unerwünschte Ereignisse (UE)_RR Baseline body weight (kg) - >= 75



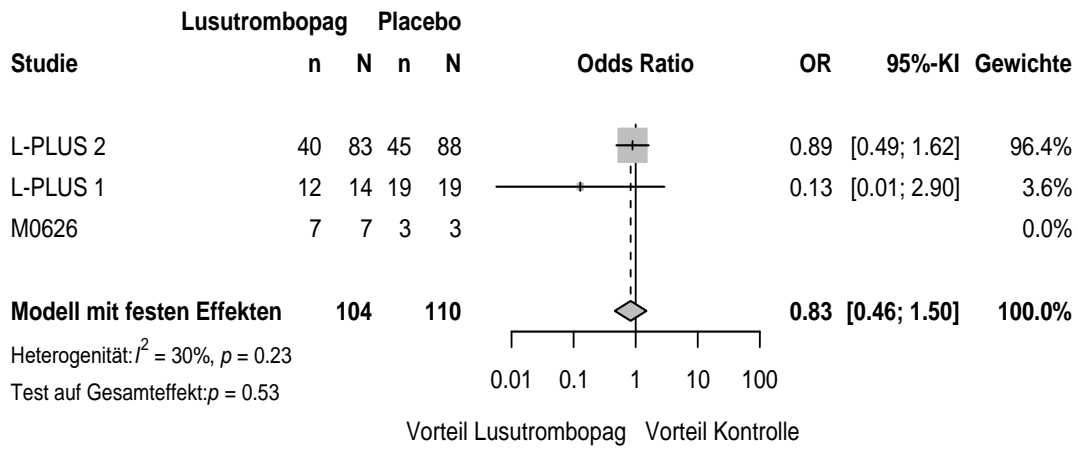
157 Unerwünschte Ereignisse (UE)_RR Treatment duration (days) - < 7



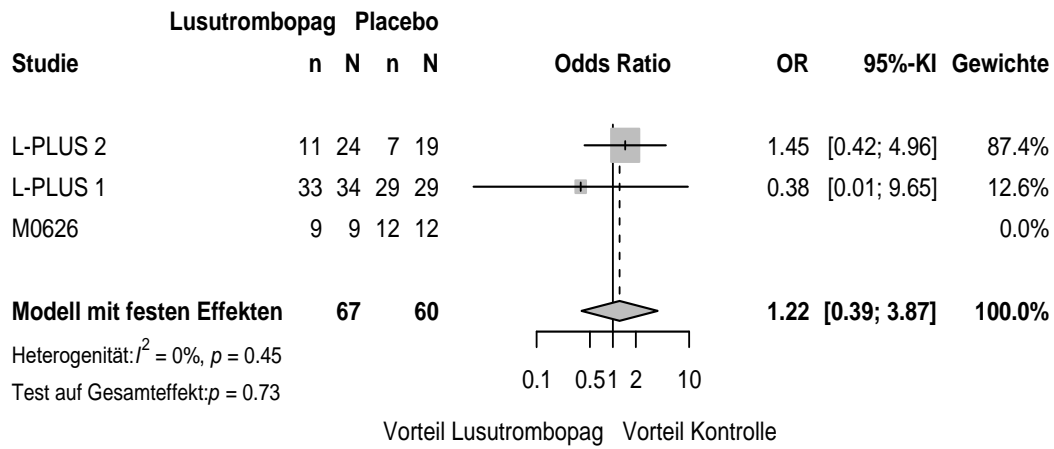
158 Unerwünschte Ereignisse (UE)_RR Treatment duration (days) -7



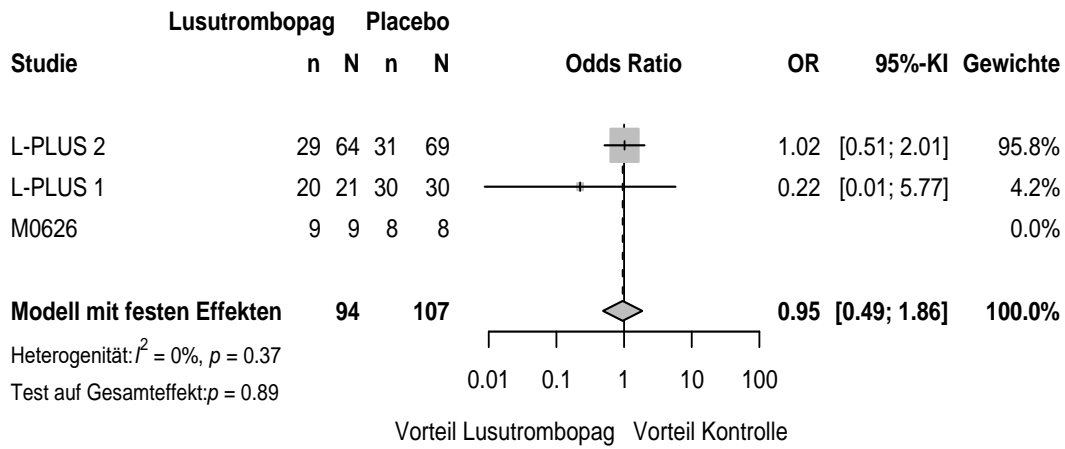
159 Unerwünschte Ereignisse (UE)_OR Age (years) - < 65



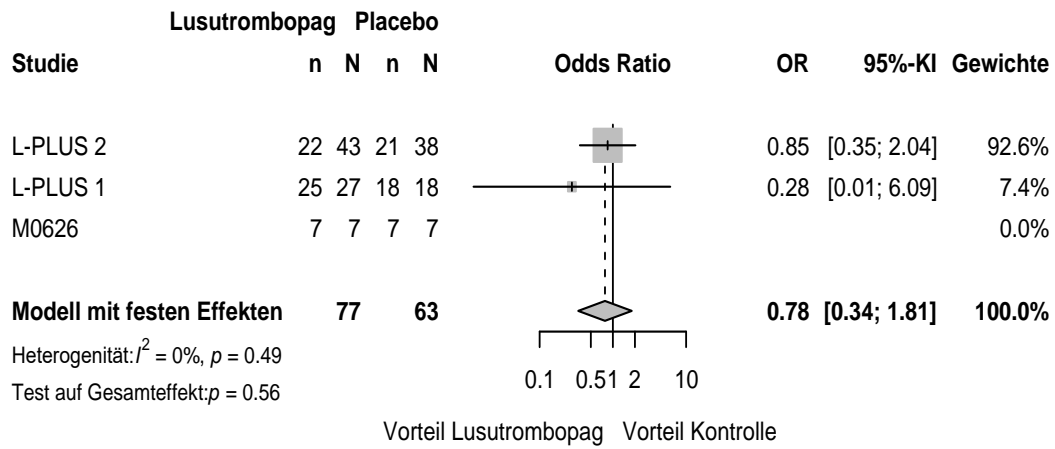
160 Unerwünschte Ereignisse (UE)_OR Age (years) - >=65



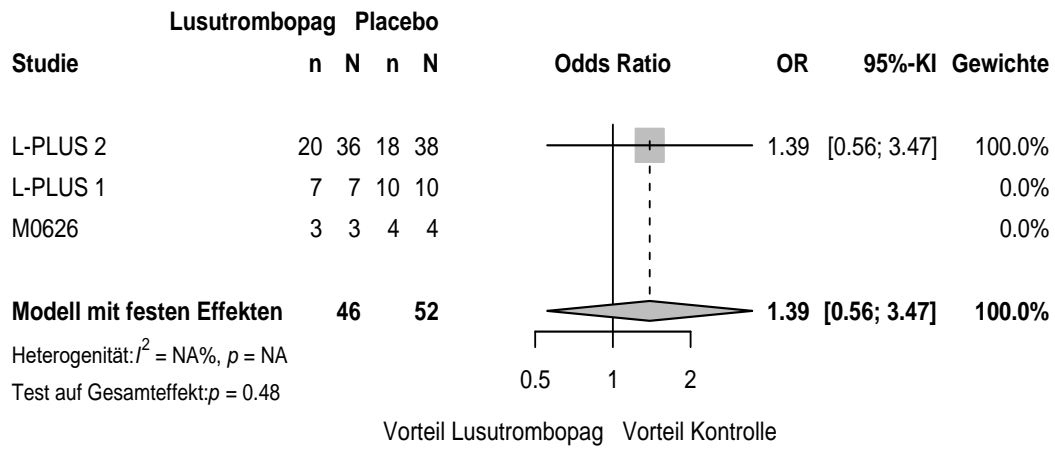
161 Unerwünschte Ereignisse (UE)_OR Gender - Male



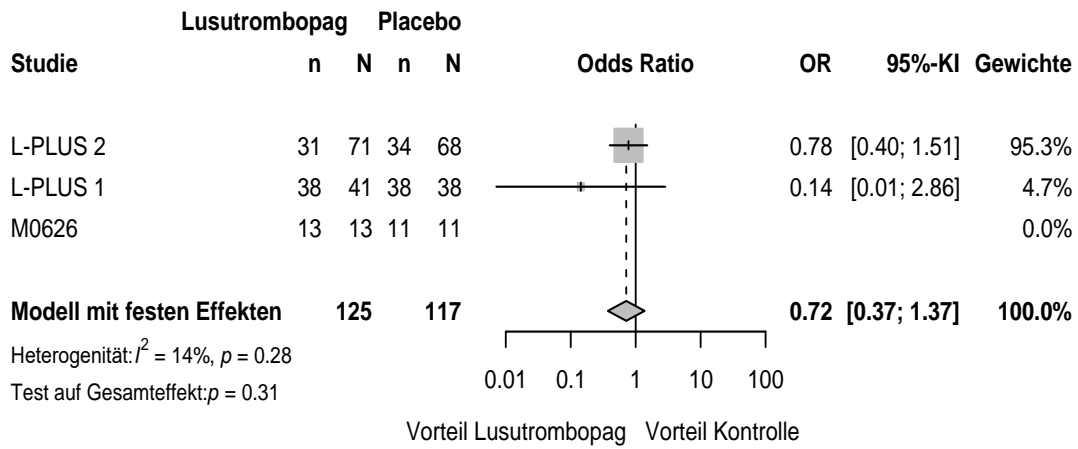
162 Unerwünschte Ereignisse (UE)_OR Gender - Female



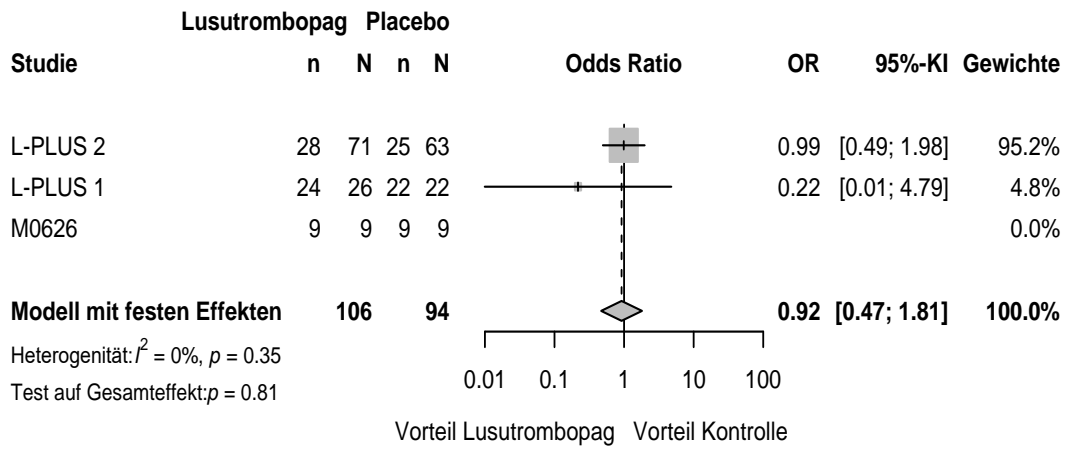
163 Unerwünschte Ereignisse (UE)_OR Baseline platelet count (*10⁴/uL) - < 3.5



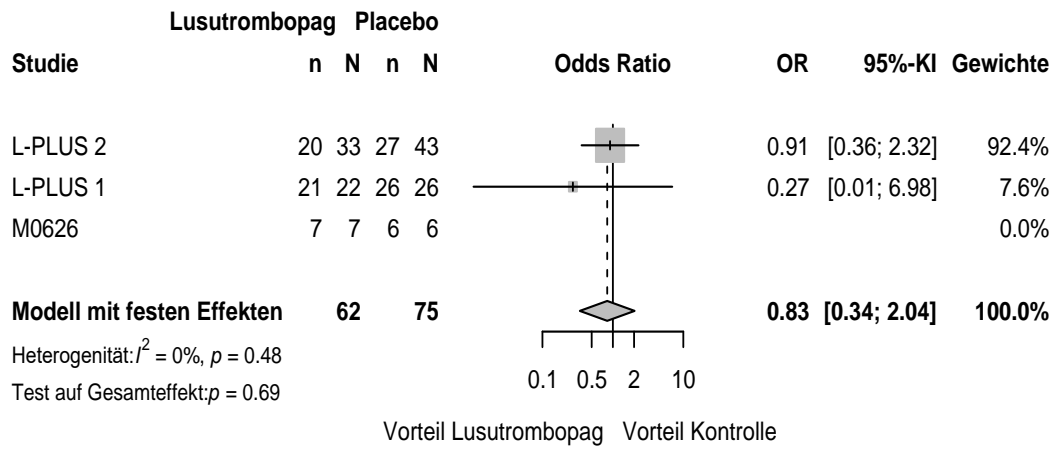
164 Unerwünschte Ereignisse (UE)_OR Baseline platelet count (*10⁴/uL) - >= 3.5



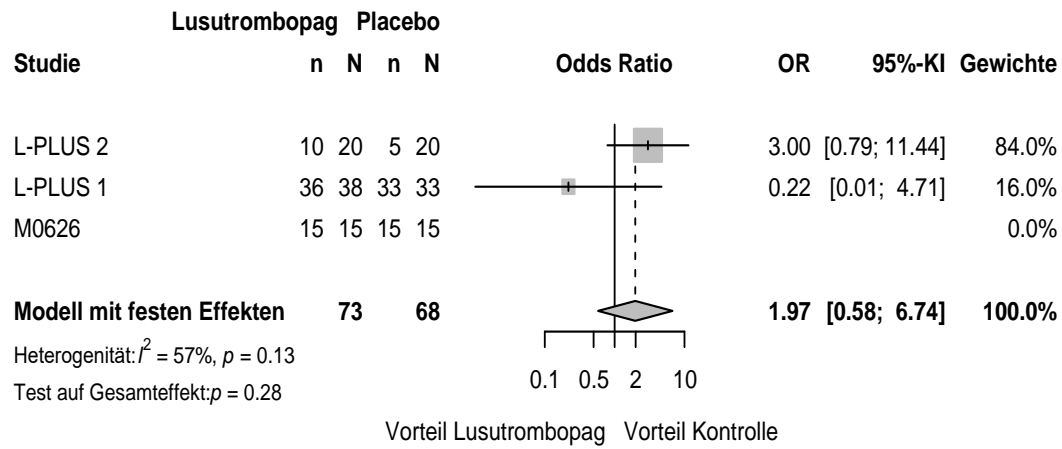
165 Unerwünschte Ereignisse (UE)_OR Child-Pugh class - A



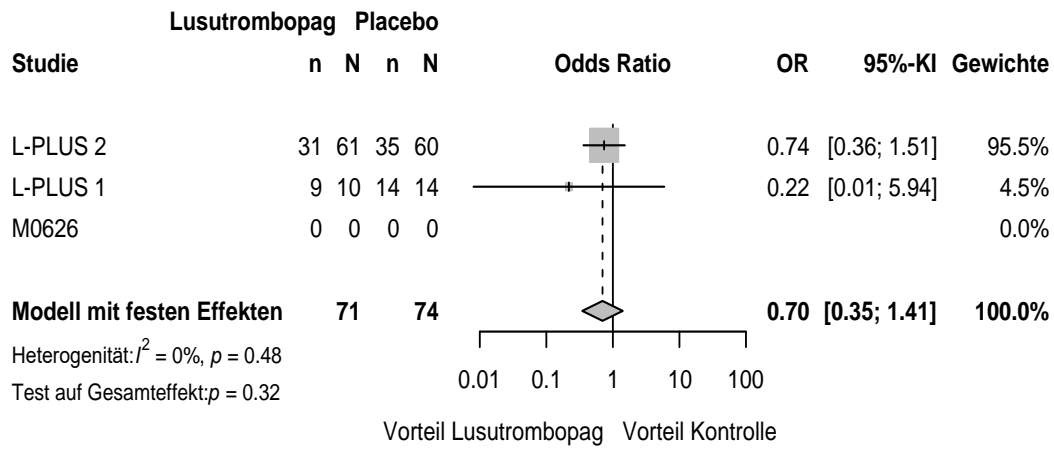
166 Unerwünschte Ereignisse (UE)_OR Child-Pugh class - B



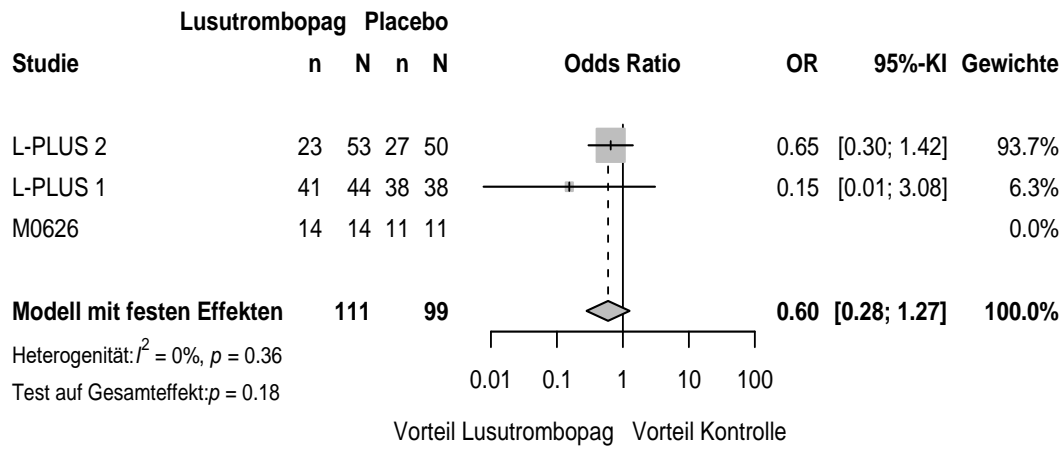
167 Unerwünschte Ereignisse (UE)_OR Invasive procedure liver-related



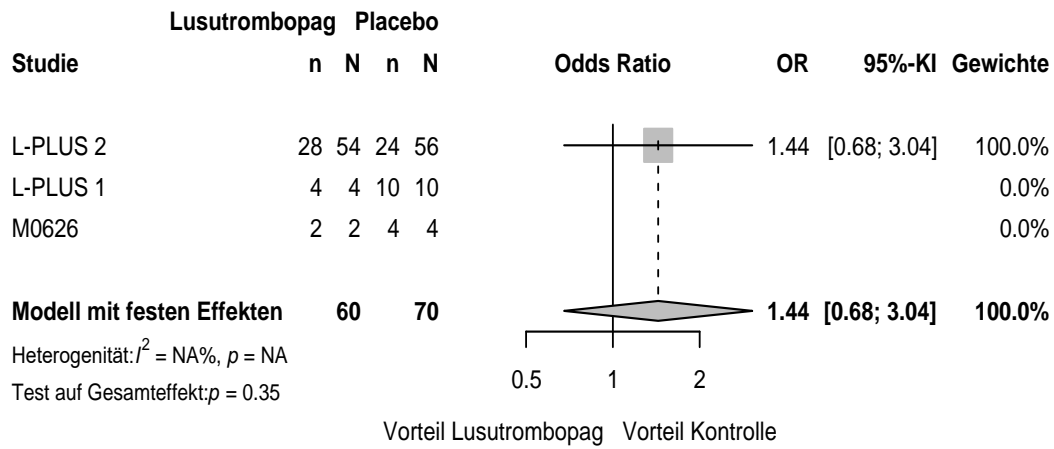
168 Unerwünschte Ereignisse (UE)_OR Invasive procedure gi-related



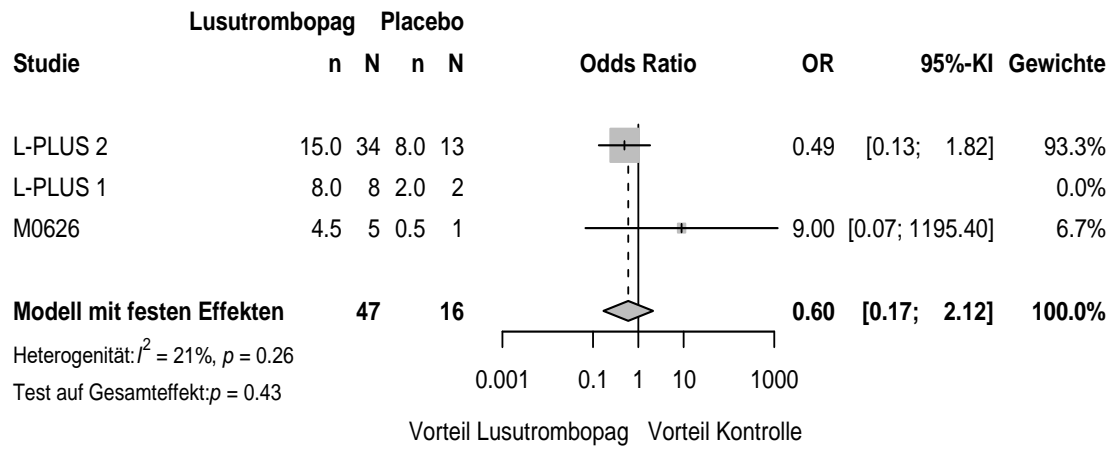
169 Unerwünschte Ereignisse (UE)_OR Baseline body weight (kg) - < 75



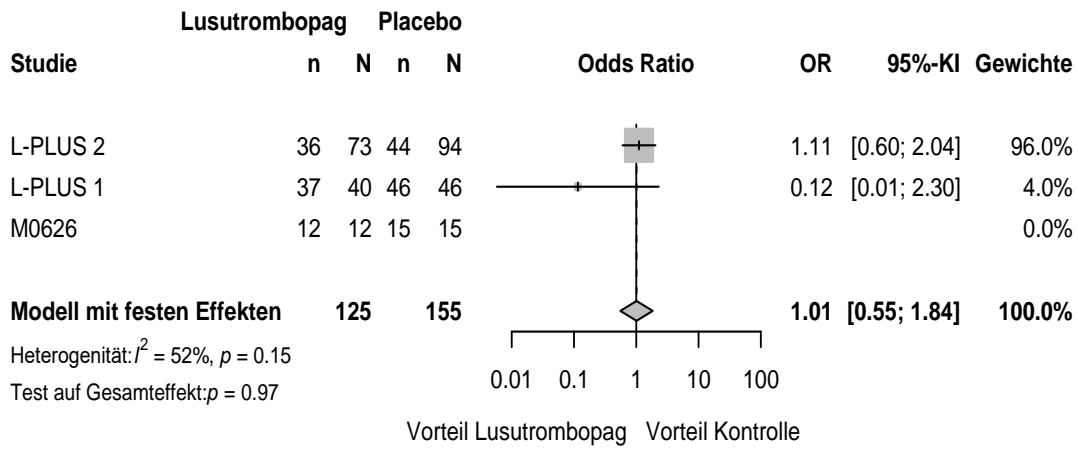
170 Unerwünschte Ereignisse (UE)_OR Baseline body weight (kg) - >= 75



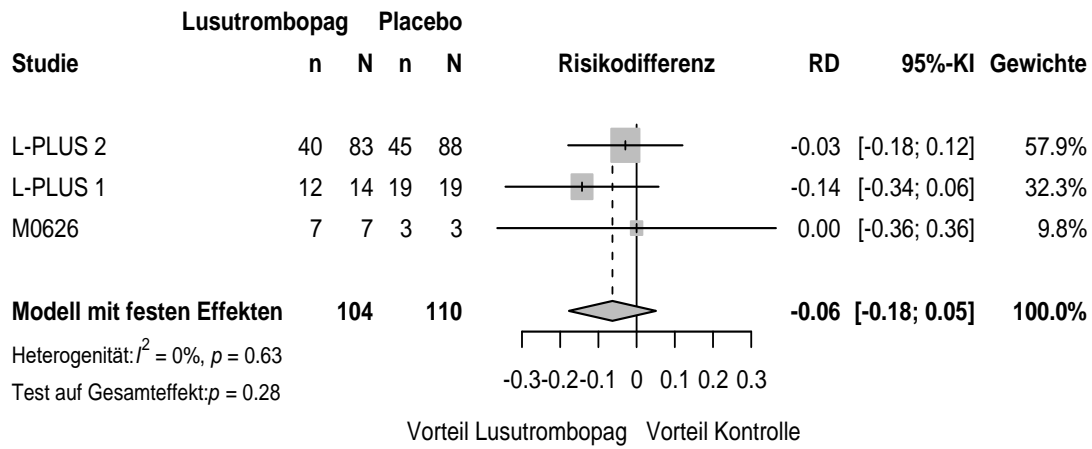
171 Unerwünschte Ereignisse (UE)_OR Treatment duration (days) - < 7



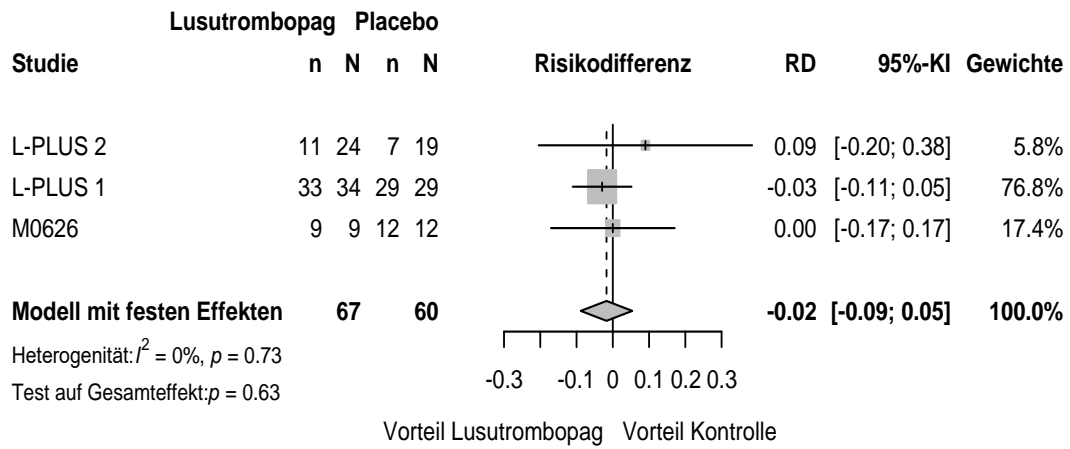
172 Unerwünschte Ereignisse (UE)_OR Treatment duration (days) -7



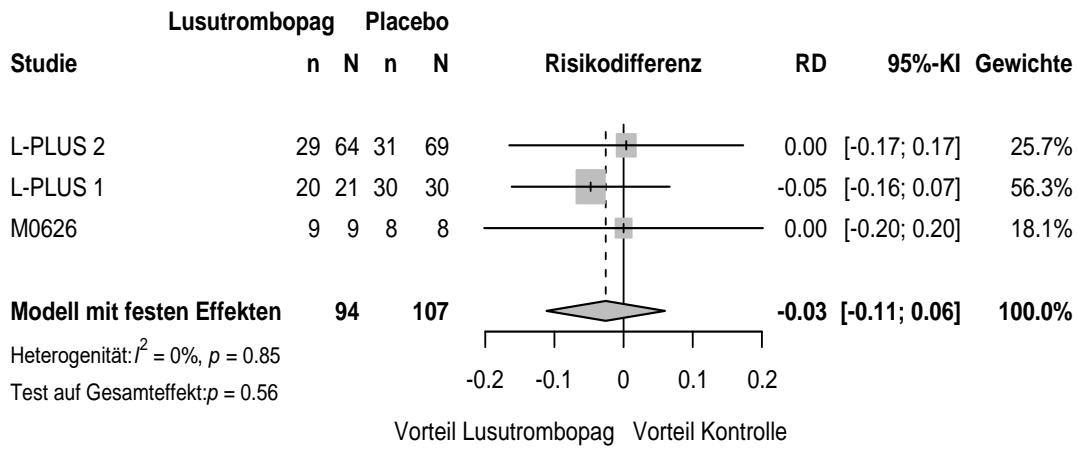
173 Unerwünschte Ereignisse (UE)_RD Age (years) - < 65



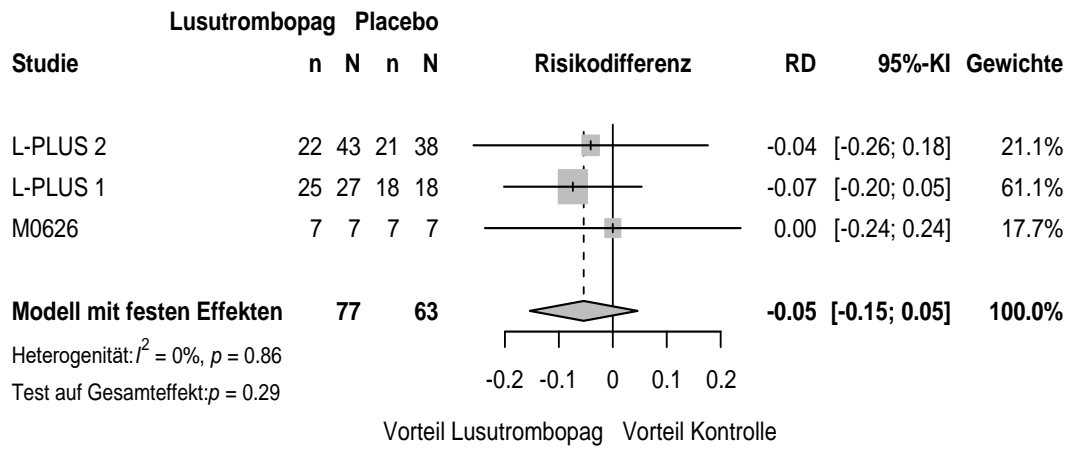
174 Unerwünschte Ereignisse (UE)_RD Age (years) - >=65



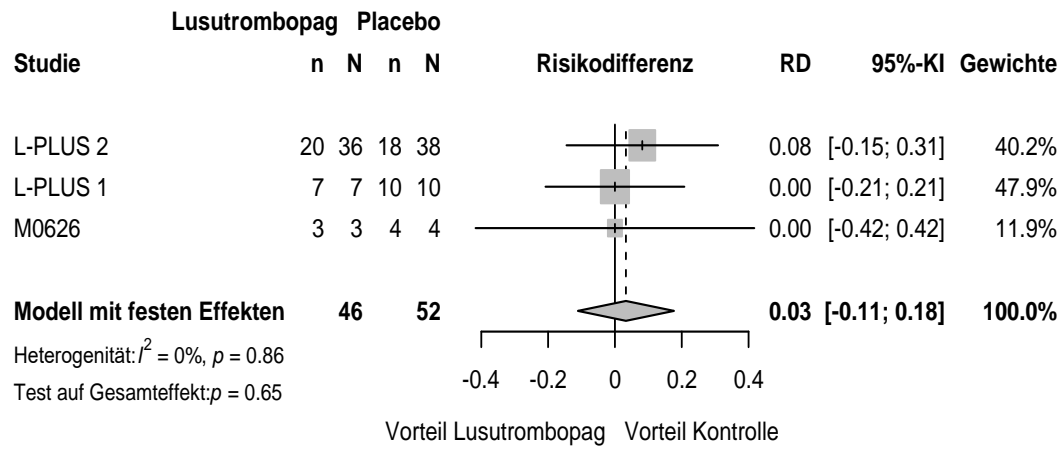
175 Unerwünschte Ereignisse (UE)_RD Gender - Male



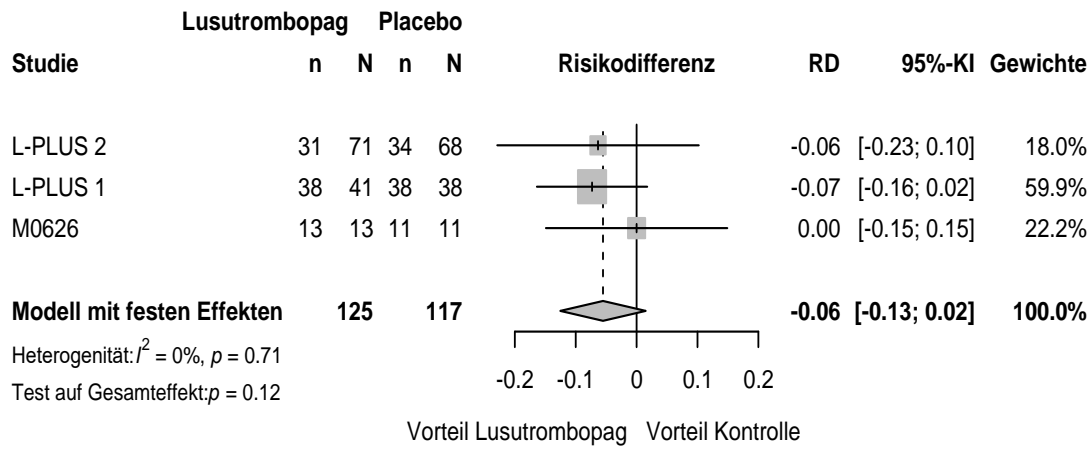
176 Unerwünschte Ereignisse (UE)_RD Gender - Female



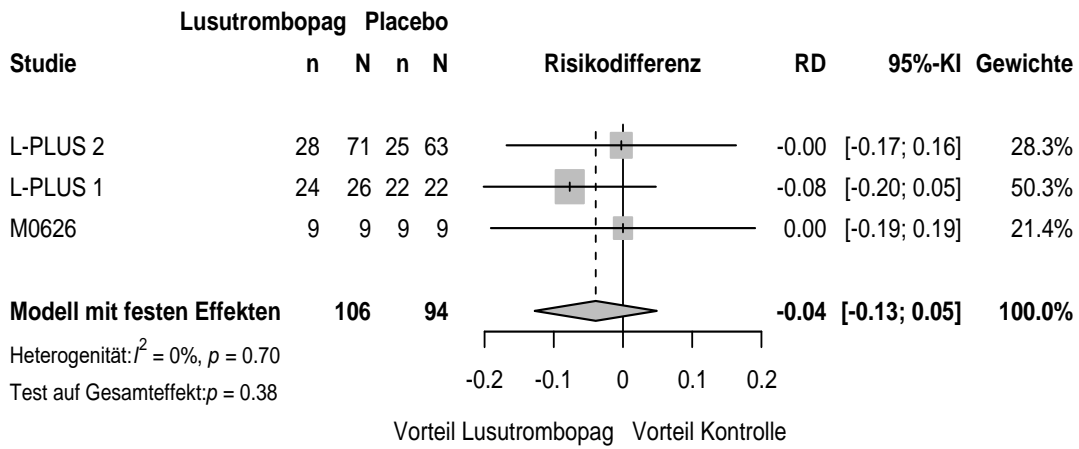
177 Unerwünschte Ereignisse (UE)_RD Baseline platelet count (*10⁴/uL) - < 3.5



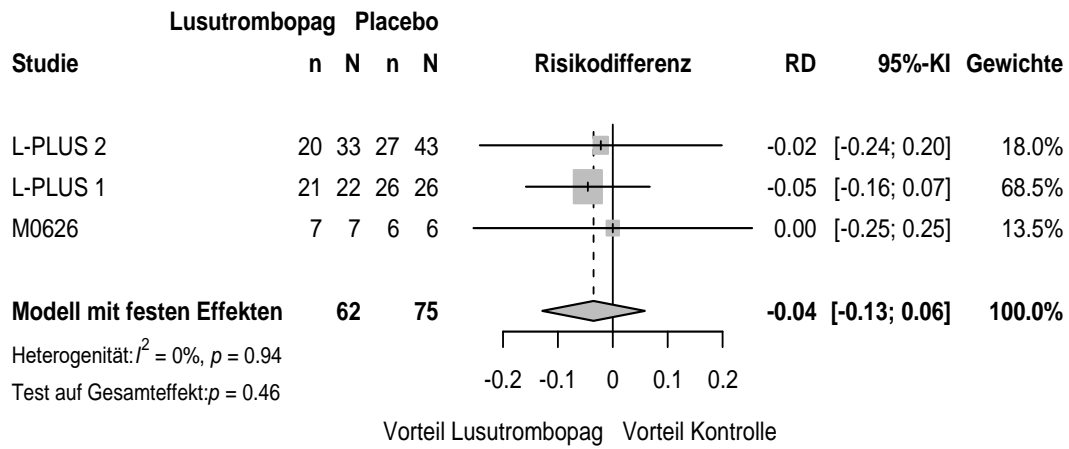
178 Unerwünschte Ereignisse (UE)_RD Baseline platelet count (*10⁴/uL) - >= 3.5



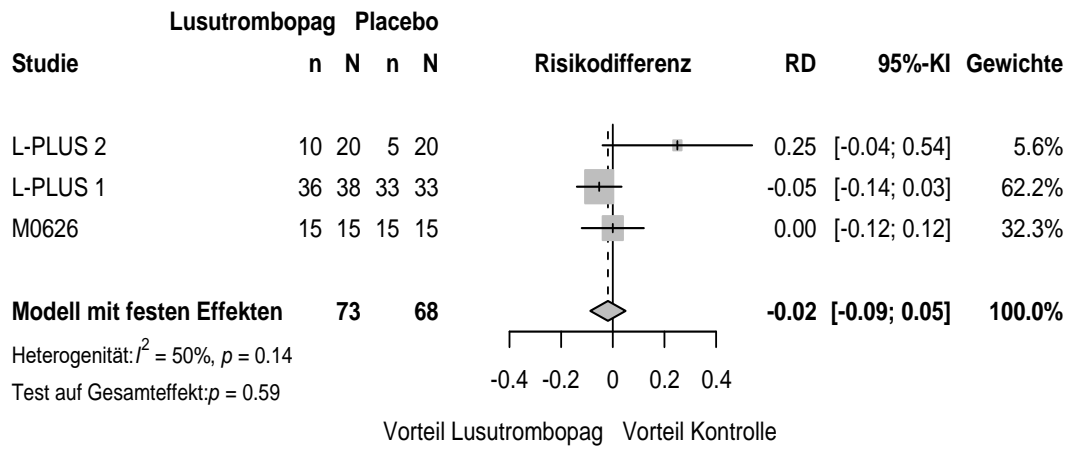
179 Unerwünschte Ereignisse (UE)_RD Child-Pugh class - A



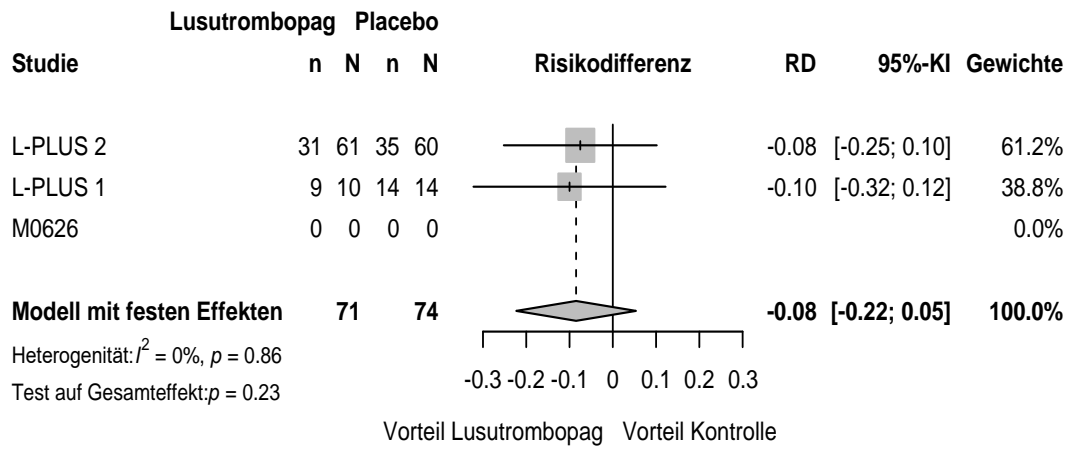
180 Unerwünschte Ereignisse (UE)_RD Child-Pugh class - B



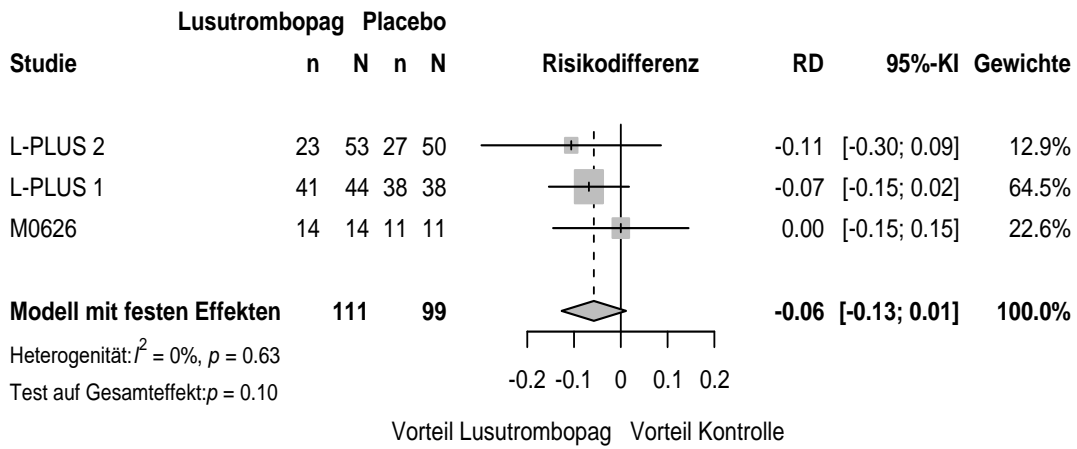
181 Unerwünschte Ereignisse (UE)_RD Invasive procedure liver-related



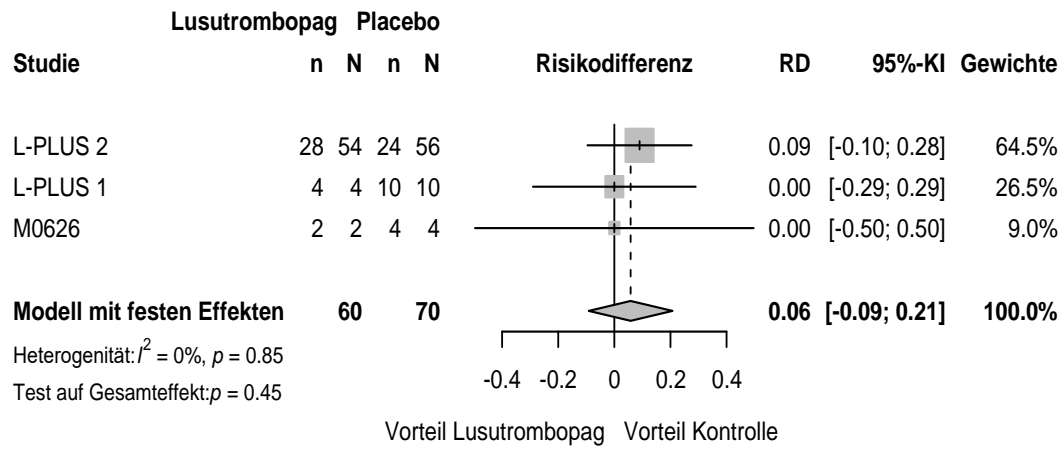
182 Unerwünschte Ereignisse (UE)_RD Invasive procedure gi-related



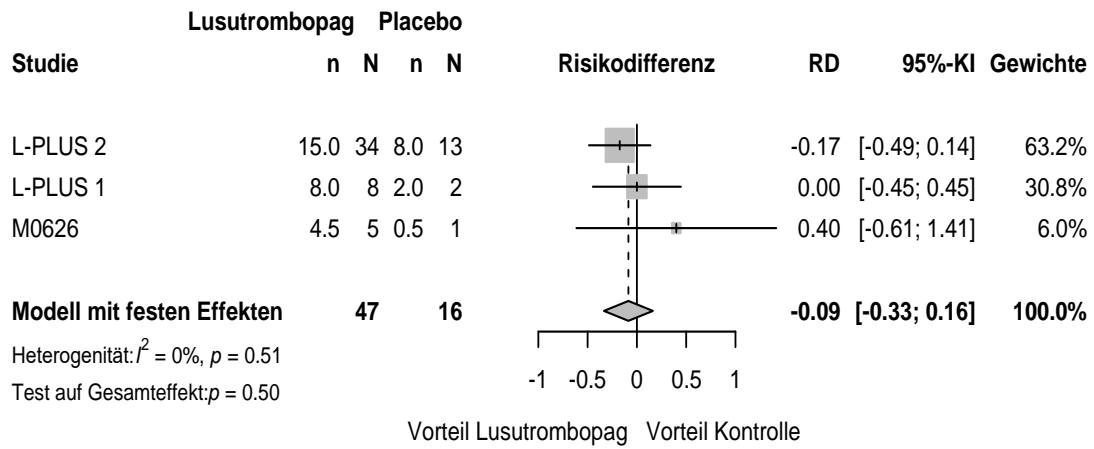
183 Unerwünschte Ereignisse (UE)_RD Baseline body weight (kg) - < 75



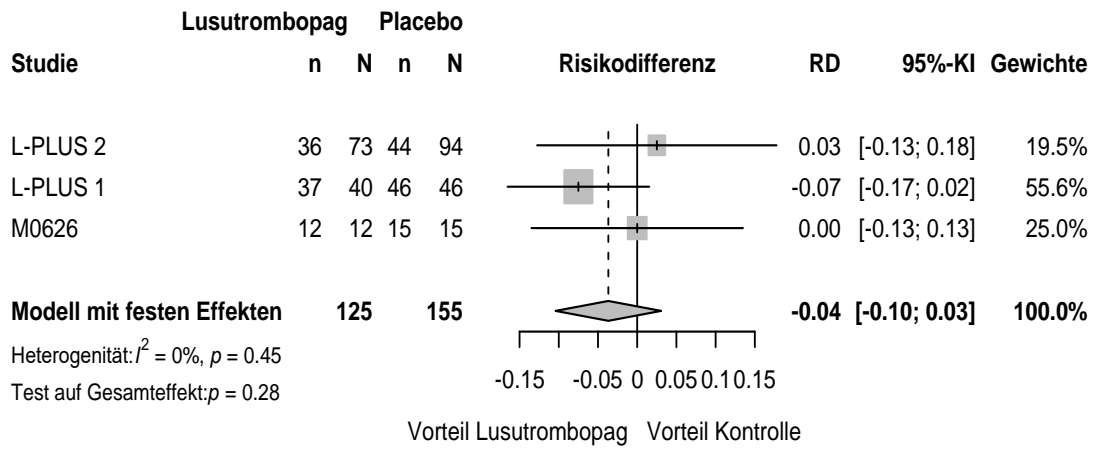
184 Unerwünschte Ereignisse (UE)_RD Baseline body weight (kg) - >= 75



185 Unerwünschte Ereignisse (UE)_RD Treatment duration (days) - < 7

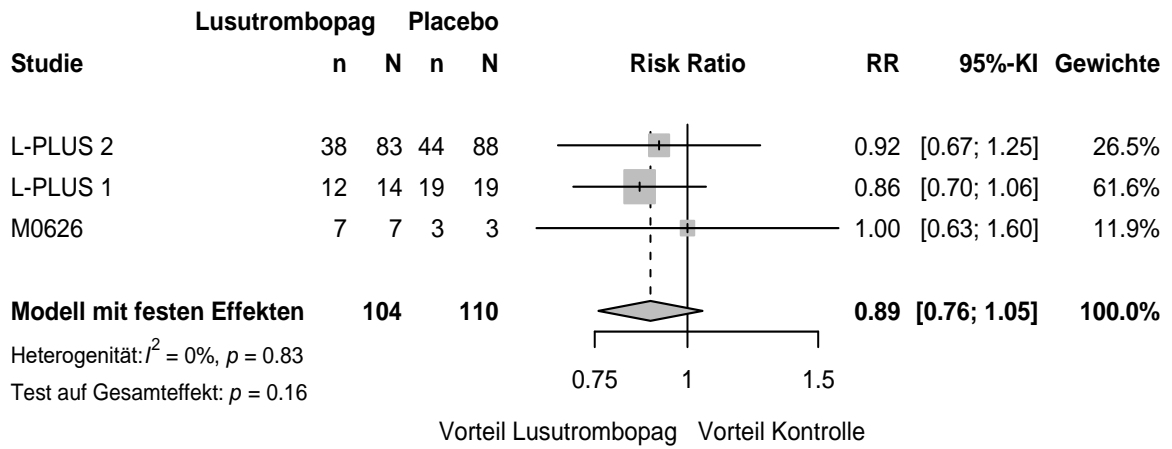


186 Unerwünschte Ereignisse (UE)_RD Treatment duration (days) -7

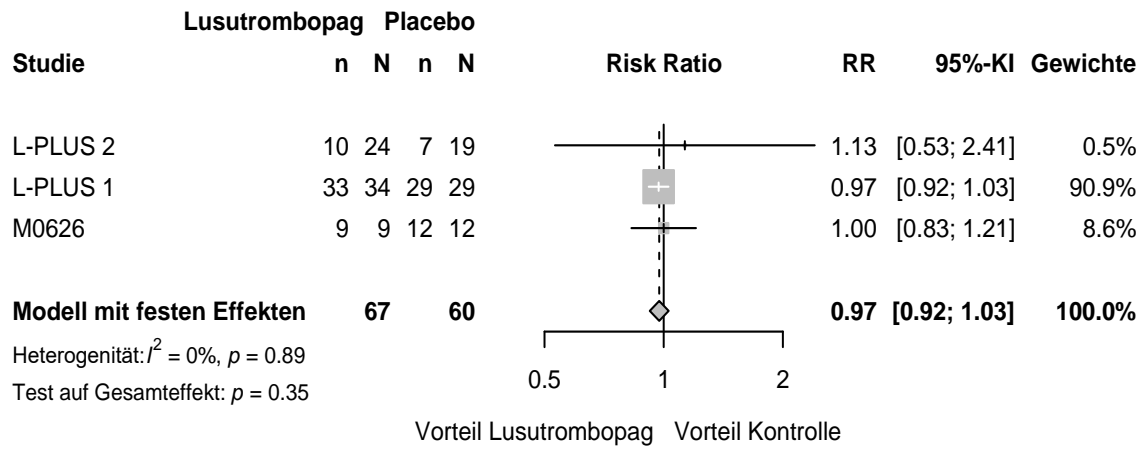


Forest Plots der Subgruppen (Sicherheit - Sensitivitätsanalysen)

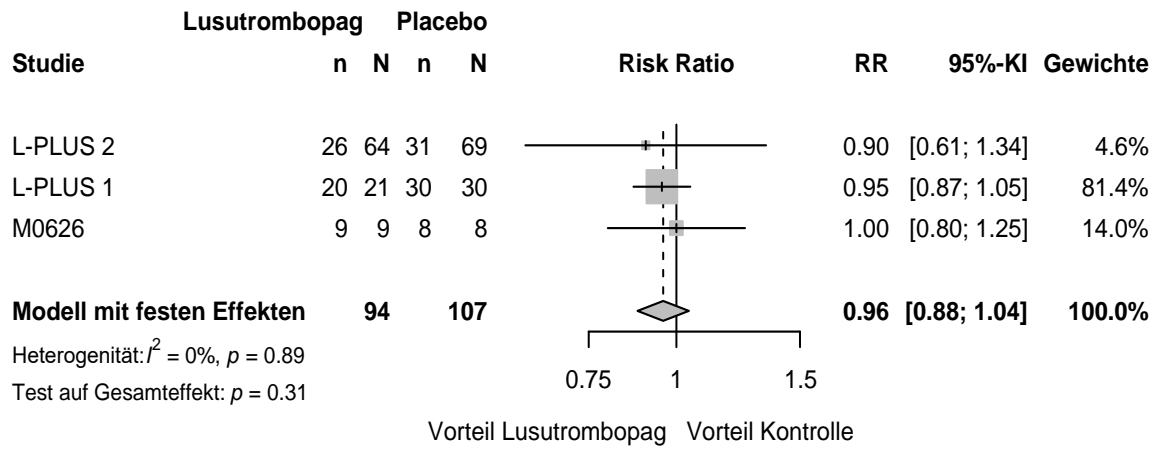
1 UE unter Ausschluss Morbidität_RR Age (years) - < 65



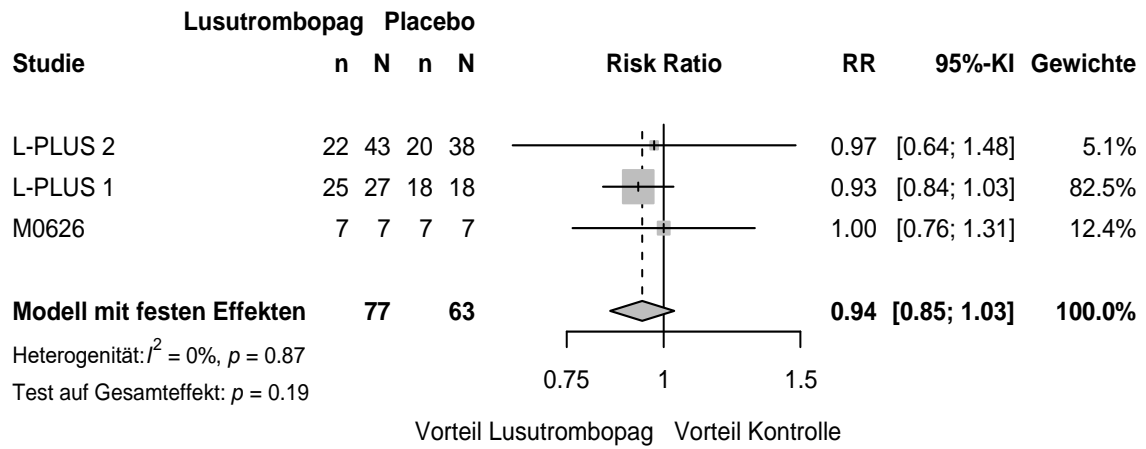
2 UE unter Ausschluss Morbidität_RR Age (years) - >=65



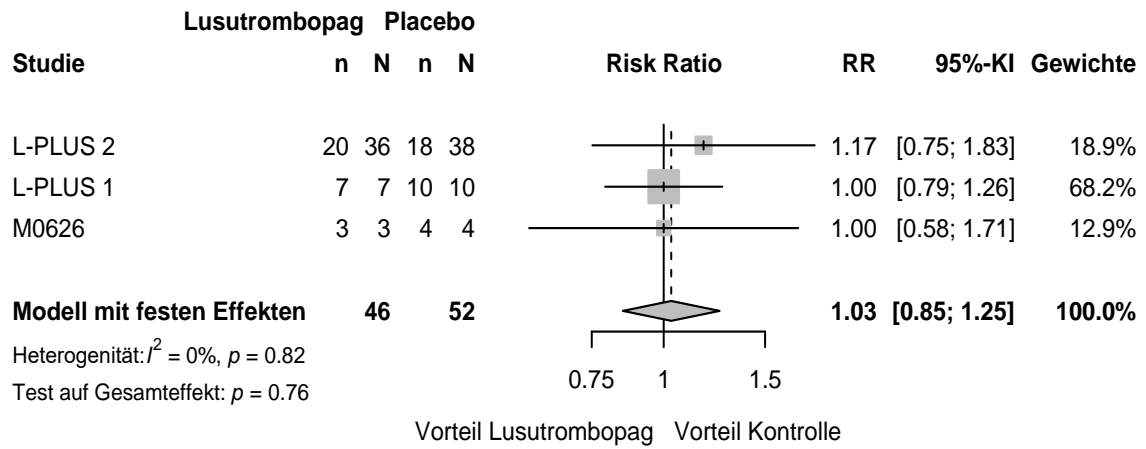
3 UE unter Ausschluss Morbidität_RR Gender - Male



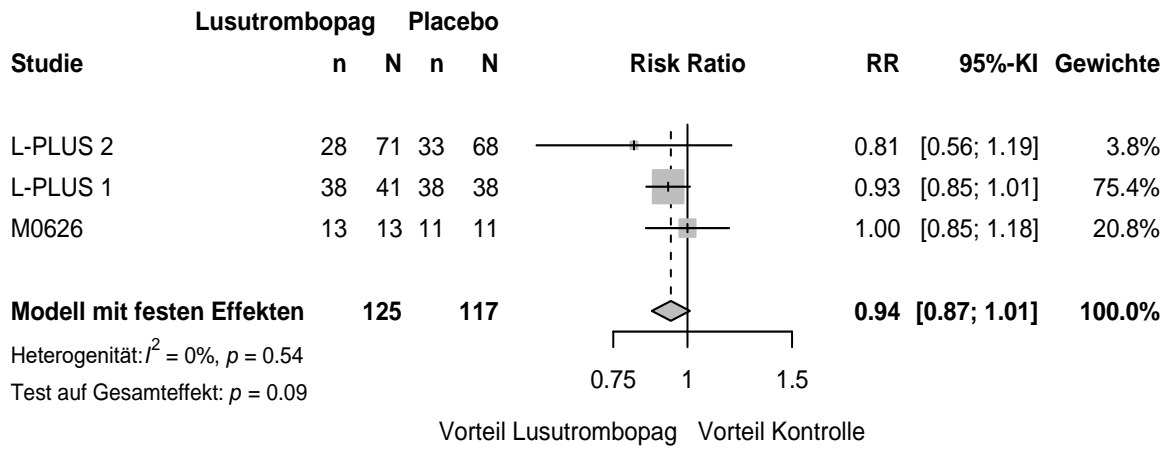
4 UE unter Ausschluss Morbidität_RR Gender - Female



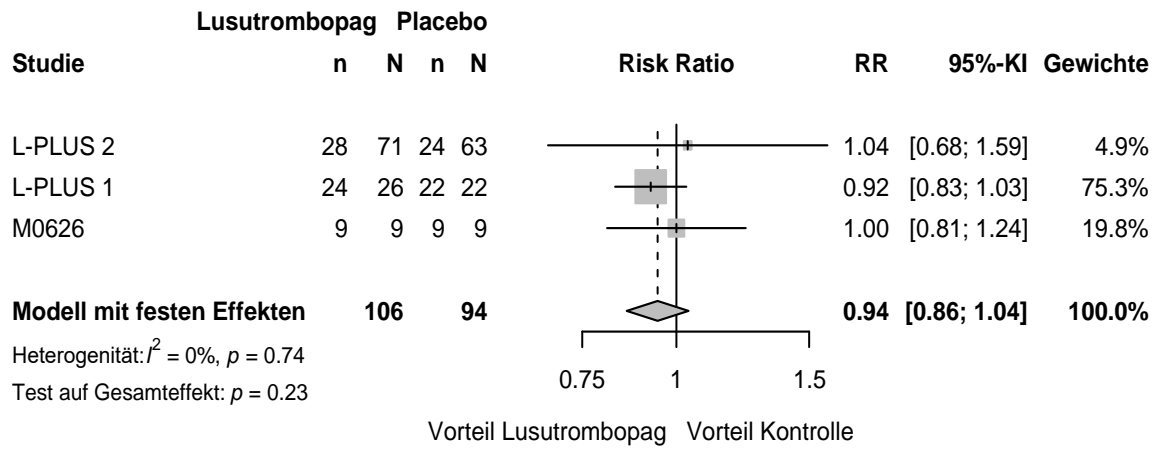
5 UE unter Ausschluss Morbidität_RR Baseline platelet count (*10⁴/uL) - < 3.5



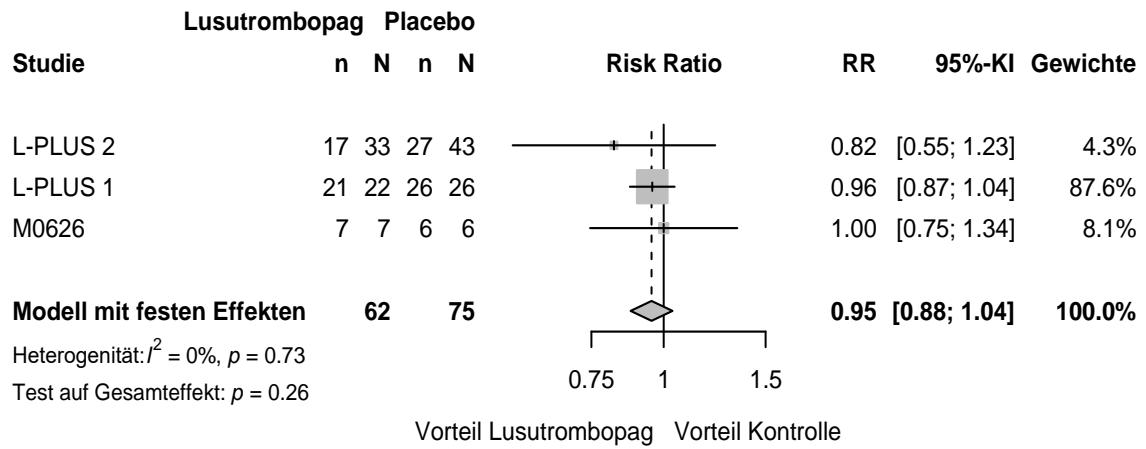
6 UE unter Ausschluss Morbidität_RR Baseline platelet count (*10⁴/uL) - >= 3.5



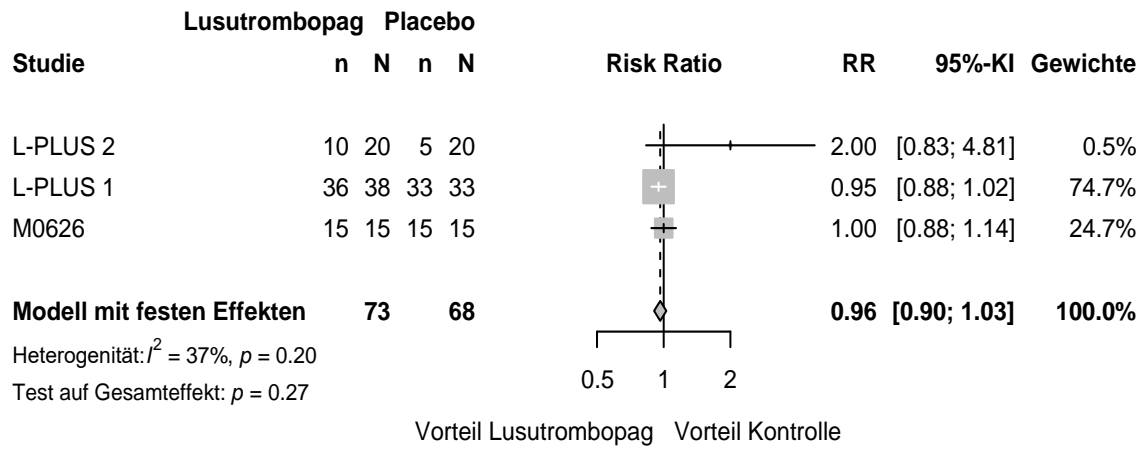
7 UE unter Ausschluss Morbidität_RR Child-Pugh class - A



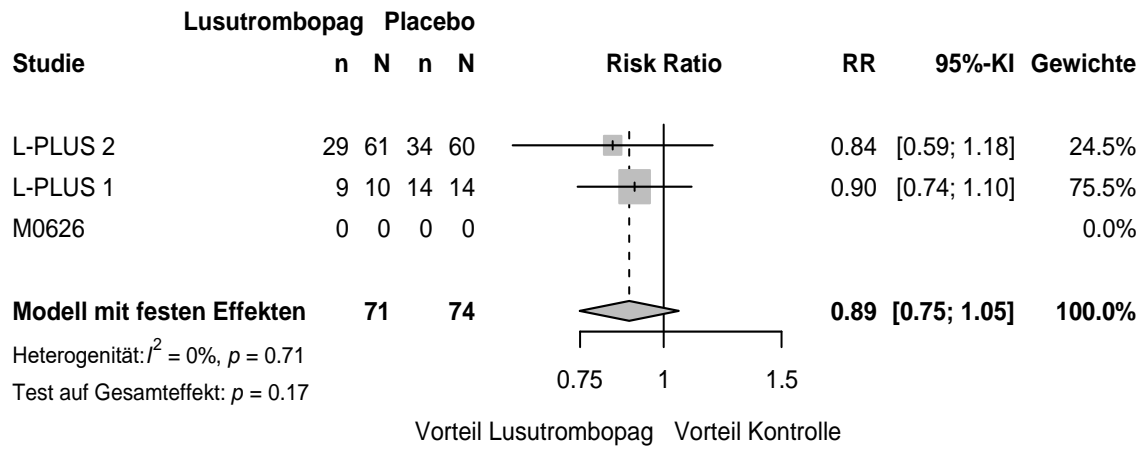
8 UE unter Ausschluss Morbidität_RR Child-Pugh class - B



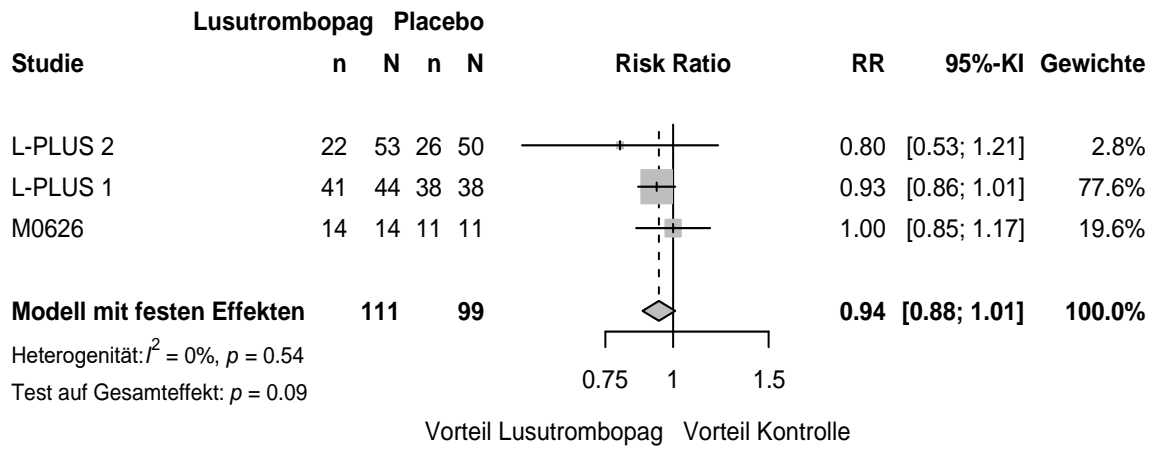
9 UE unter Ausschluss Morbidität_RR Invasive procedure liver-related



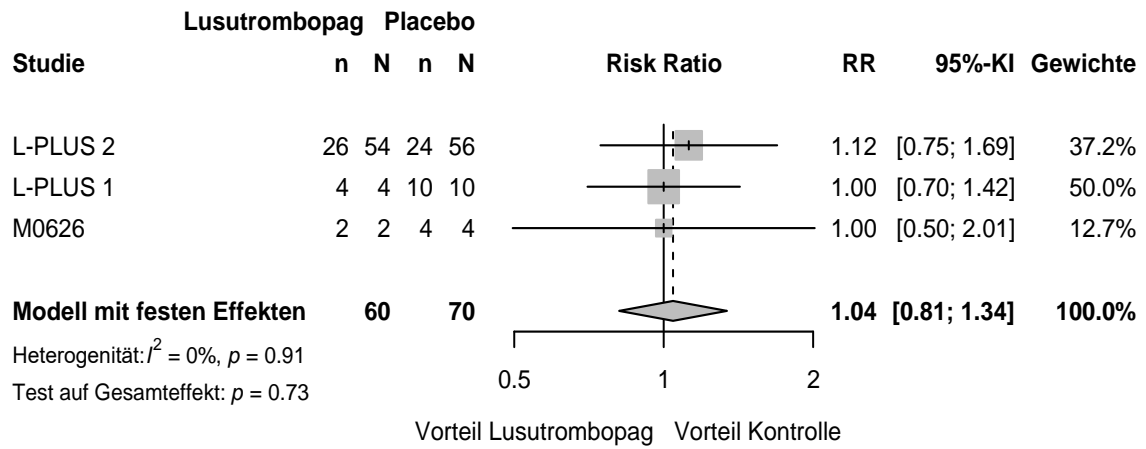
10 UE unter Ausschluss Morbidität_RR Invasive procedure gi-related



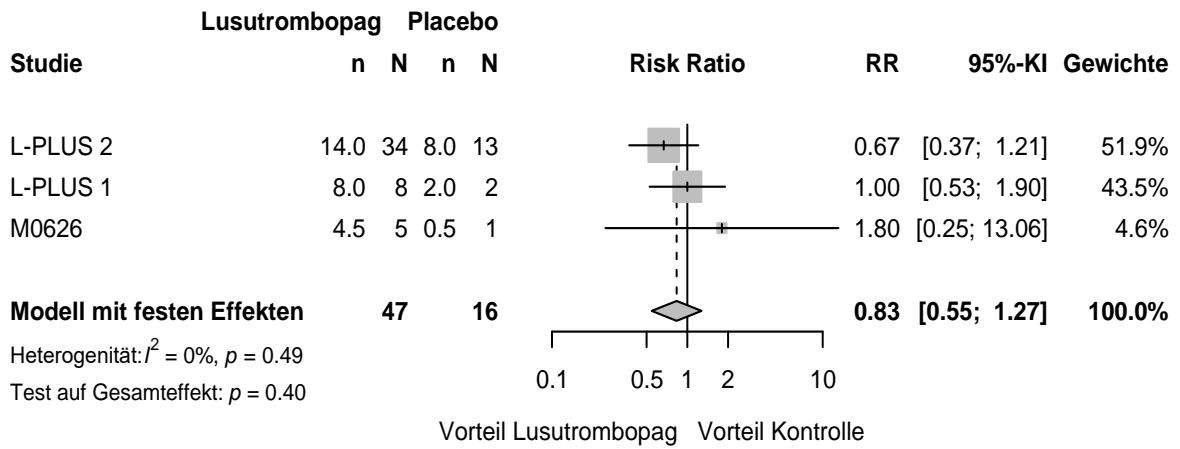
11 UE unter Ausschluss Morbidität_RR Baseline body weight (kg) - < 75



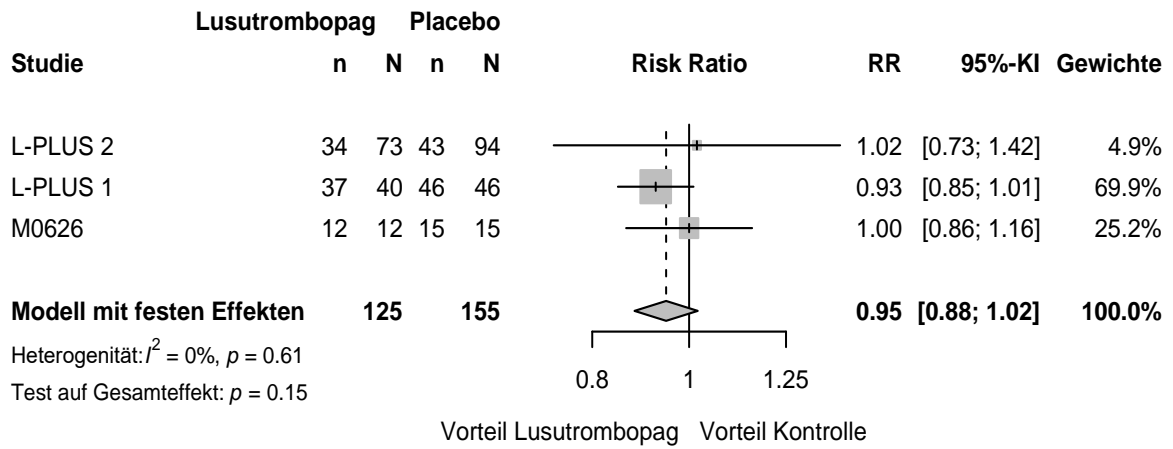
12 UE unter Ausschluss Morbidität_RR Baseline body weight (kg) - >= 75



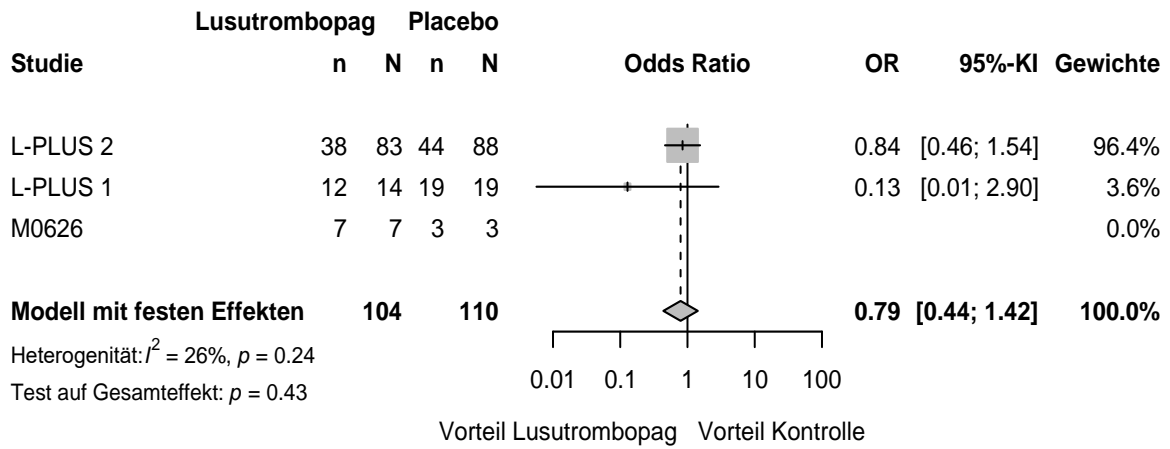
13 UE unter Ausschluss Morbidität_RR Treatment duration (days) - < 7



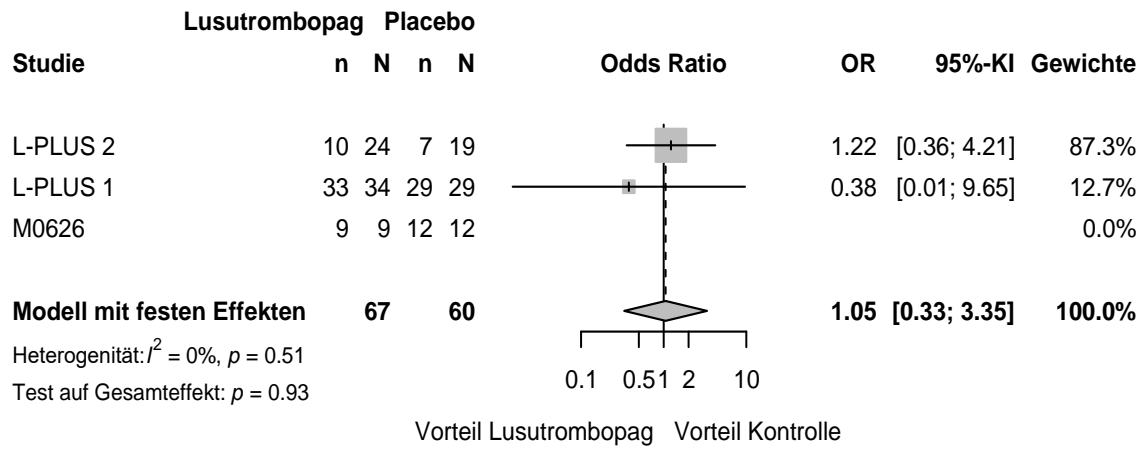
14 UE unter Ausschluss Morbidität_RR Treatment duration (days) -7



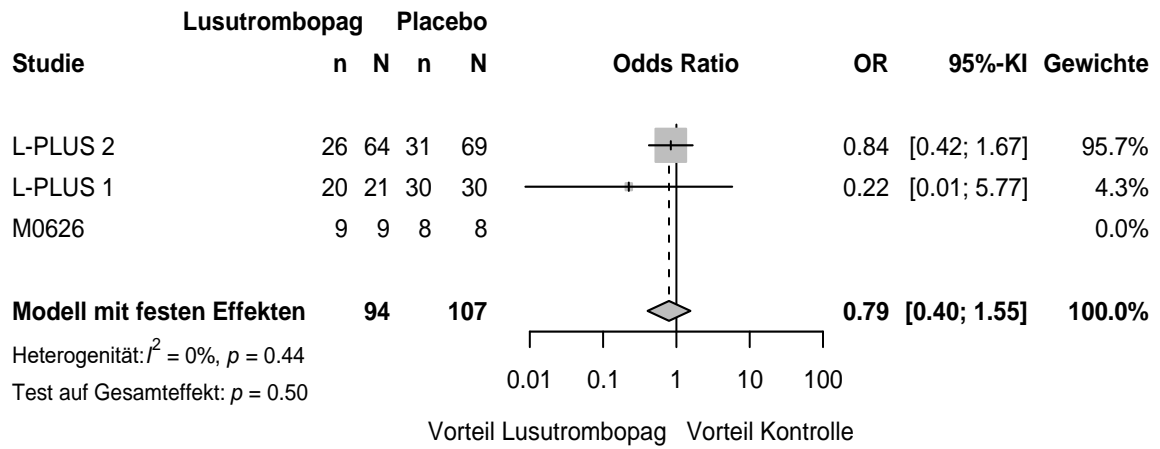
15 UE unter Ausschluss Morbidität_OR Age (years) - < 65



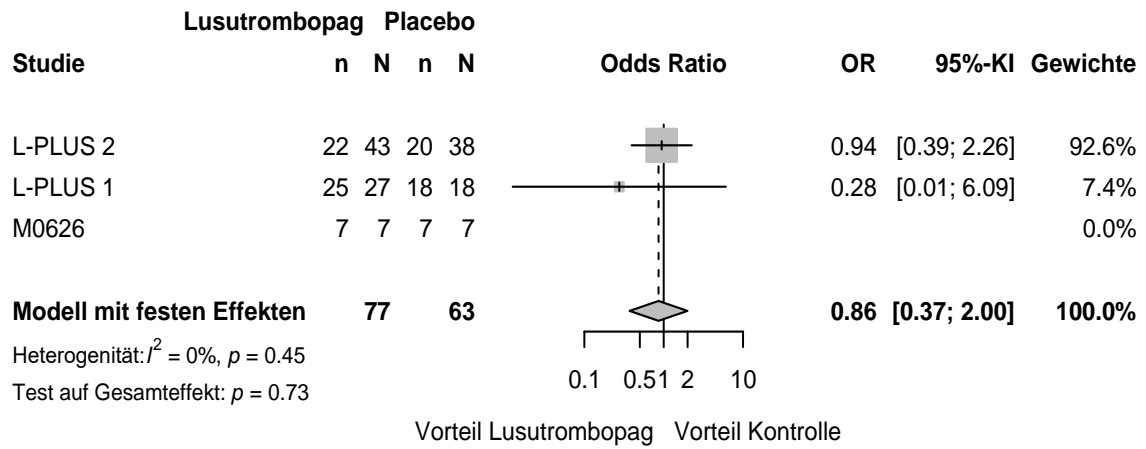
16 UE unter Ausschluss Morbidität_OR Age (years) - >=65



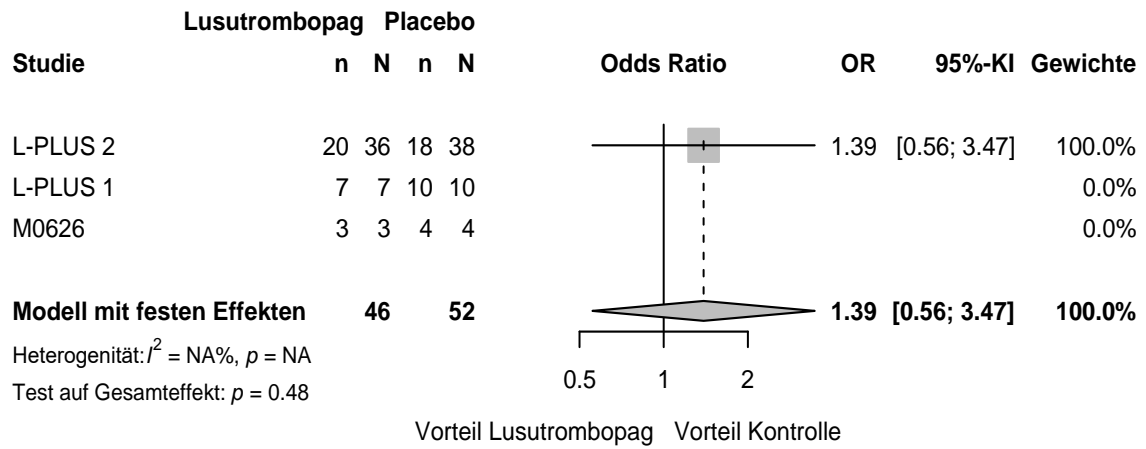
17 UE unter Ausschluss Morbidität_OR Gender - Male



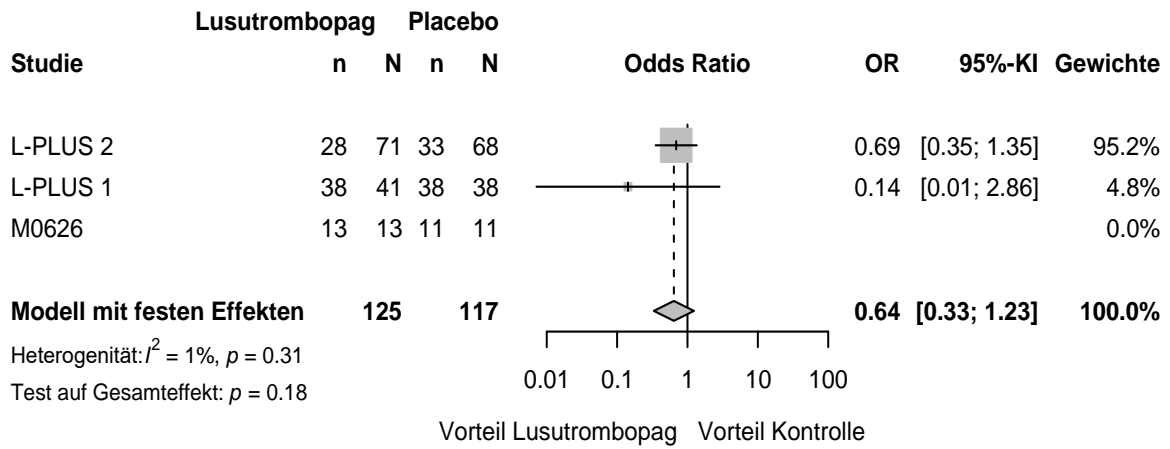
18 UE unter Ausschluss Morbidität_OR Gender - Female



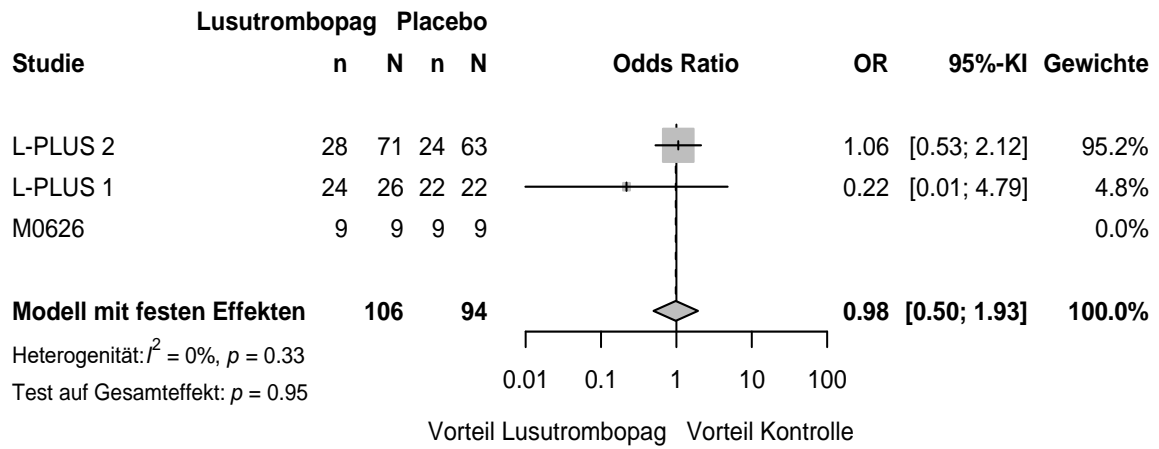
19 UE unter Ausschluss Morbidität_OR Baseline platelet count ($\cdot 10^4/uL$) - < 3.5



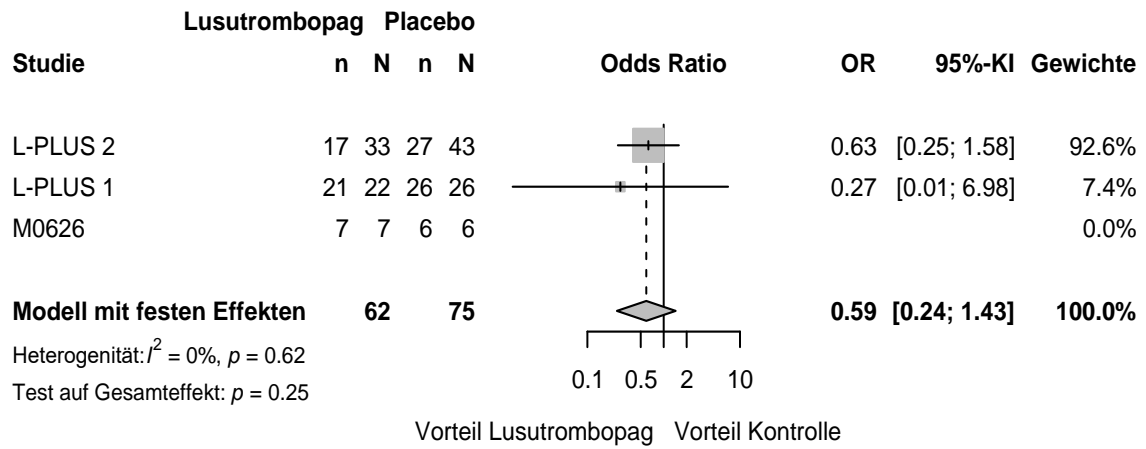
20 UE unter Ausschluss Morbidität_OR Baseline platelet count (*10⁴/uL) - >= 3.5



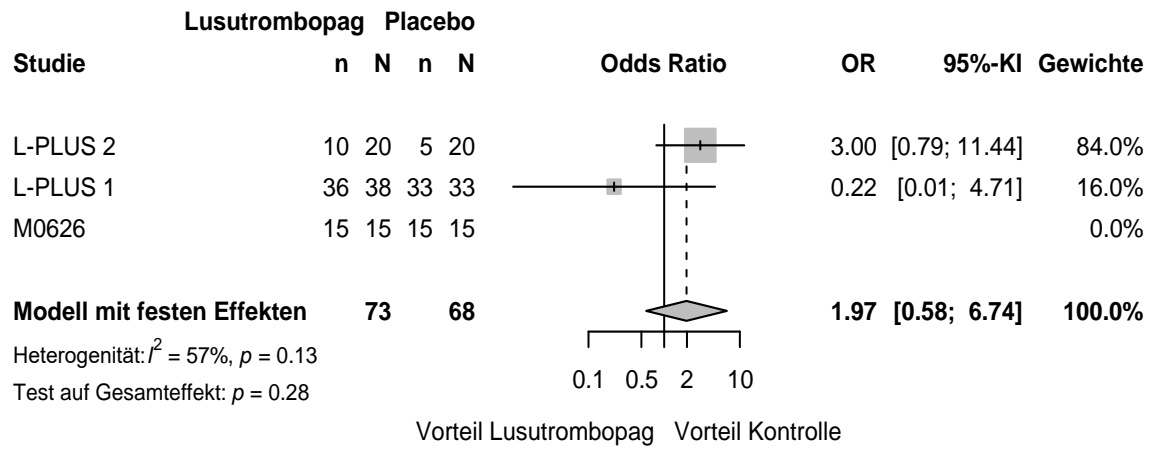
21 UE unter Ausschluss Morbidität_OR Child-Pugh class - A



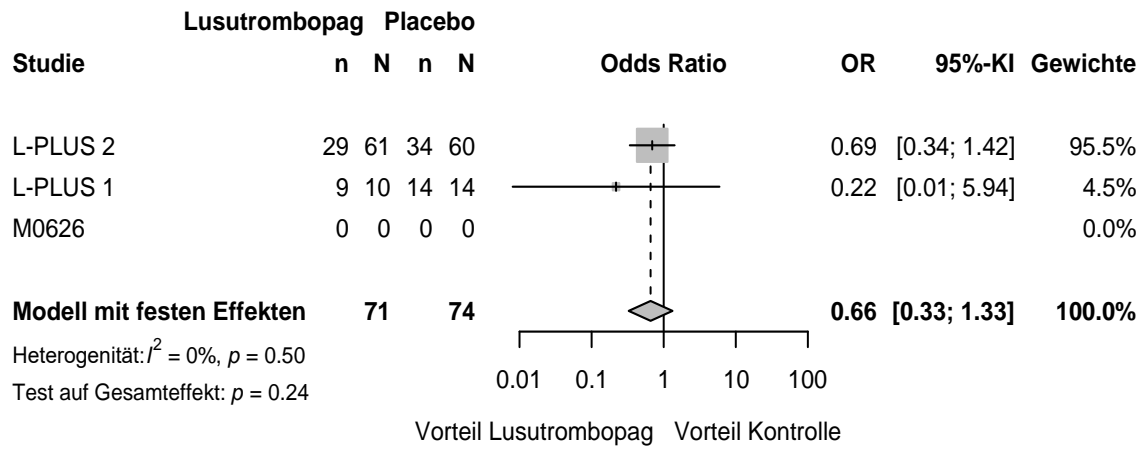
22 UE unter Ausschluss Morbidität_OR Child-Pugh class - B



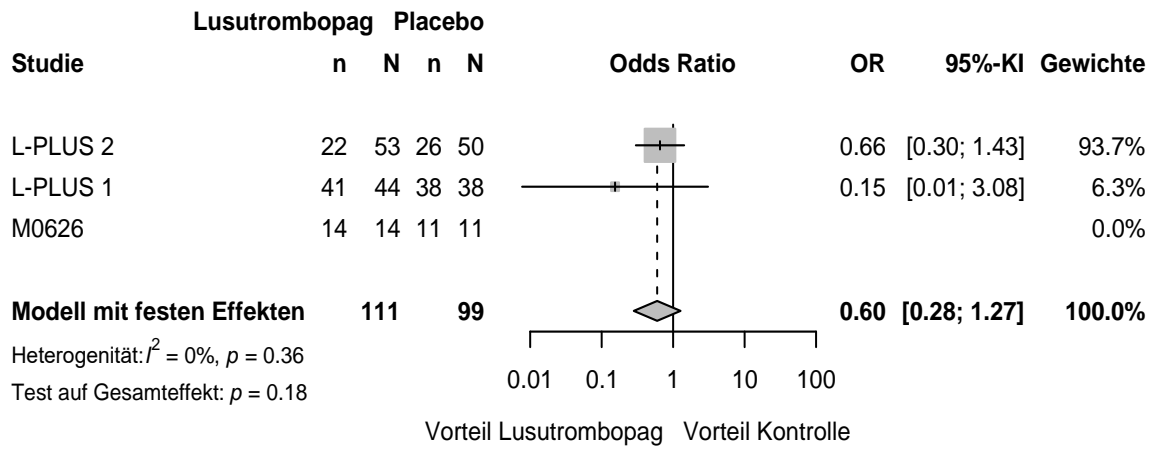
23 UE unter Ausschluss Morbidität_OR Invasive procedure liver-related



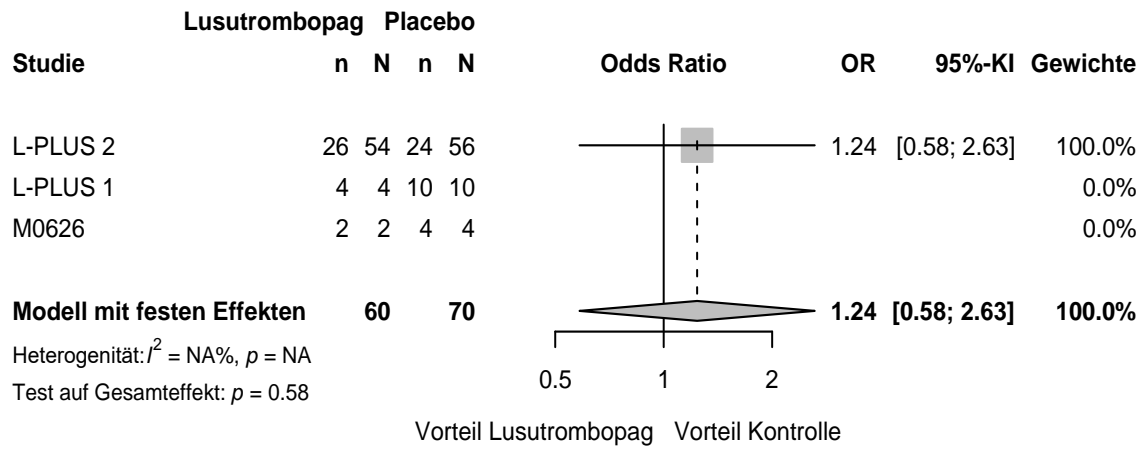
24 UE unter Ausschluss Morbidität_OR Invasive procedure gi-related



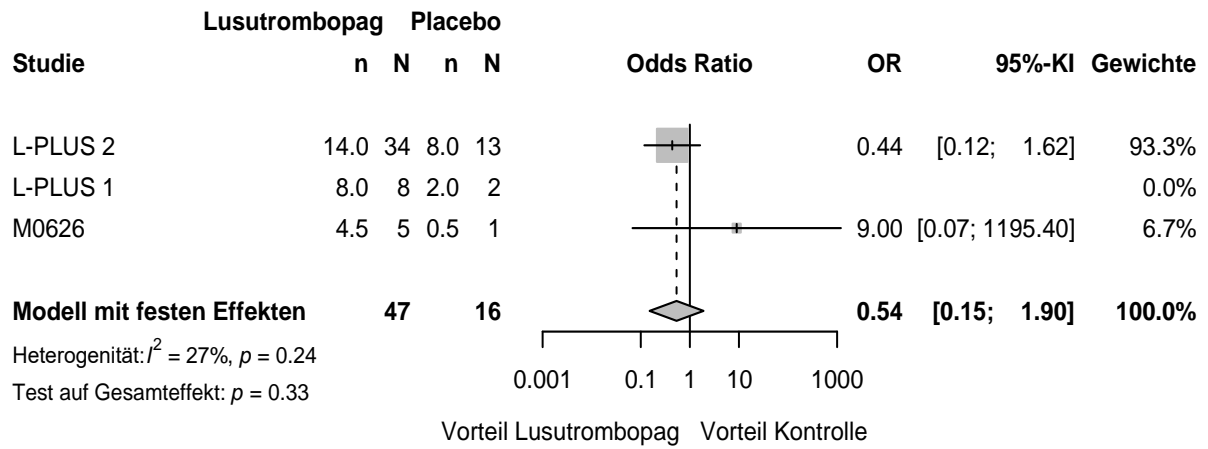
25 UE unter Ausschluss Morbidität_OR Baseline body weight (kg) - < 75



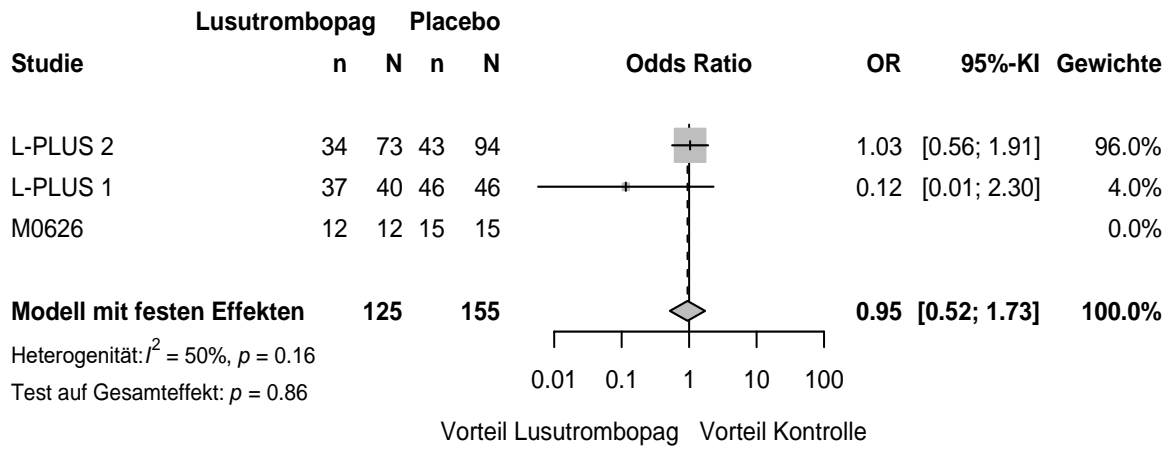
26 UE unter Ausschluss Morbidität_OR Baseline body weight (kg) - >= 75



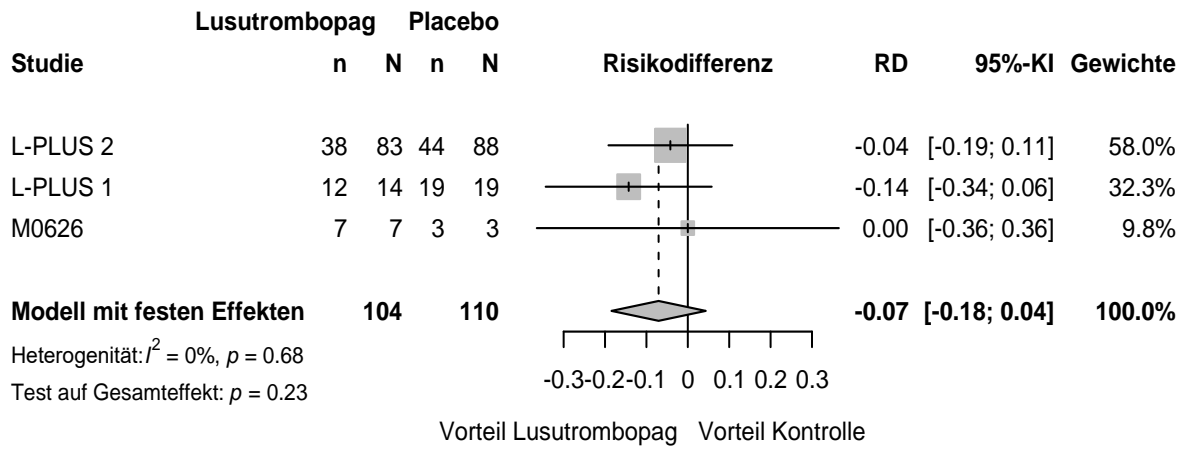
27 UE unter Ausschluss Morbidität_OR Treatment duration (days) - < 7



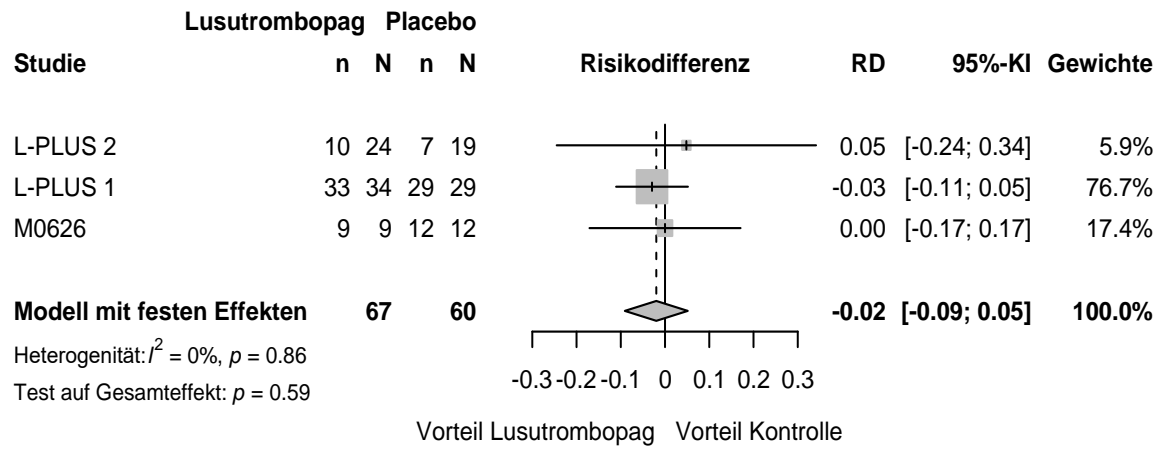
28 UE unter Ausschluss Morbidität_OR Treatment duration (days) -7



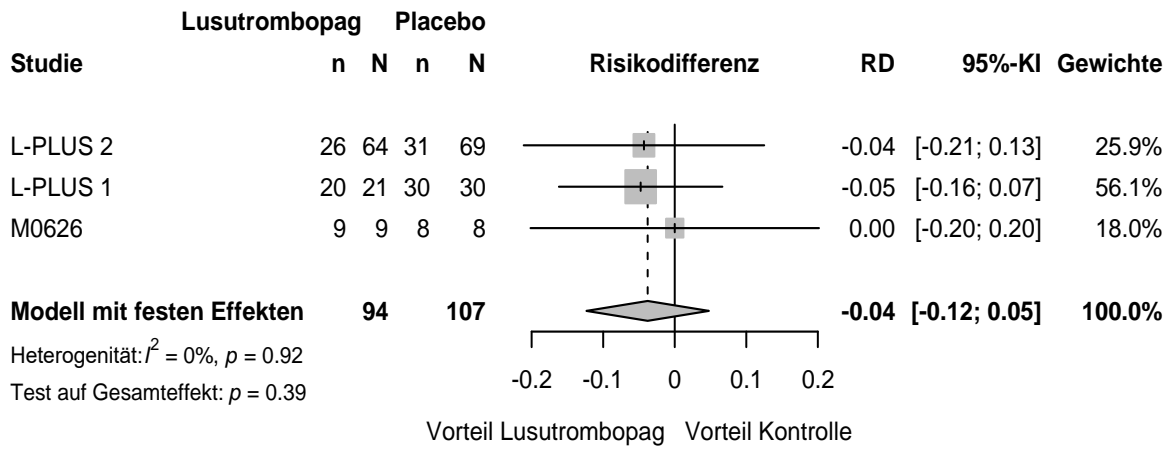
29 UE unter Ausschluss Morbidität_RD Age (years) - < 65



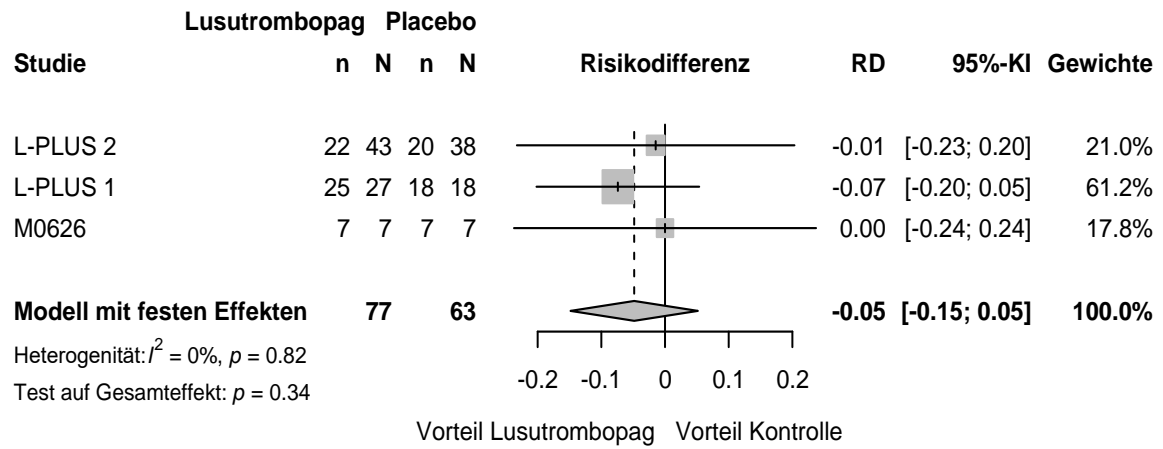
30 UE unter Ausschluss Morbidität_RD Age (years) - >=65



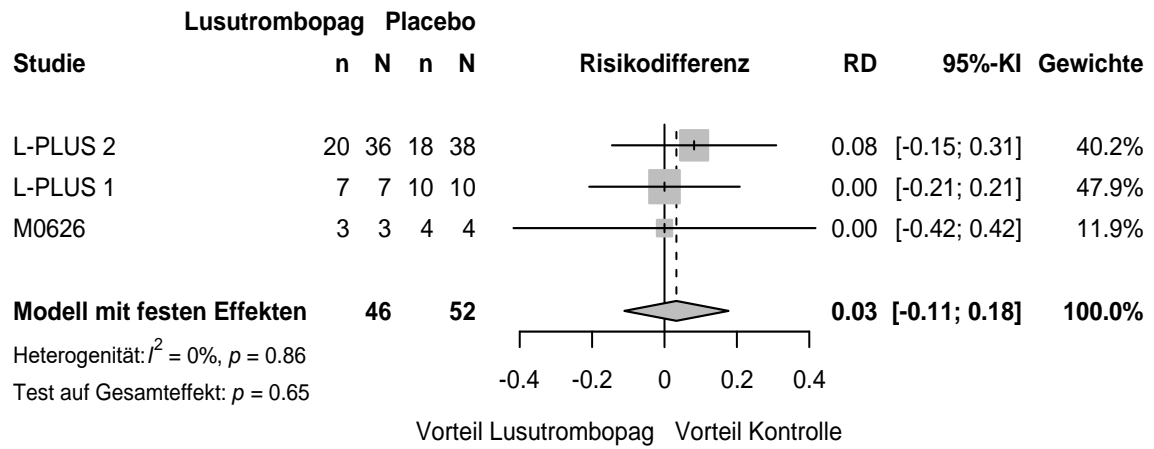
31 UE unter Ausschluss Morbidität_RD Gender - Male



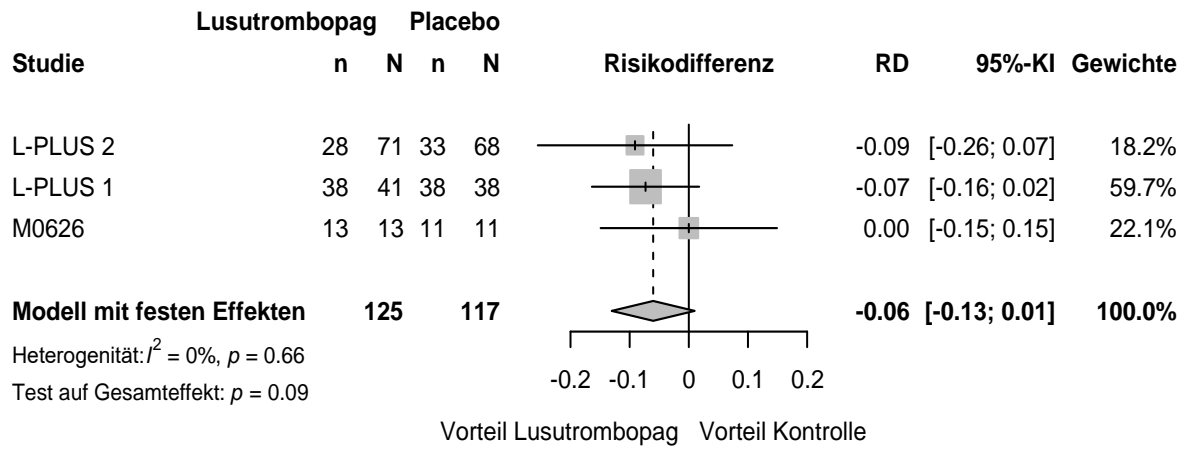
32 UE unter Ausschluss Morbidität_RD Gender - Female



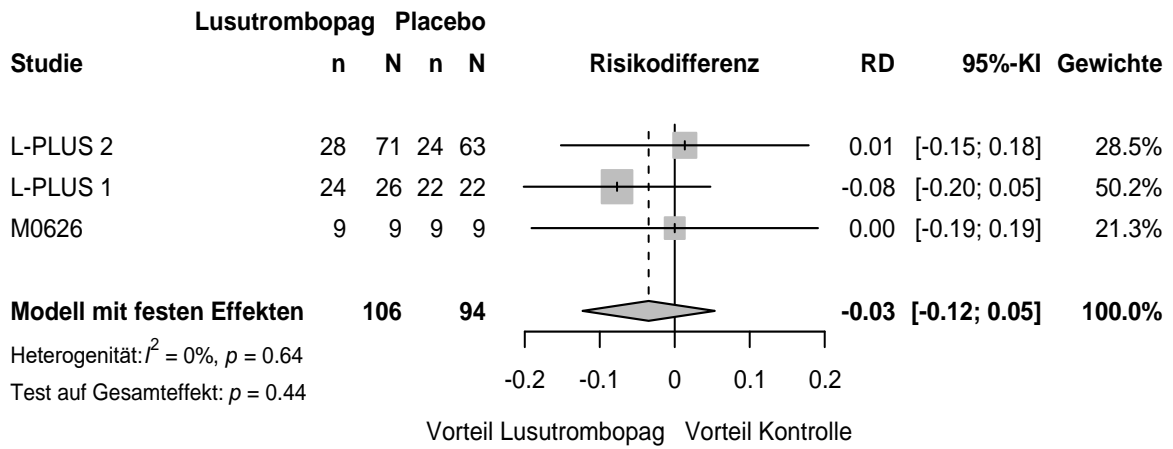
33 UE unter Ausschluss Morbidität_RD Baseline platelet count (*10⁴/uL) - < 3.5



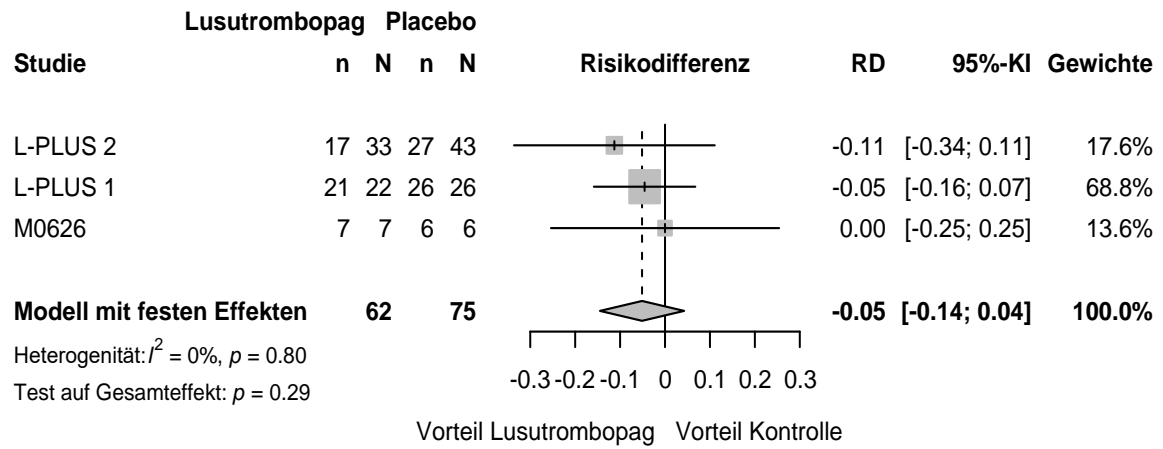
34 UE unter Ausschluss Morbidität_RD Baseline platelet count (*10⁴/uL) - >= 3.5



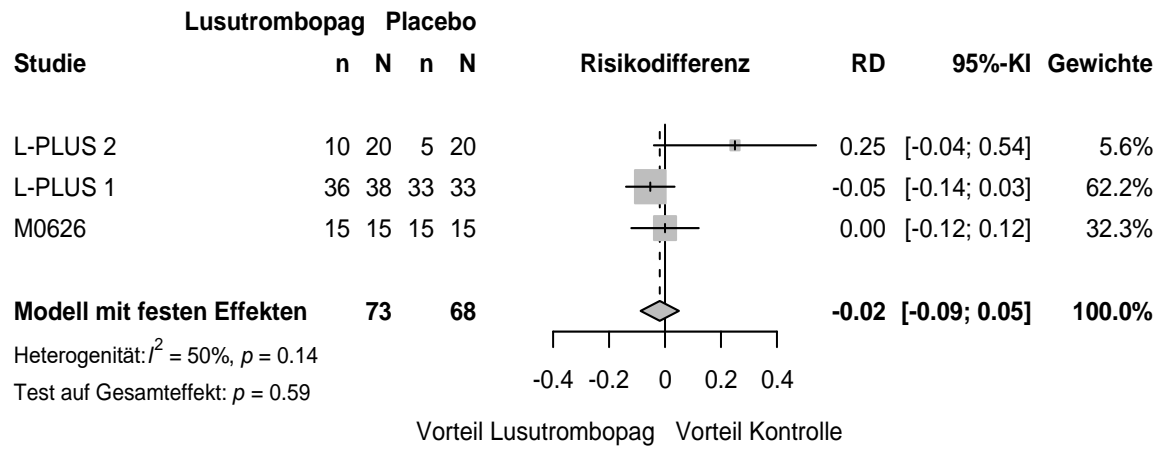
35 UE unter Ausschluss Morbidität_RD Child-Pugh class - A



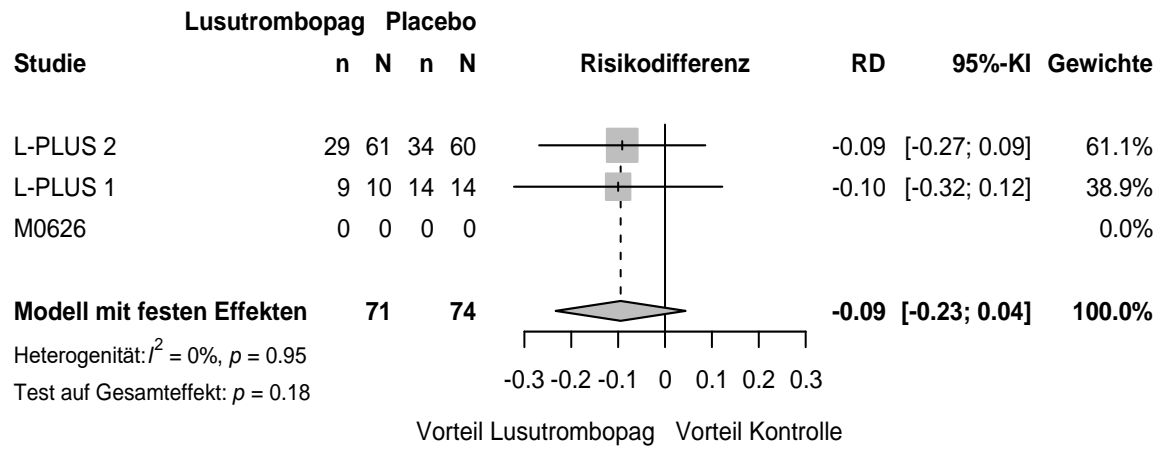
36 UE unter Ausschluss Morbidität_RD Child-Pugh class - B



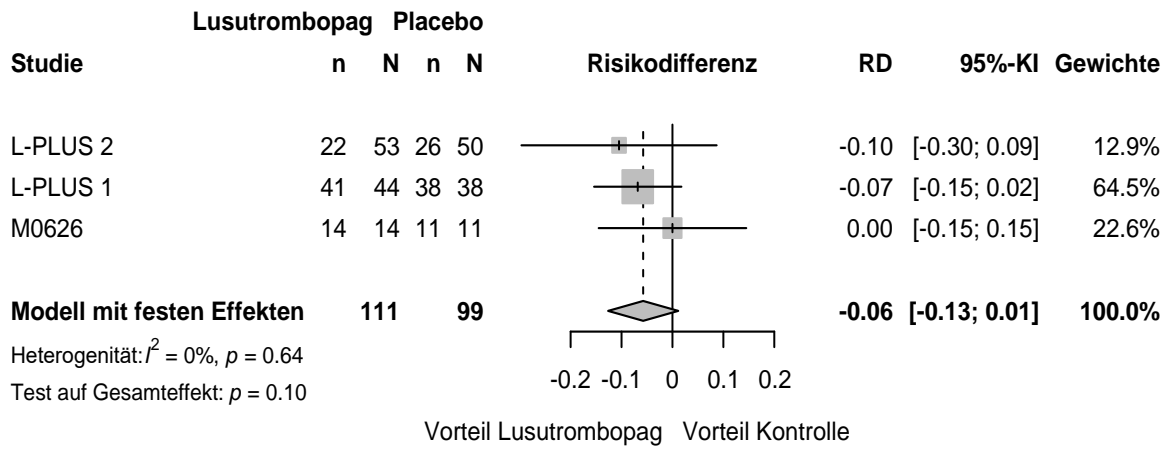
37 UE unter Ausschluss Morbidität_RD Invasive procedure liver-related



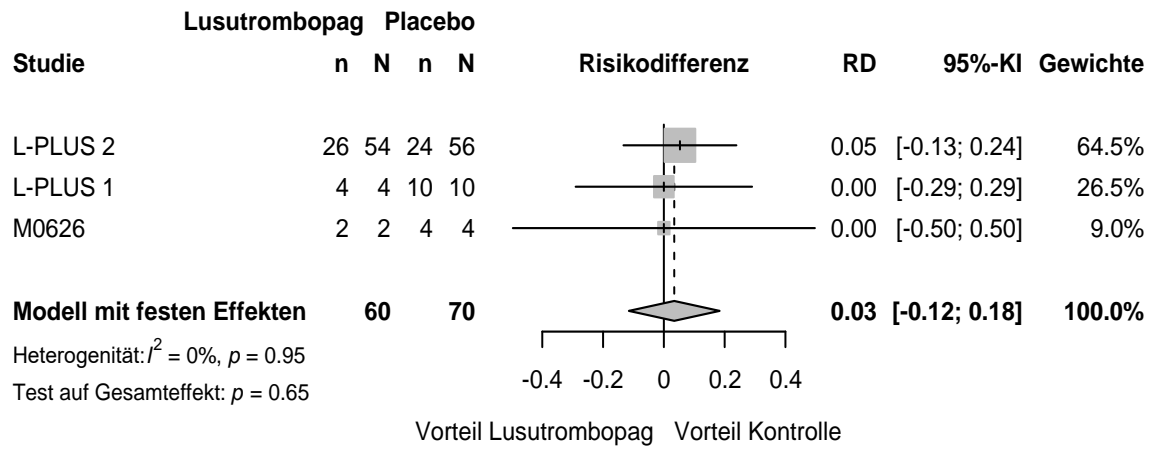
38 UE unter Ausschluss Morbidität_RD Invasive procedure gi-related



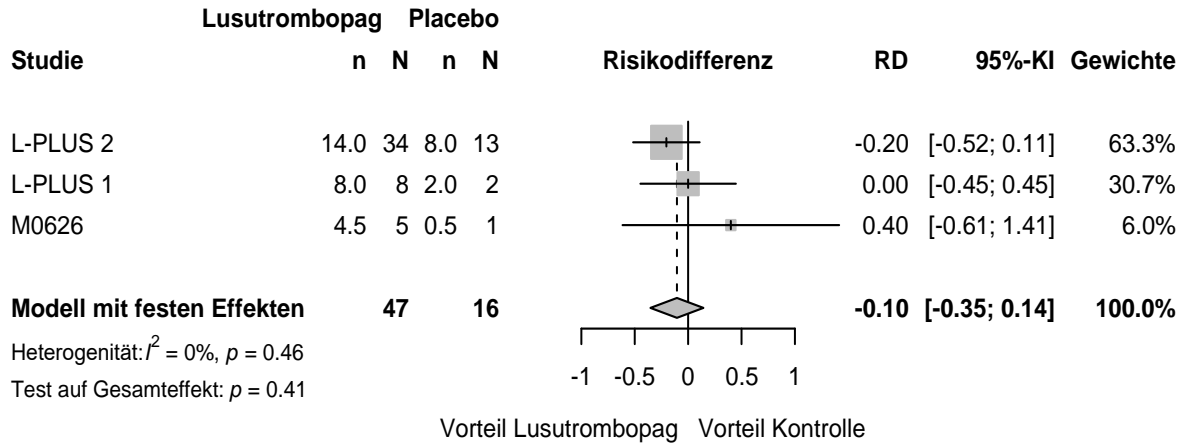
39 UE unter Ausschluss Morbidität_RD Baseline body weight (kg) - < 75



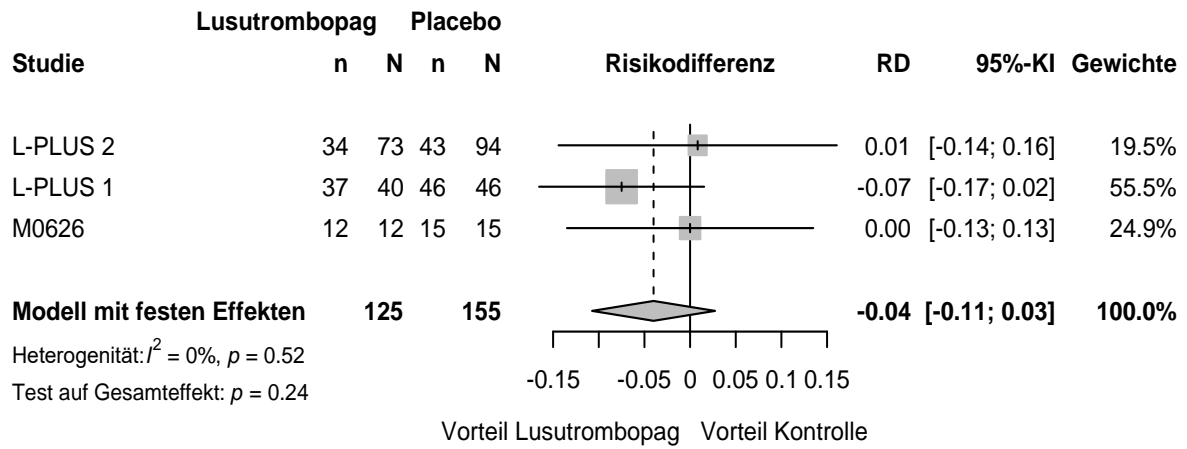
40 UE unter Ausschluss Morbidität_RD Baseline body weight (kg) - >= 75



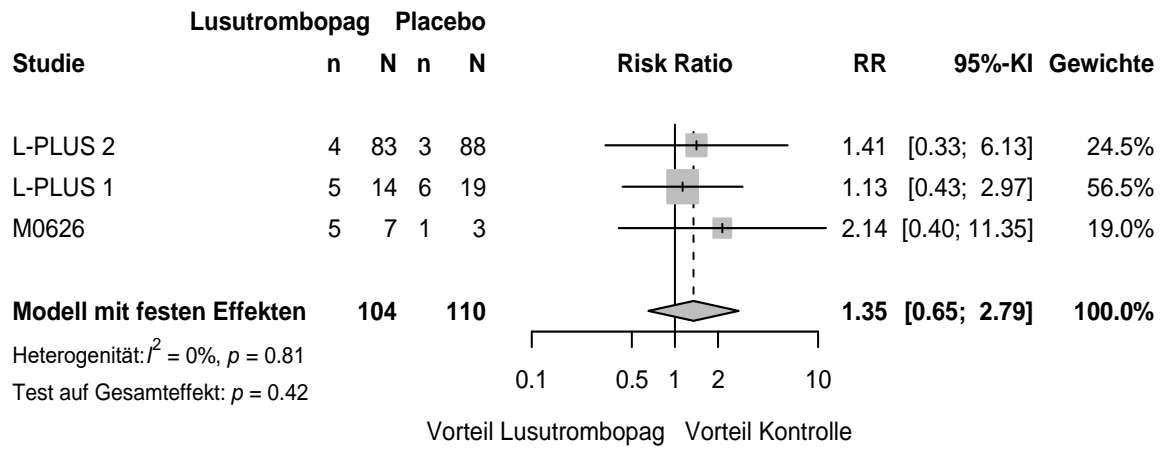
41 UE unter Ausschluss Morbidität_RD Treatment duration (days) - < 7



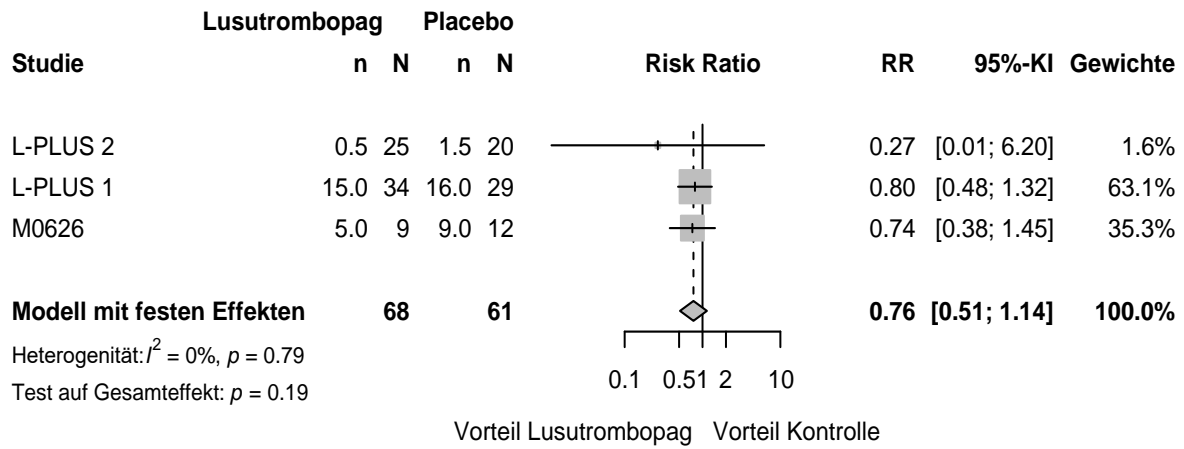
42 UE unter Ausschluss Morbidität_RD Treatment duration (days) -7



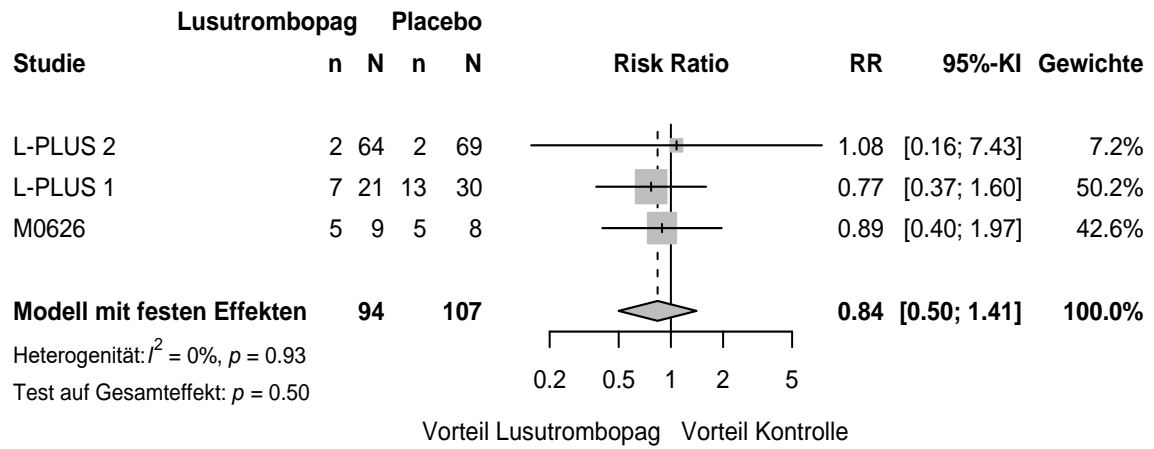
43 Schwere UE unter Ausschluss Morbidität_RR Age (years) - < 65



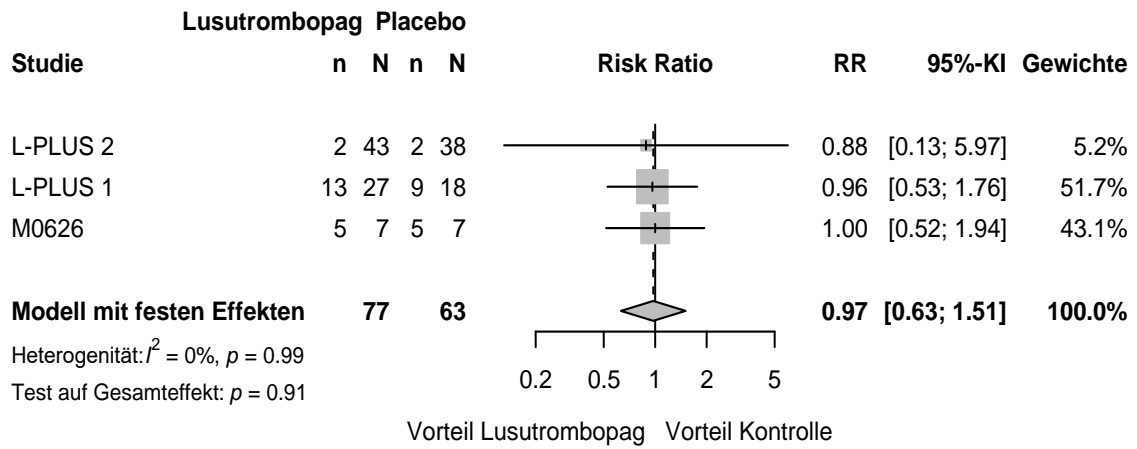
44 Schwere UE unter Ausschluss Morbidität_RR Age (years) - >=65



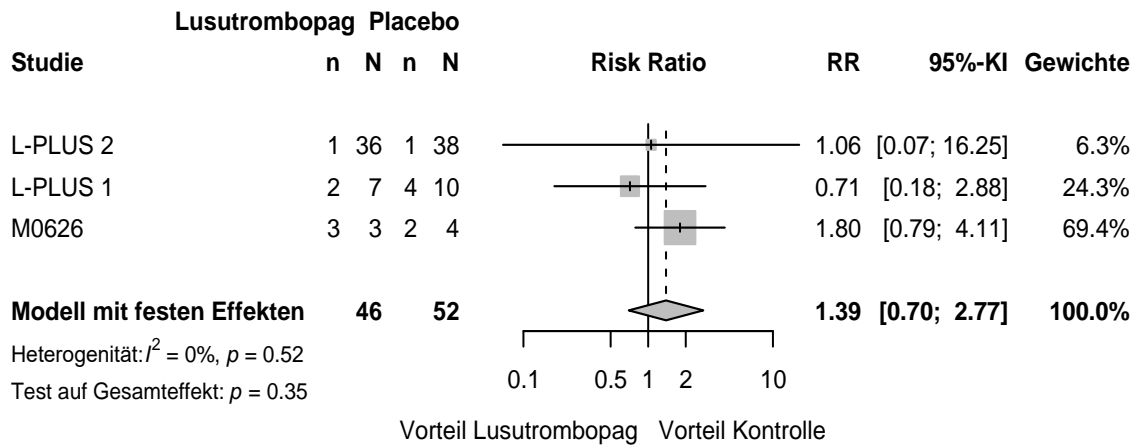
45 Schwere UE unter Ausschluss Morbidität_RR Gender - Male



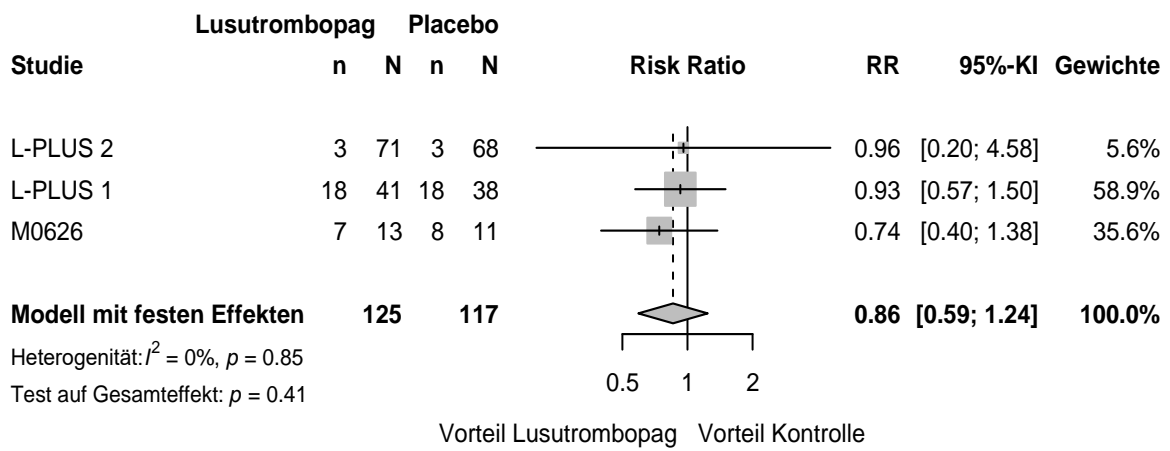
46 Schwere UE unter Ausschluss Morbidität_RR Gender - Female



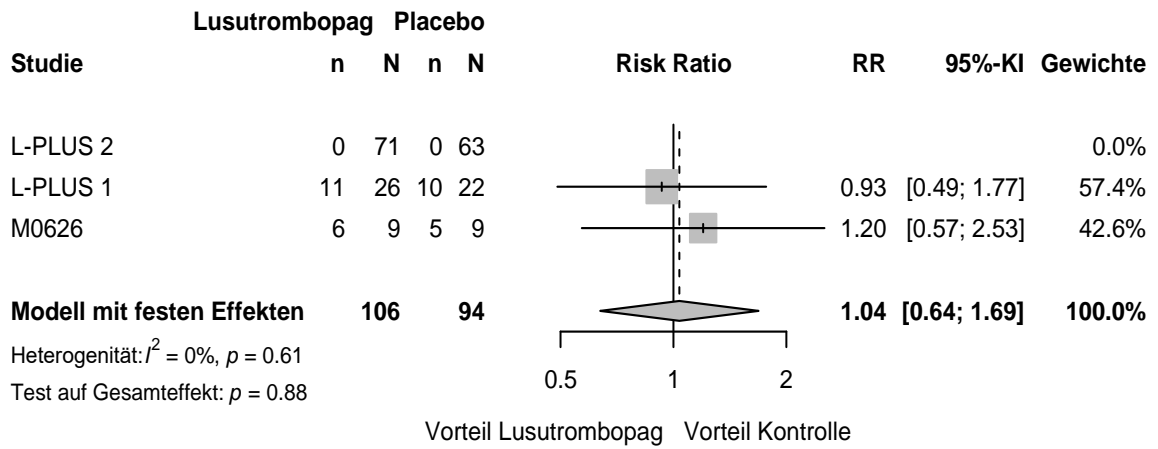
47 Schwere UE unter Ausschluss Morbidität_RR Baseline platelet count (*10⁴/uL) - < 3.5



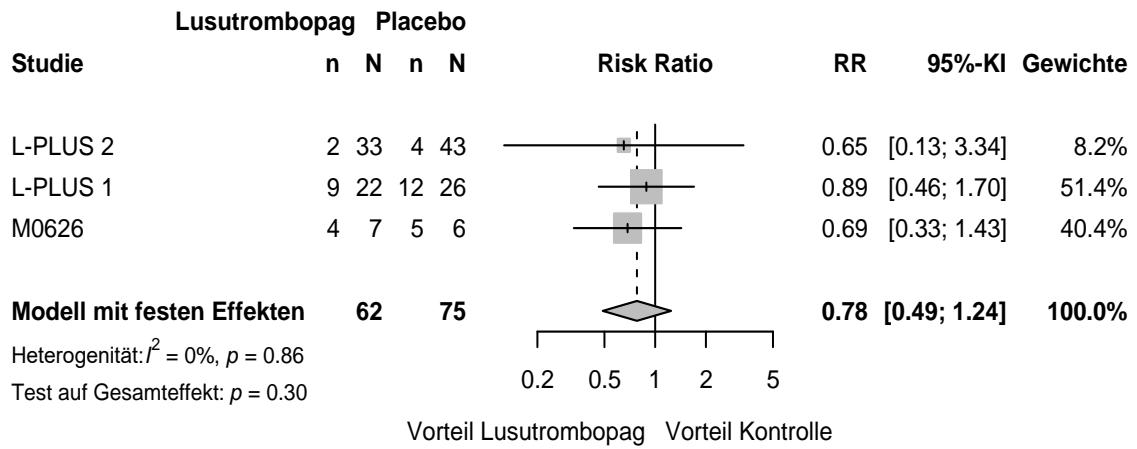
48 Schwere UE unter Ausschluss Morbidität_RR Baseline platelet count (*10⁴/uL) - >= 3.5



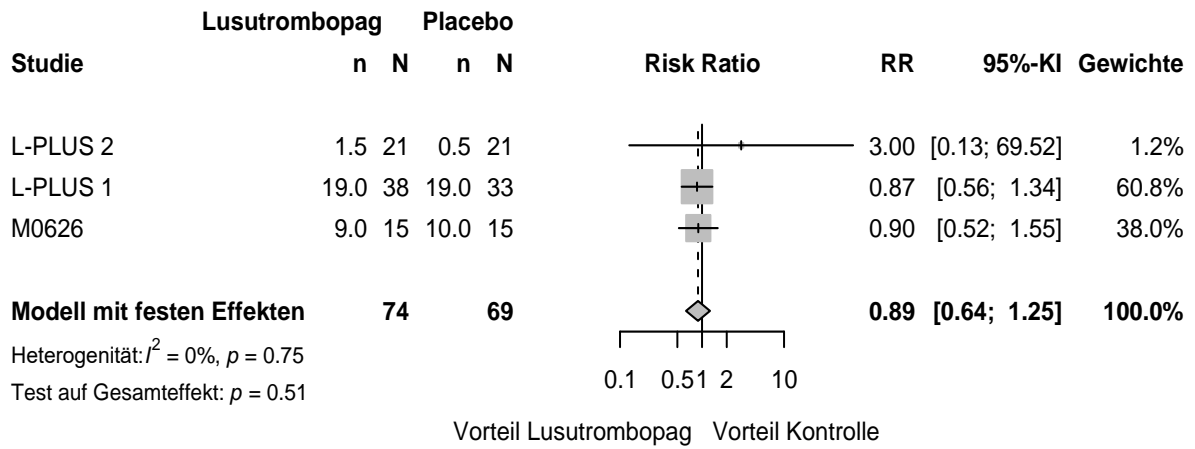
49 Schwere UE unter Ausschluss Morbidität_RR Child-Pugh class - A



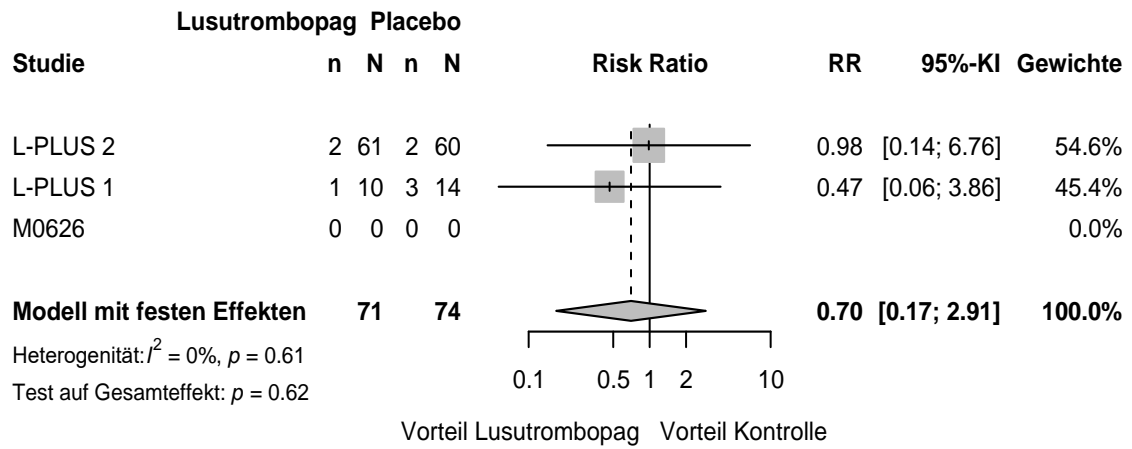
50 Schwere UE unter Ausschluss Morbidität_RR Child-Pugh class - B



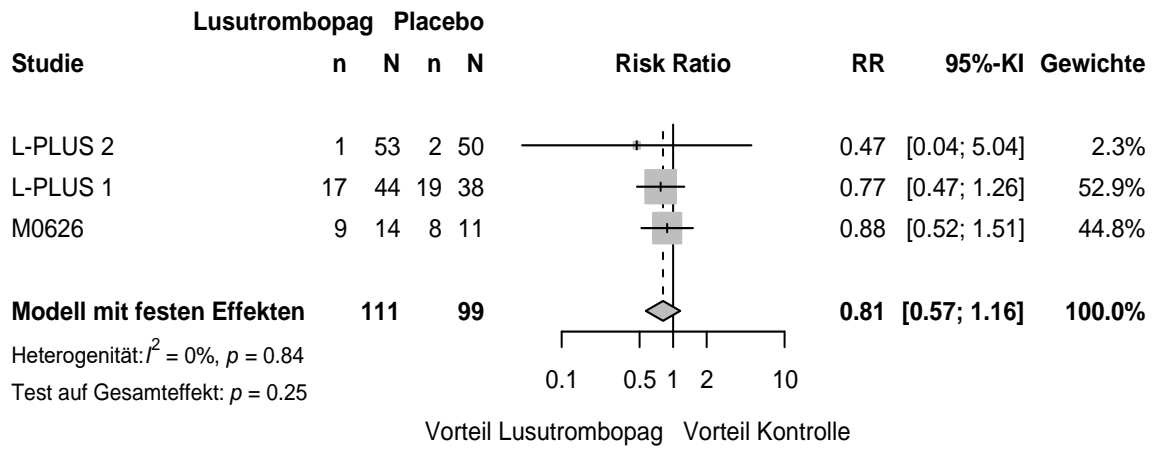
51 Schwere UE unter Ausschluss Morbidität_RR Invasive procedure liver-related



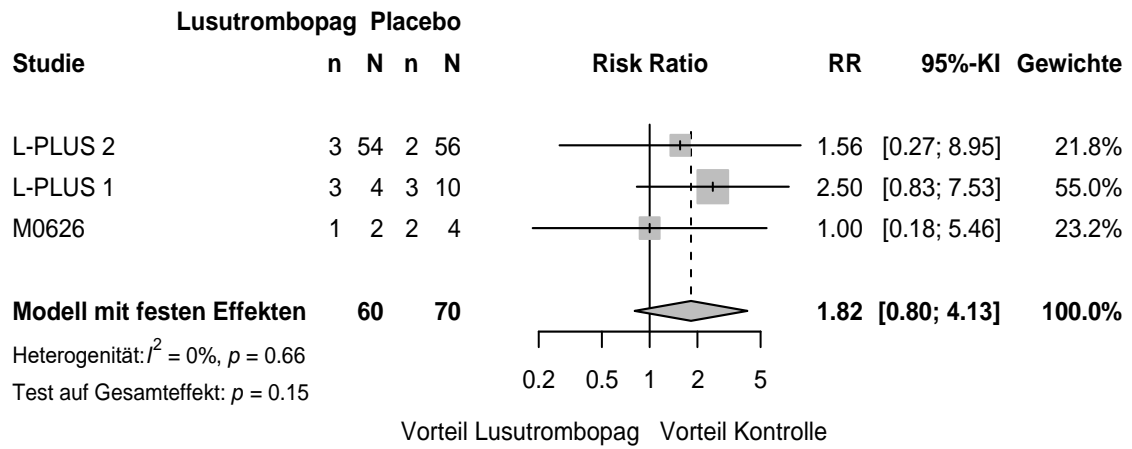
52 Schwere UE unter Ausschluss Morbidität_RR Invasive procedure gi-related



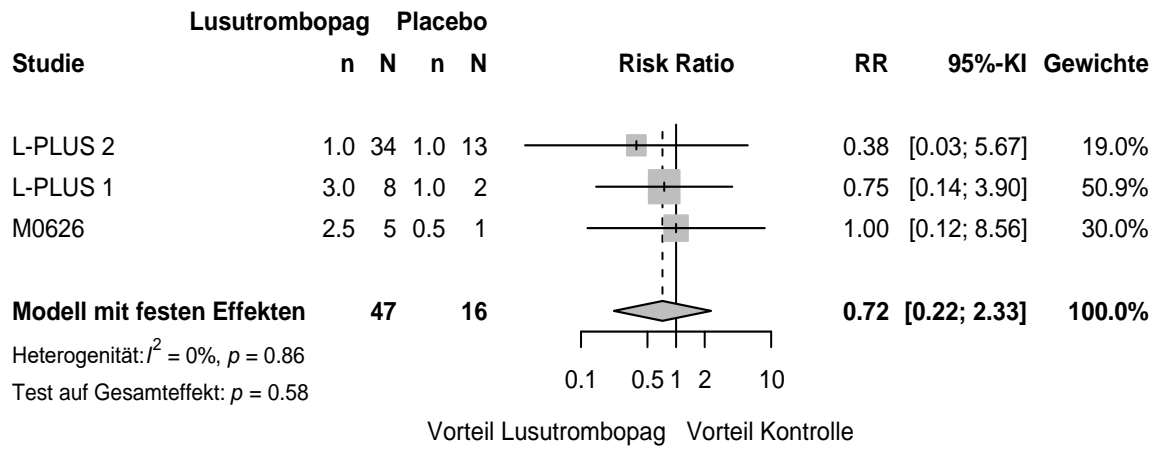
53 Schwere UE unter Ausschluss Morbidität_RR Baseline body weight (kg) - < 75



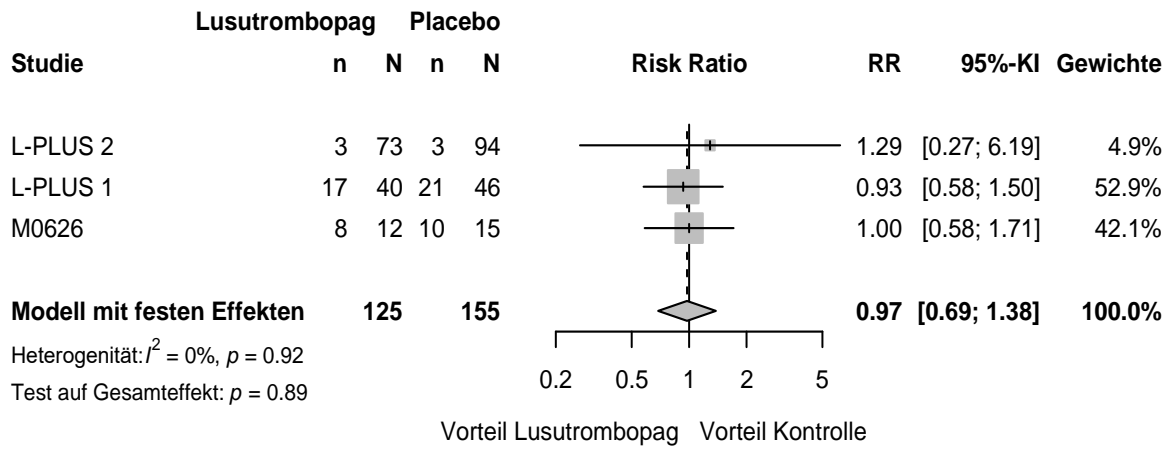
54 Schwere UE unter Ausschluss Morbidität_RR Baseline body weight (kg) - >= 75



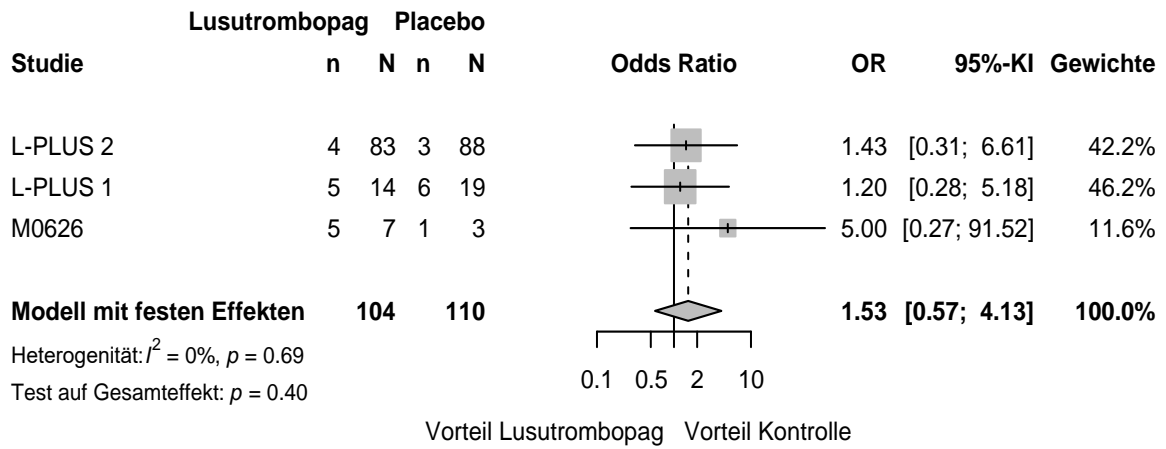
55 Schwere UE unter Ausschluss Morbidität_RR Treatment duration (days) - < 7



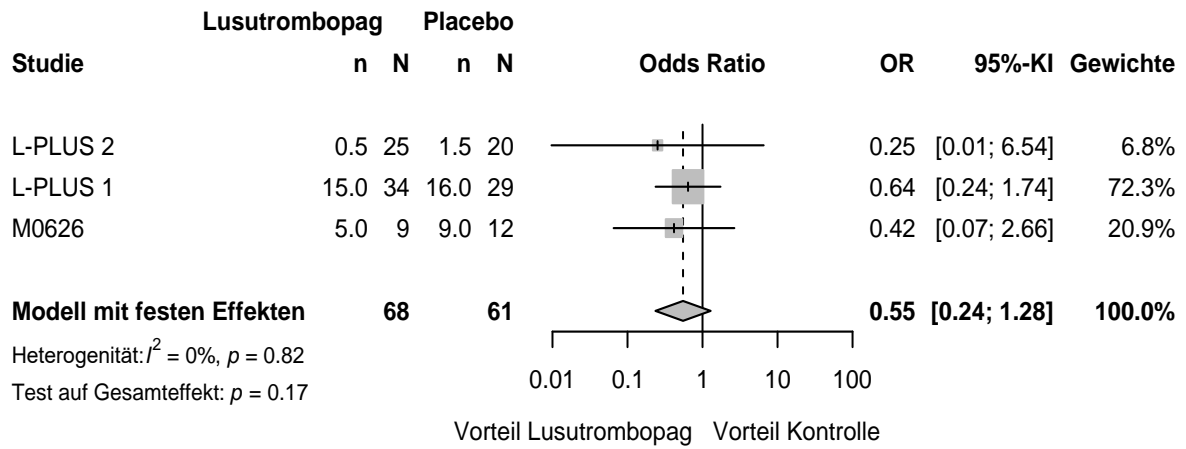
56 Schwere UE unter Ausschluss Morbidität_RR Treatment duration (days) -7



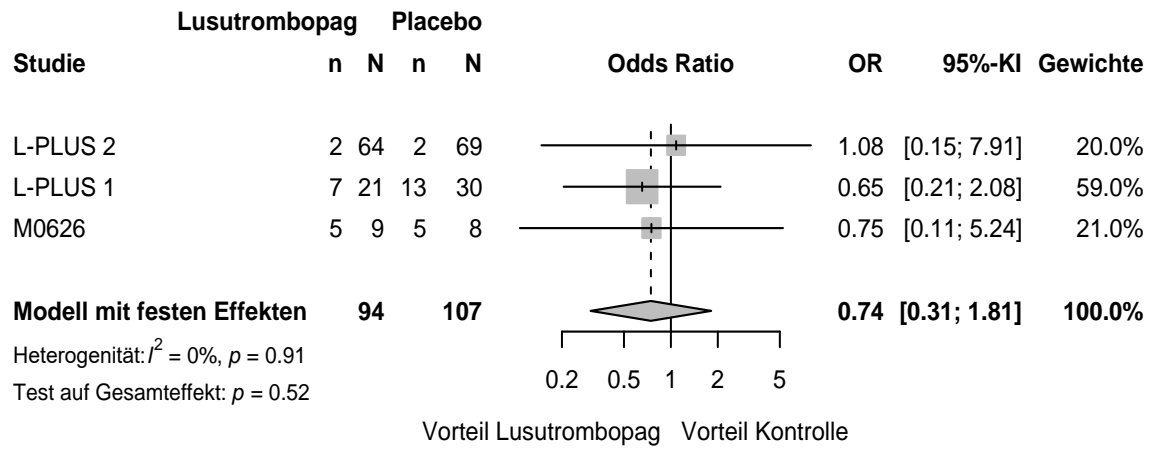
57 Schwere UE unter Ausschluss Morbidität_OR Age (years) - < 65



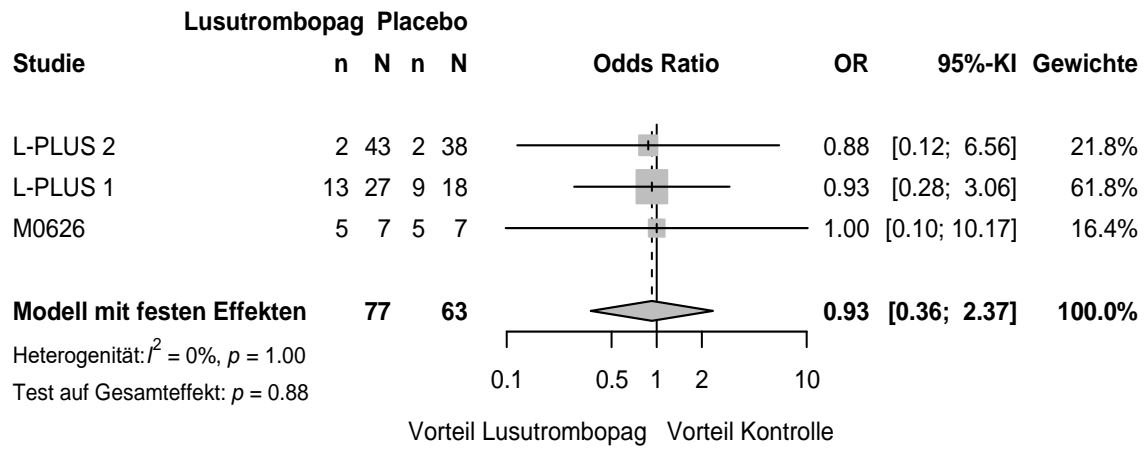
58 Schwere UE unter Ausschluss Morbidität_OR Age (years) - >=65



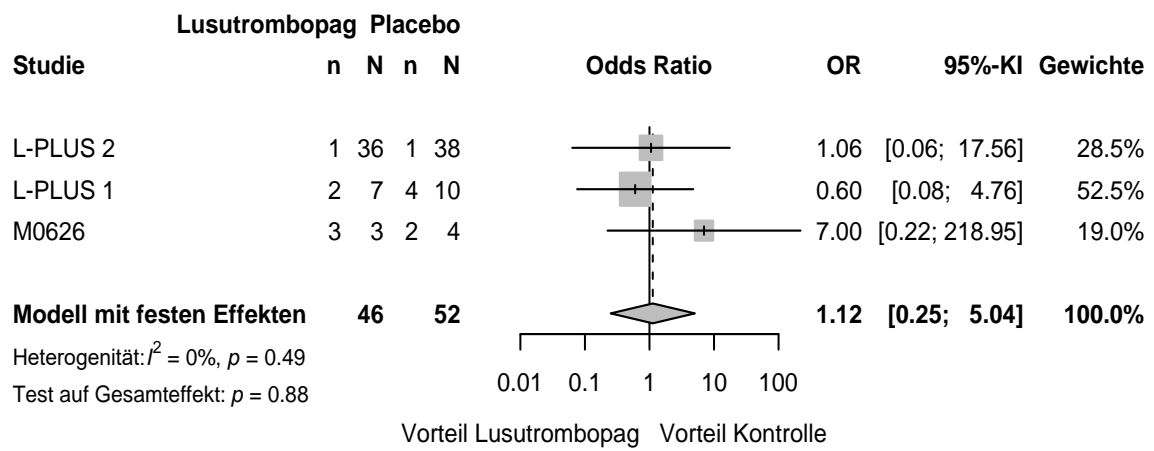
59 Schwere UE unter Ausschluss Morbidität_OR Gender - Male



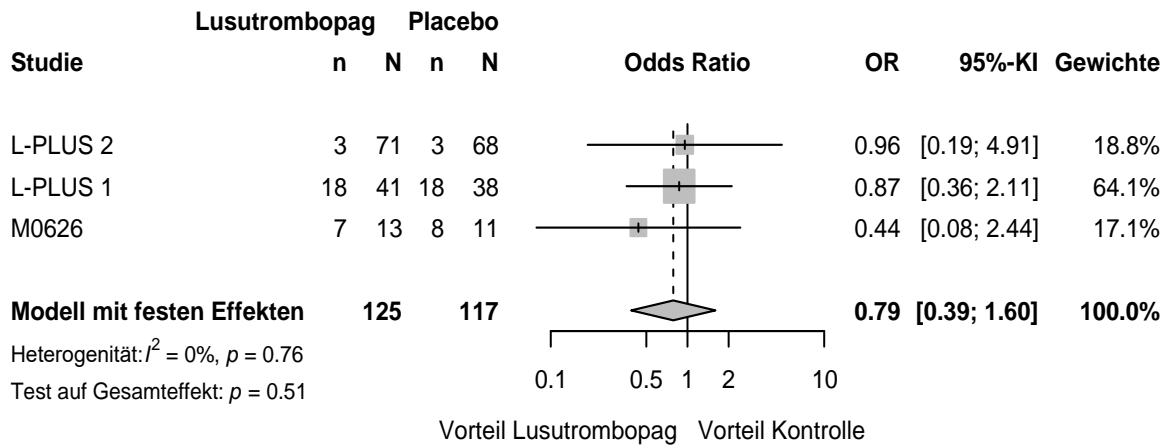
60 Schwere UE unter Ausschluss Morbidität_OR Gender - Female



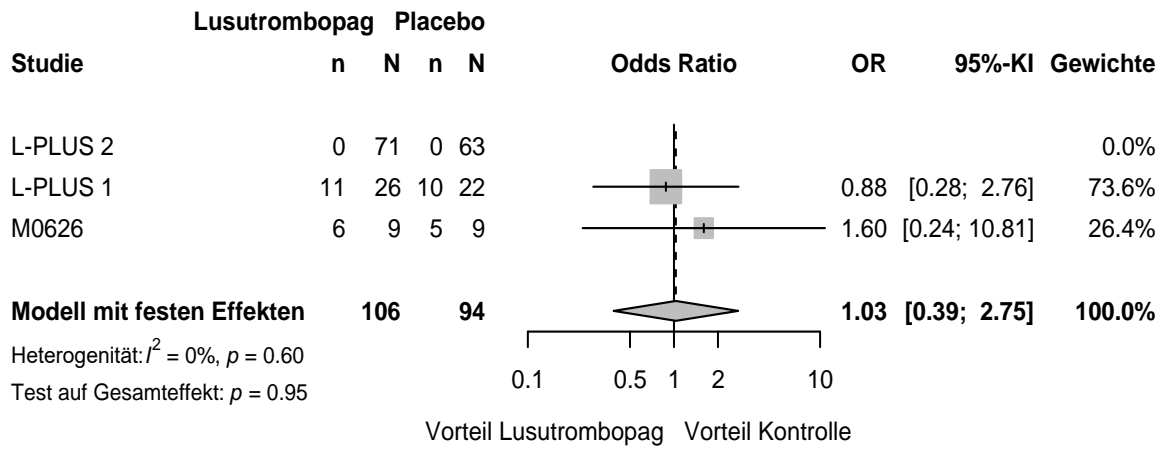
61 Schwere UE unter Ausschluss Morbidität_OR Baseline platelet count (*10⁴/uL) - < 3.5



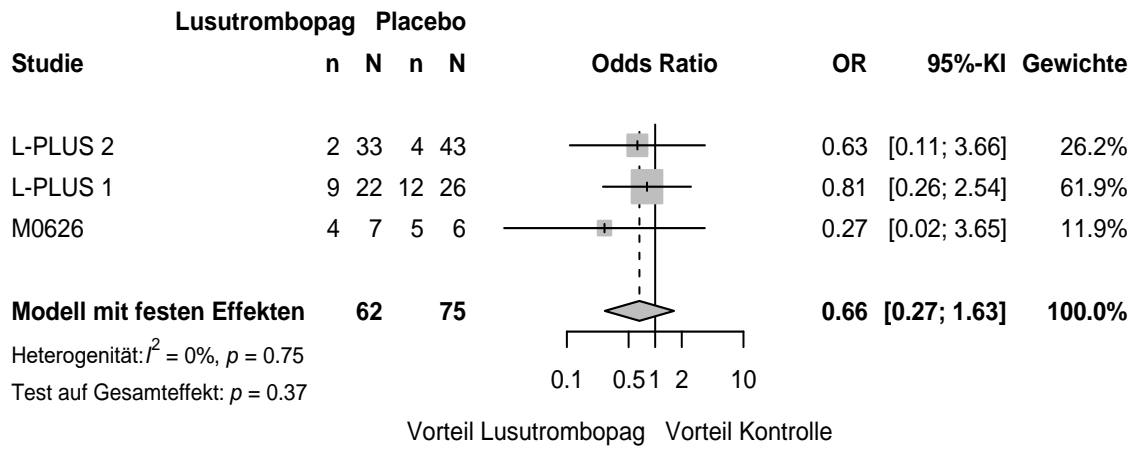
62 Schwere UE unter Ausschluss Morbidität_OR Baseline platelet count (*10⁴/uL) - >= 3.5



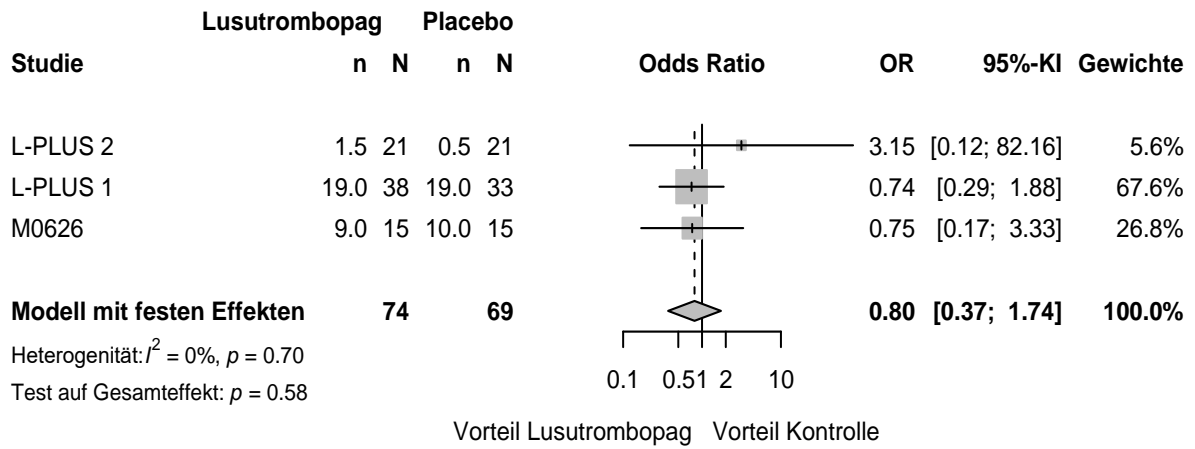
63 Schwere UE unter Ausschluss Morbidität_OR Child-Pugh class - A



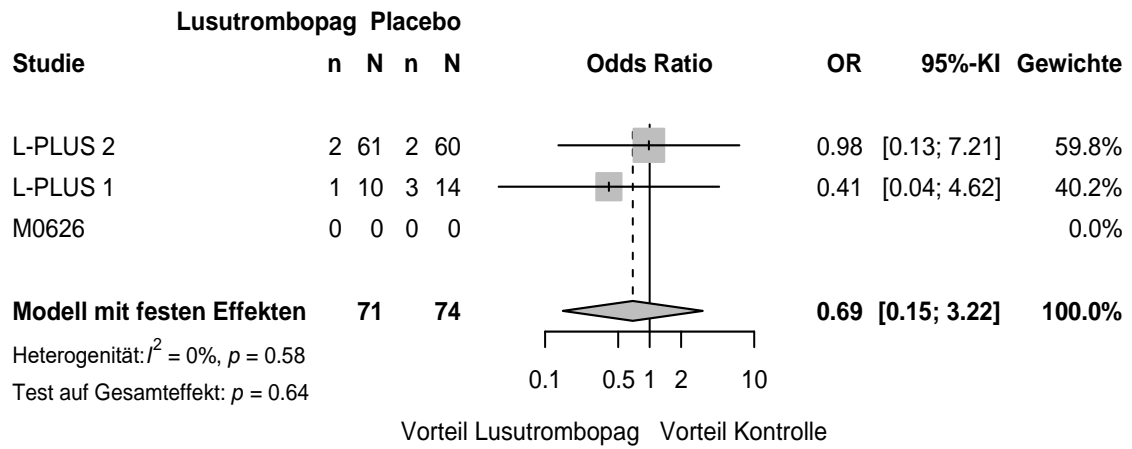
64 Schwere UE unter Ausschluss Morbidität_OR Child-Pugh class - B



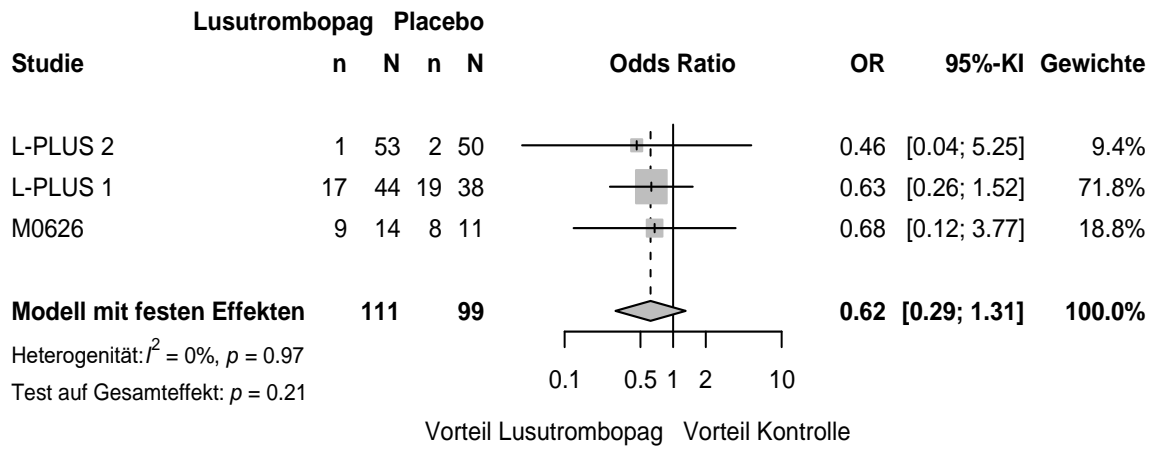
65 Schwere UE unter Ausschluss Morbidität_OR Invasive procedure liver-related



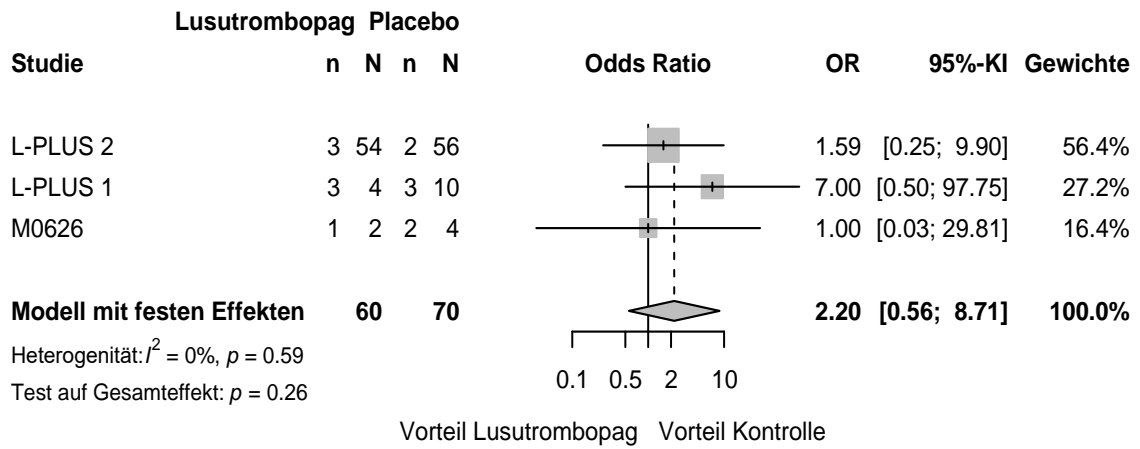
66 Schwere UE unter Ausschluss Morbidität_OR Invasive procedure gi-related



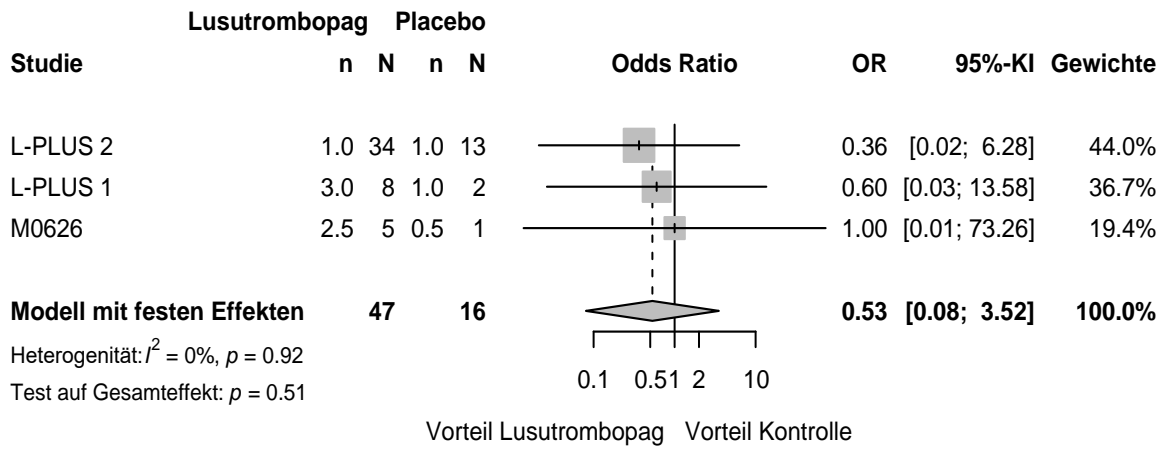
67 Schwere UE unter Ausschluss Morbidität_OR Baseline body weight (kg) - < 75



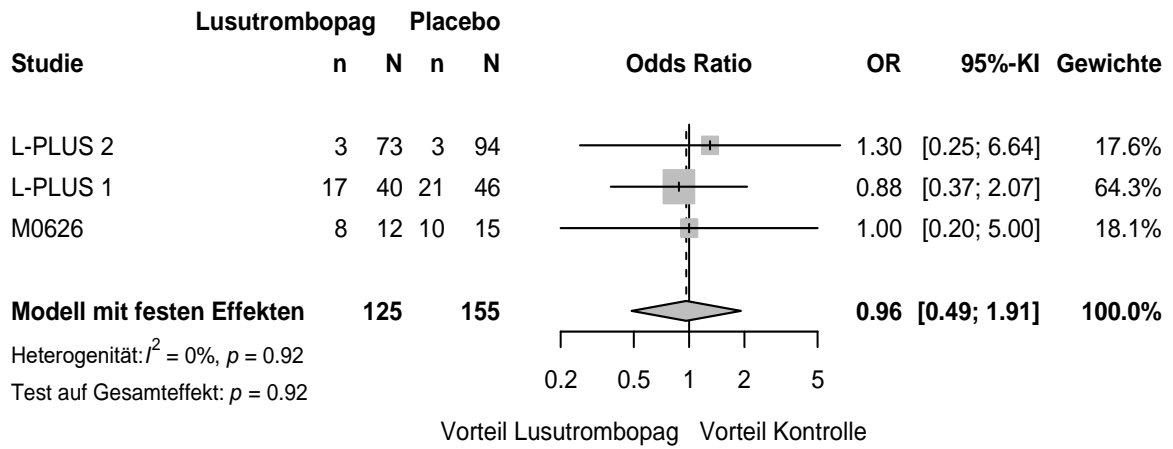
68 Schwere UE unter Ausschluss Morbidität_OR Baseline body weight (kg) - >= 75



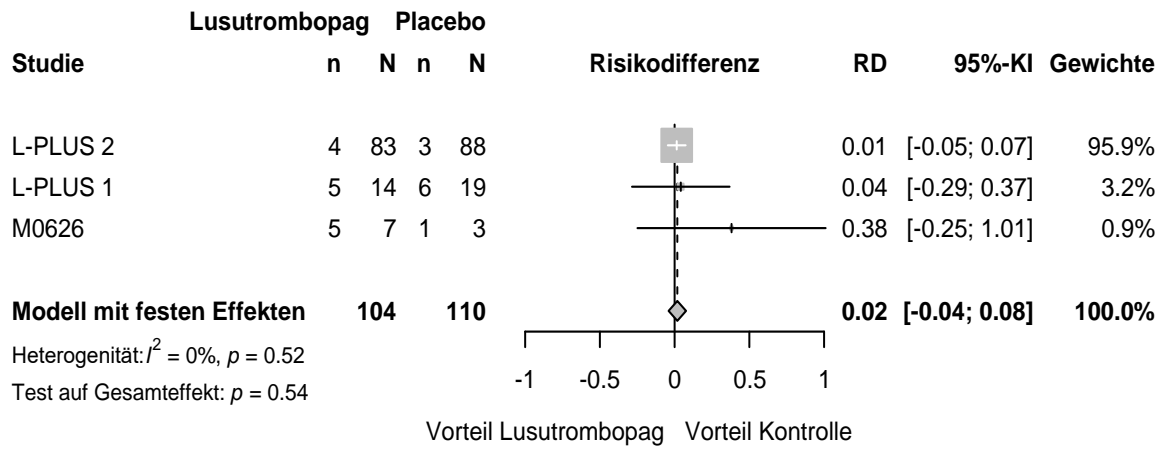
69 Schwere UE unter Ausschluss Morbidität_OR Treatment duration (days) - < 7



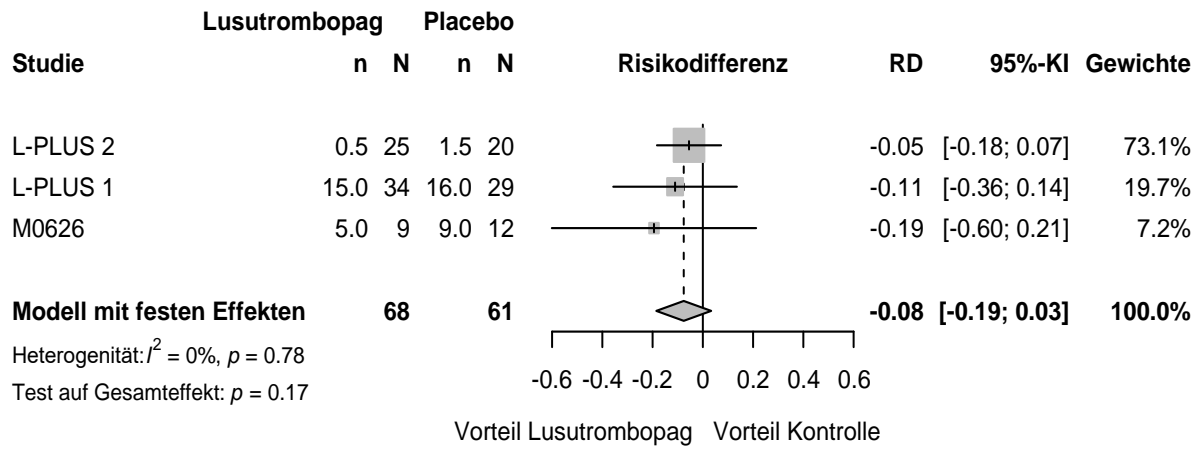
70 Schwere UE unter Ausschluss Morbidität_OR Treatment duration (days) -7



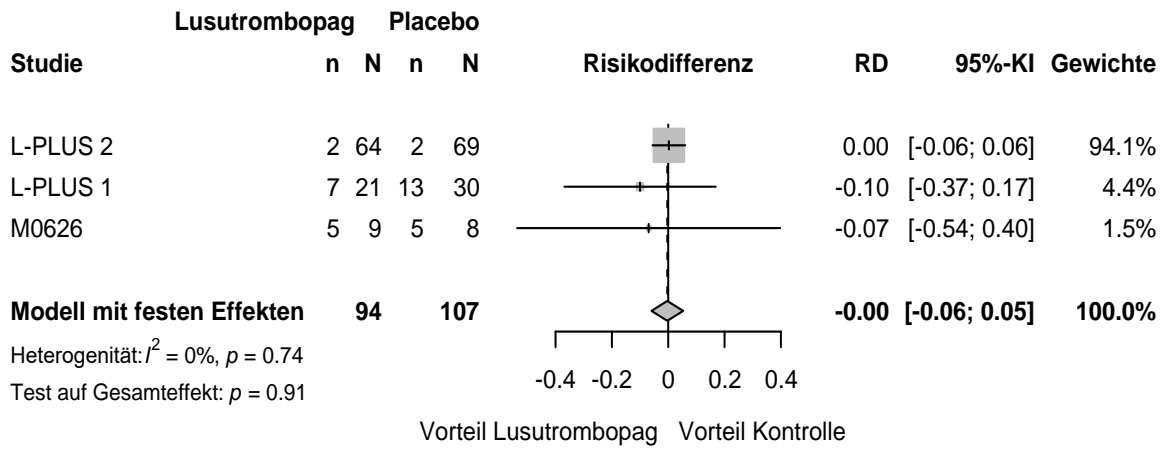
71 Schwere UE unter Ausschluss Morbidität_RD Age (years) - < 65



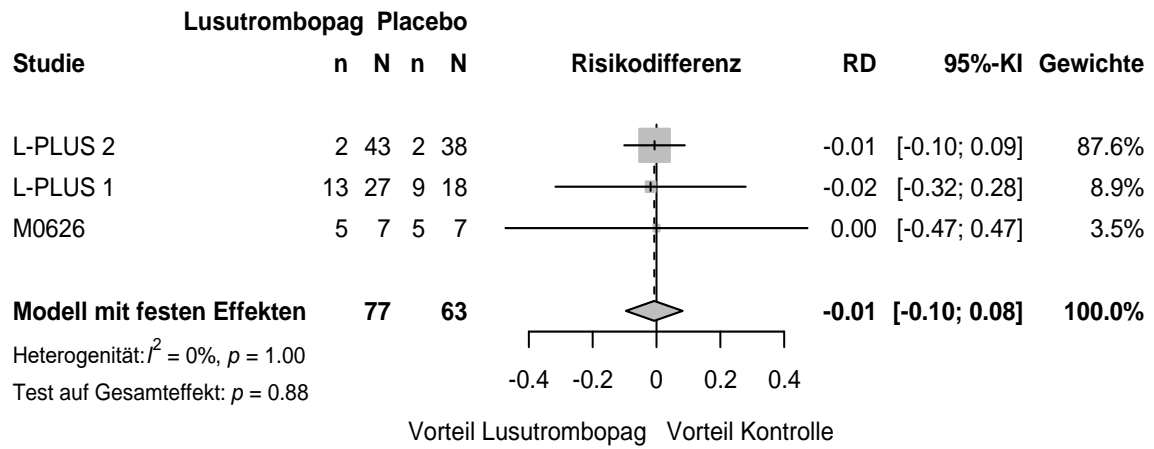
72 Schwere UE unter Ausschluss Morbidität_RD Age (years) - >=65



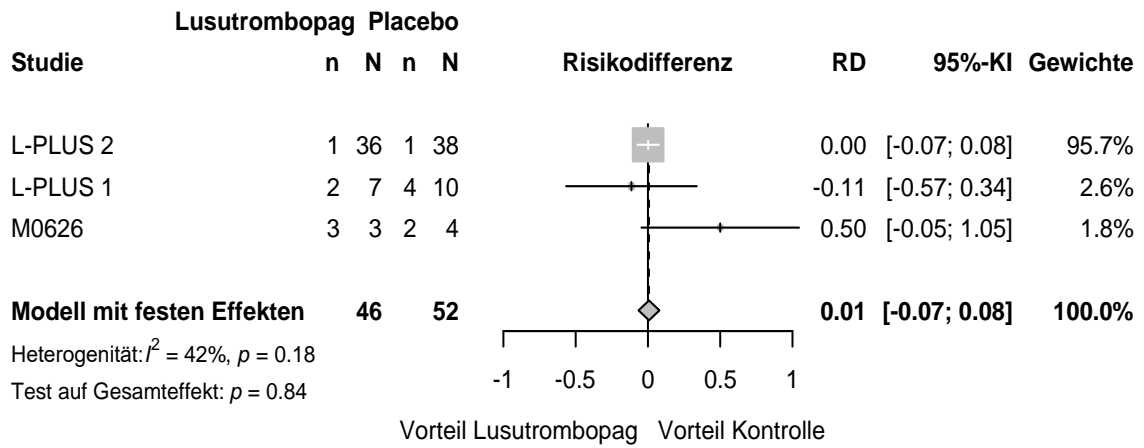
73 Schwere UE unter Ausschluss Morbidität_RD Gender - Male



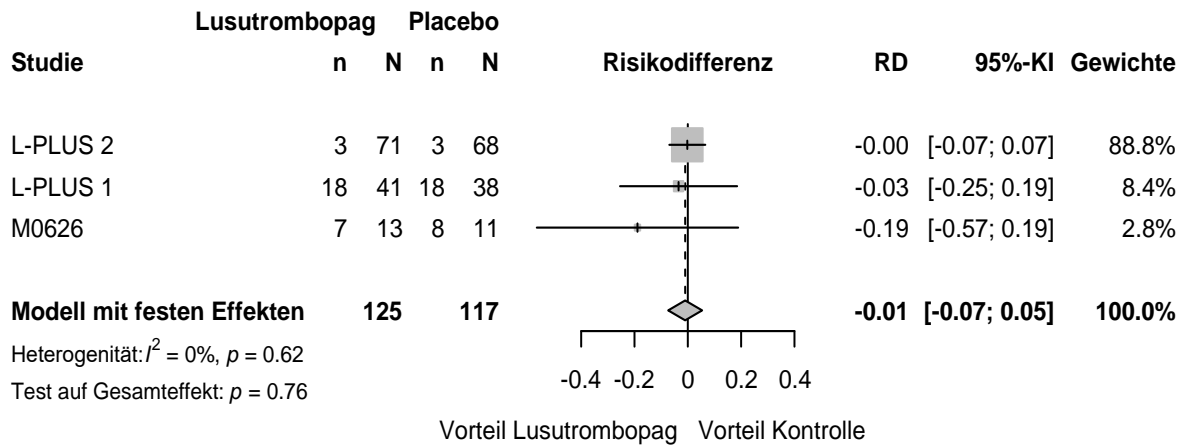
74 Schwere UE unter Ausschluss Morbidität_RD Gender - Female



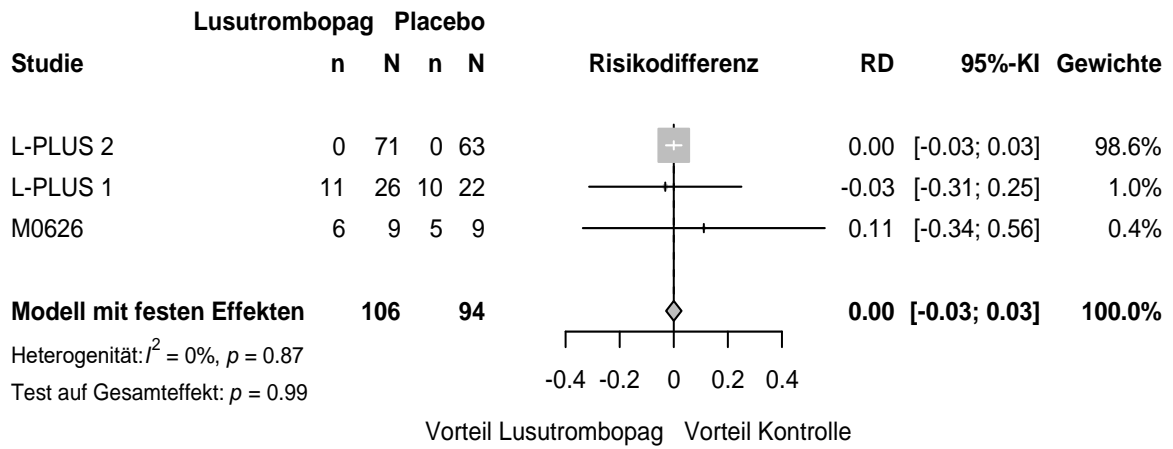
75 Schwere UE unter Ausschluss Morbidität_RD Baseline platelet count ($\cdot 10^4/uL$) - < 3.5



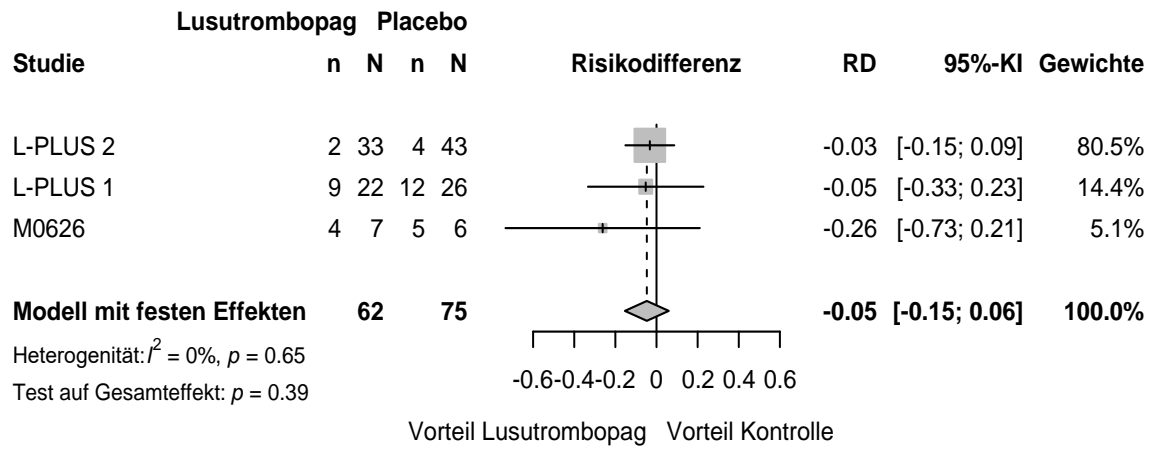
**76 Schwere UE unter Ausschluss Morbidität_RD Baseline platelet count (*10⁴/uL) -
 >= 3.5**



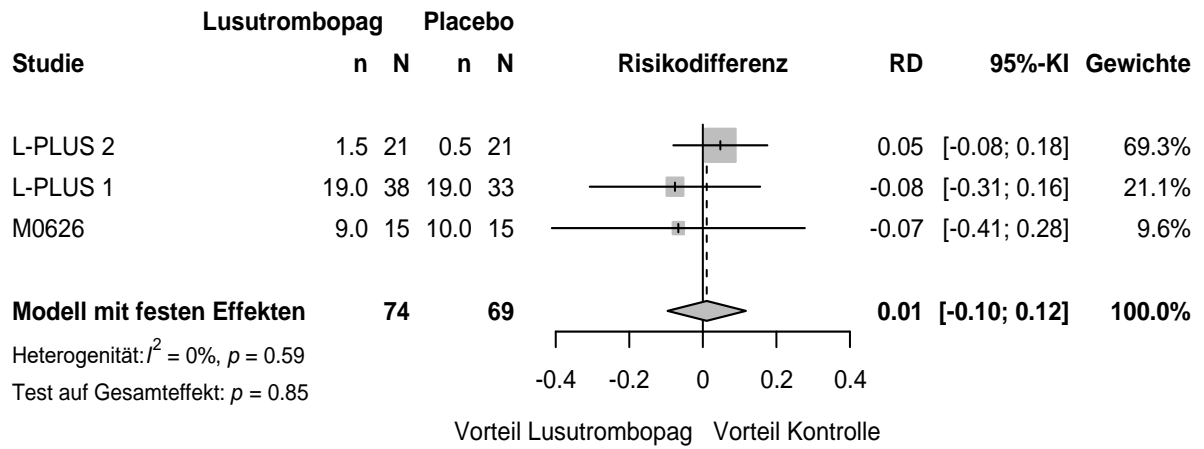
77 Schwere UE unter Ausschluss Morbidität_RD Child-Pugh class - A



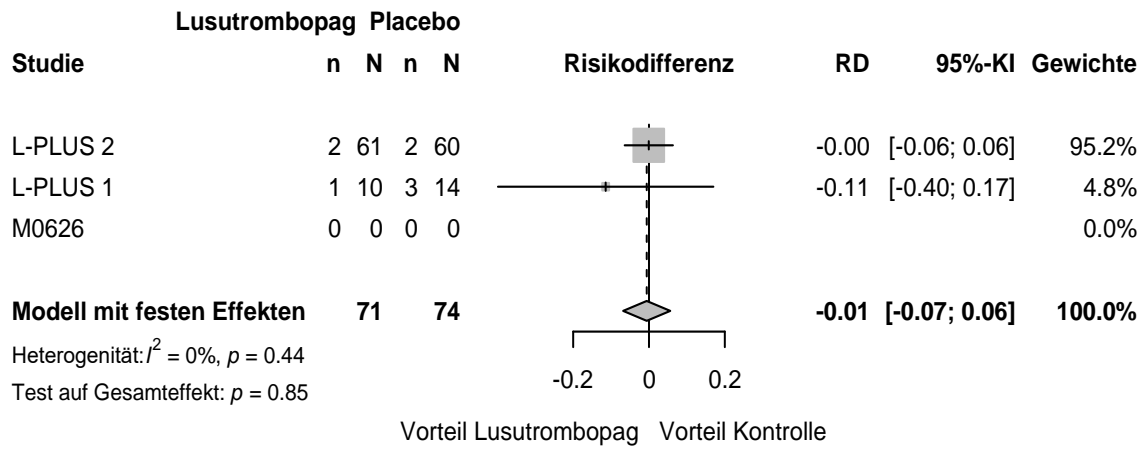
78 Schwere UE unter Ausschluss Morbidität_RD Child-Pugh class - B



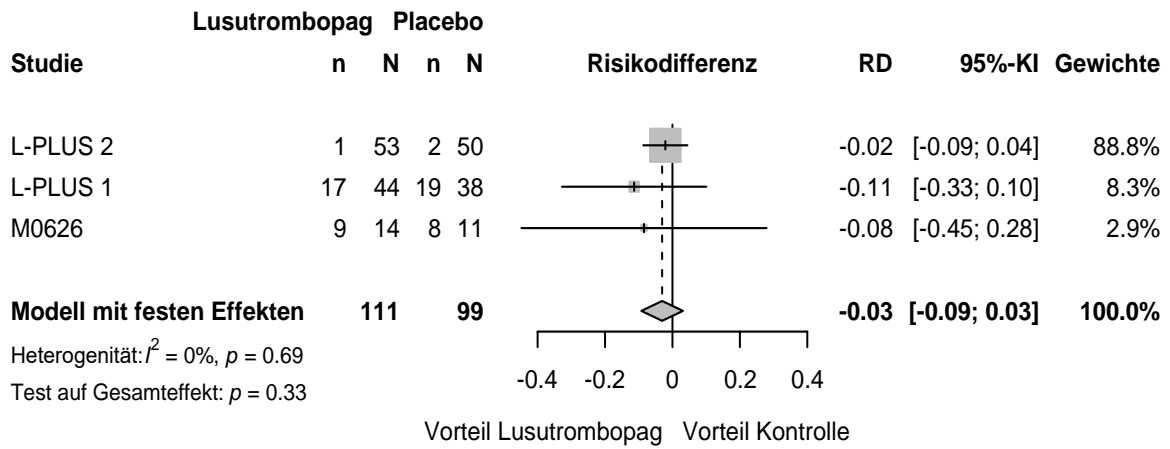
79 Schwere UE unter Ausschluss Morbidität_RD Invasive procedure liver-related



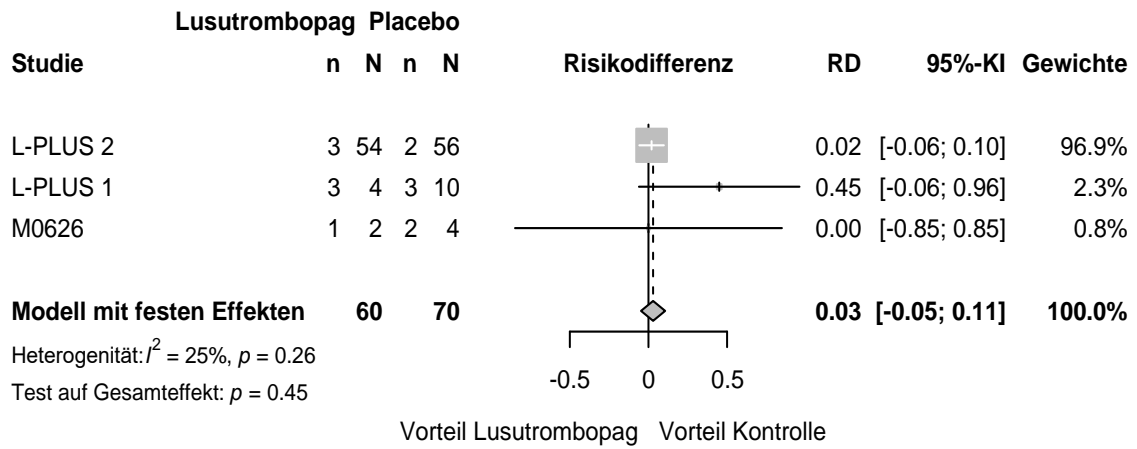
80 Schwere UE unter Ausschluss Morbidität_RD Invasive procedure gi-related



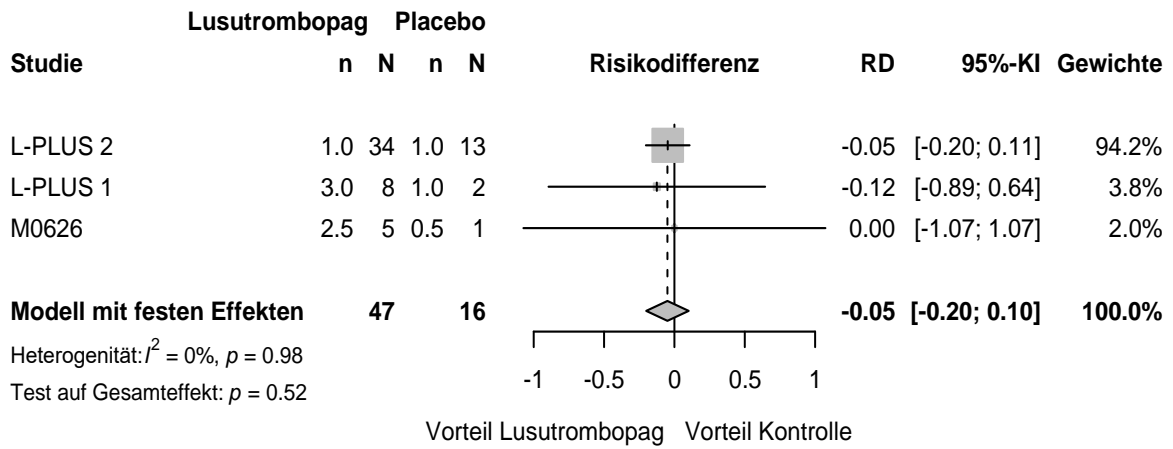
81 Schwere UE unter Ausschluss Morbidität_RD Baseline body weight (kg) - < 75



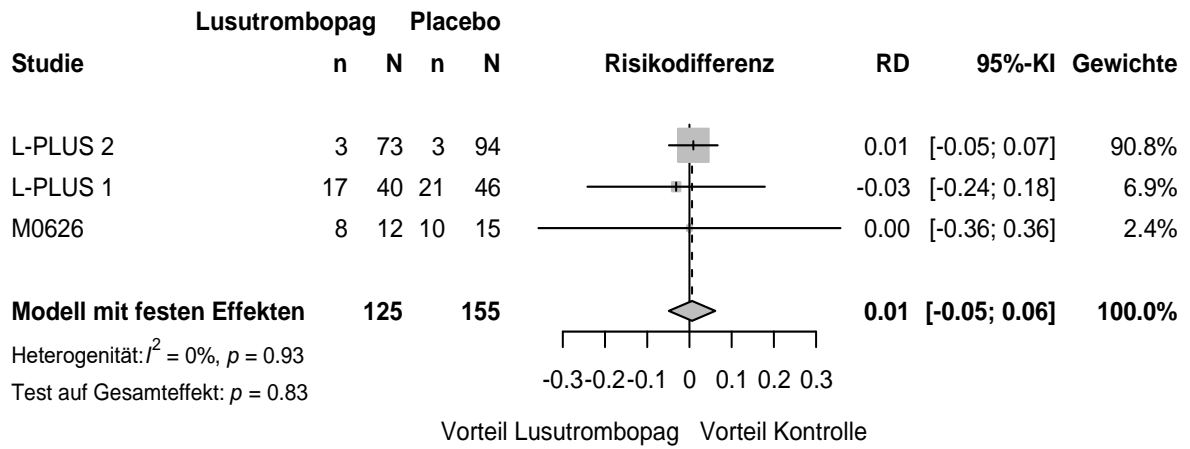
82 Schwere UE unter Ausschluss Morbidität_RD Baseline body weight (kg) - >= 75



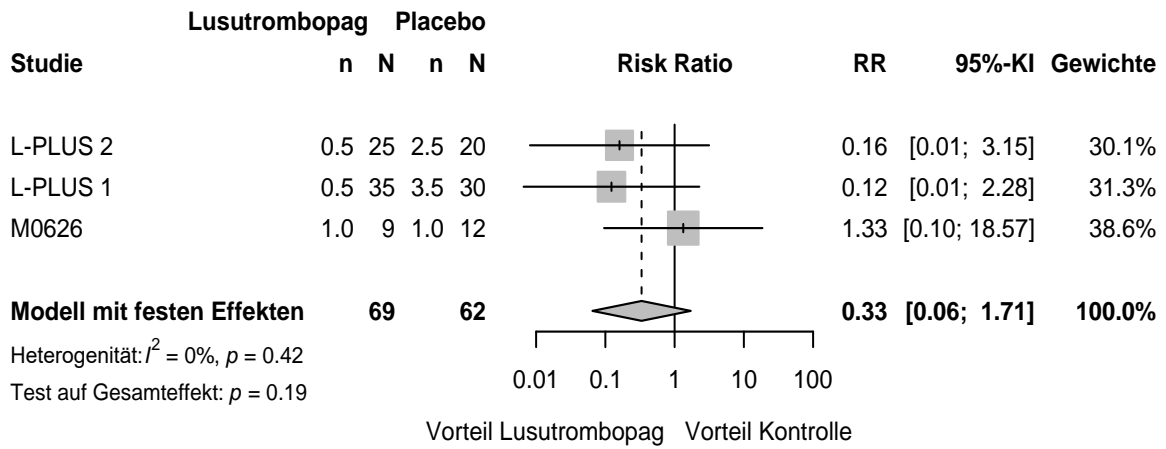
83 Schwere UE unter Ausschluss Morbidität_RD Treatment duration (days) - < 7



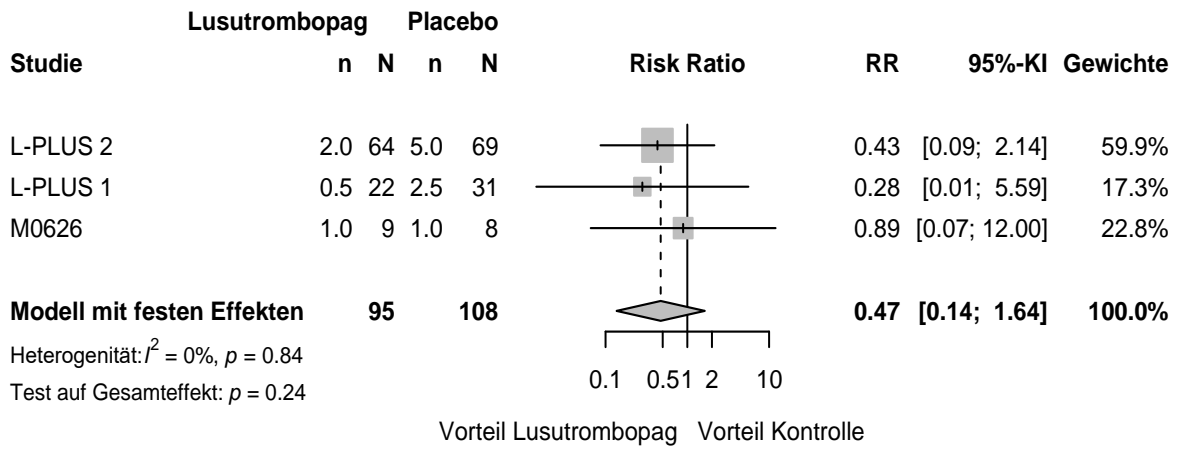
84 Schwere UE unter Ausschluss Morbidität_RD Treatment duration (days) -7



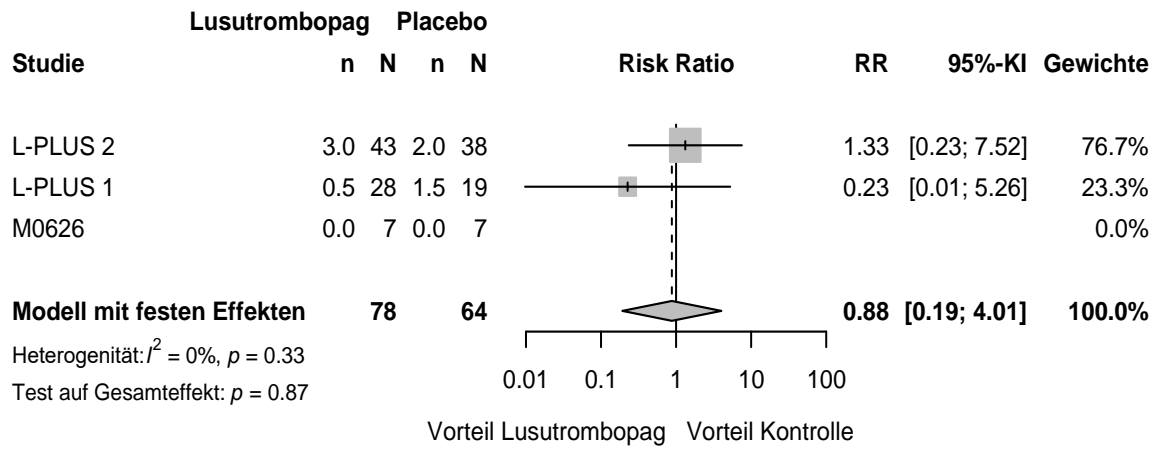
85 SUE unter Ausschluss Morbidität_RR Age (years) - >=65



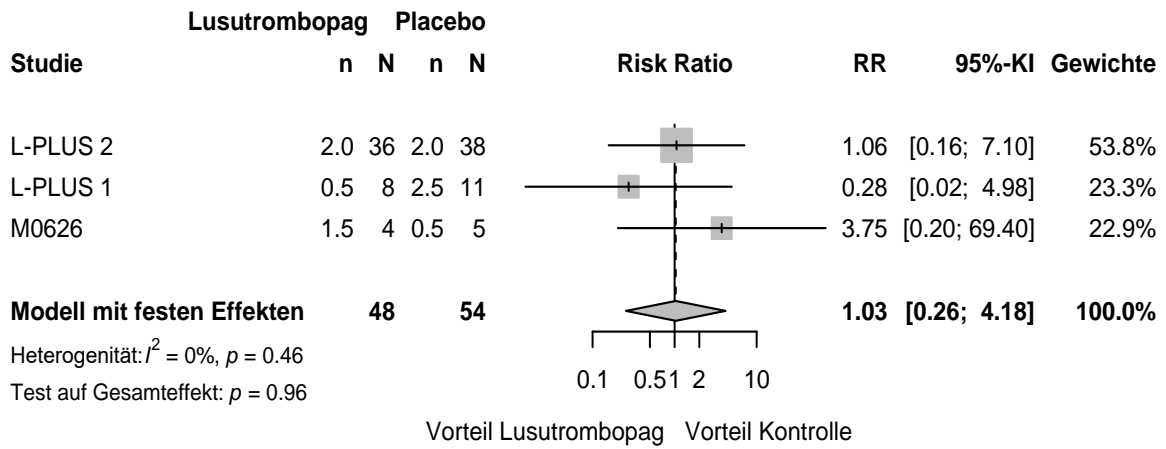
86 SUE unter Ausschluss Morbidität_RR Gender - Male



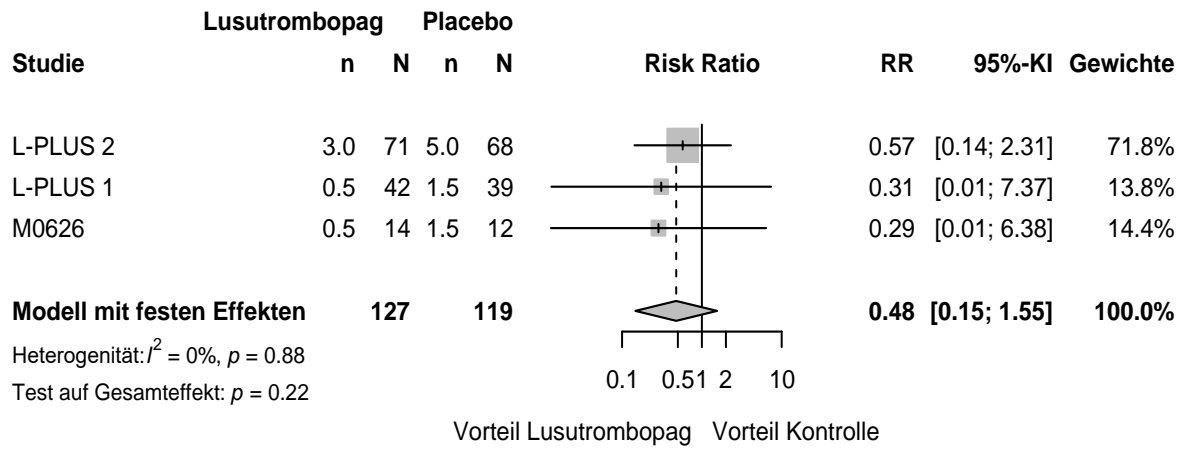
87 SUE unter Ausschluss Morbidität_RR Gender - Female



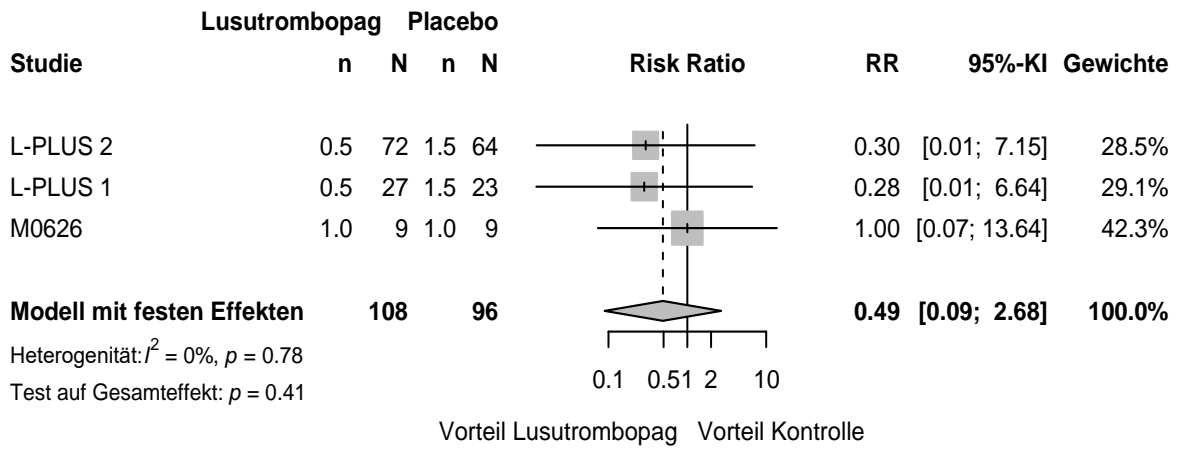
88 SUE unter Ausschluss Morbidität_RR Baseline platelet count ($\cdot 10^4/uL$) - < 3.5



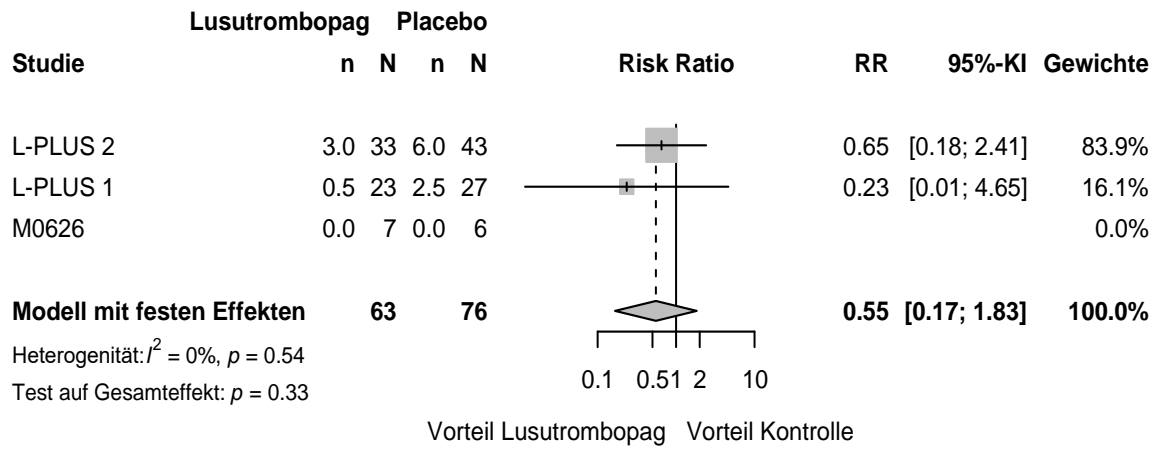
89 SUE unter Ausschluss Morbidität_RR Baseline platelet count ($\cdot 10^4/uL$) - ≥ 3.5



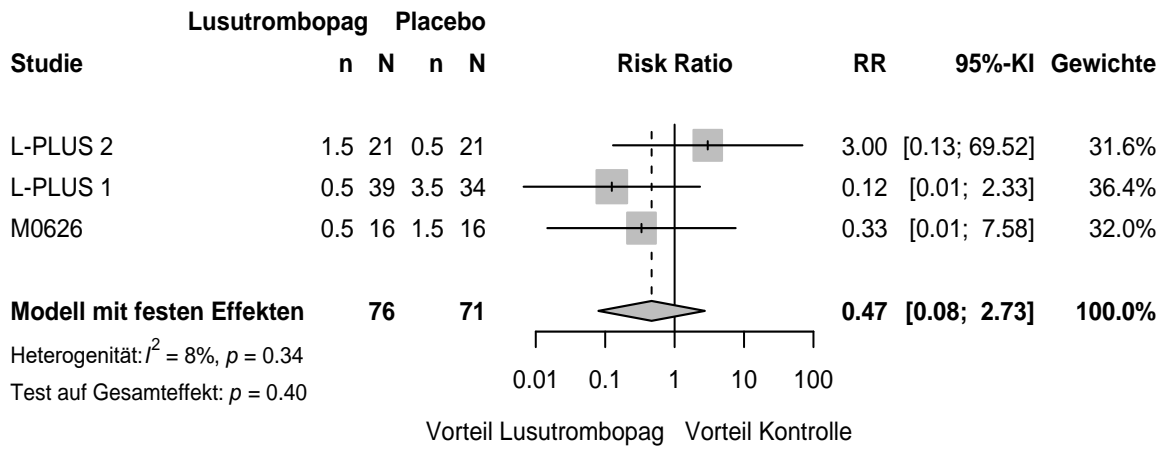
90 SUE unter Ausschluss Morbidität_RR Child-Pugh class - A



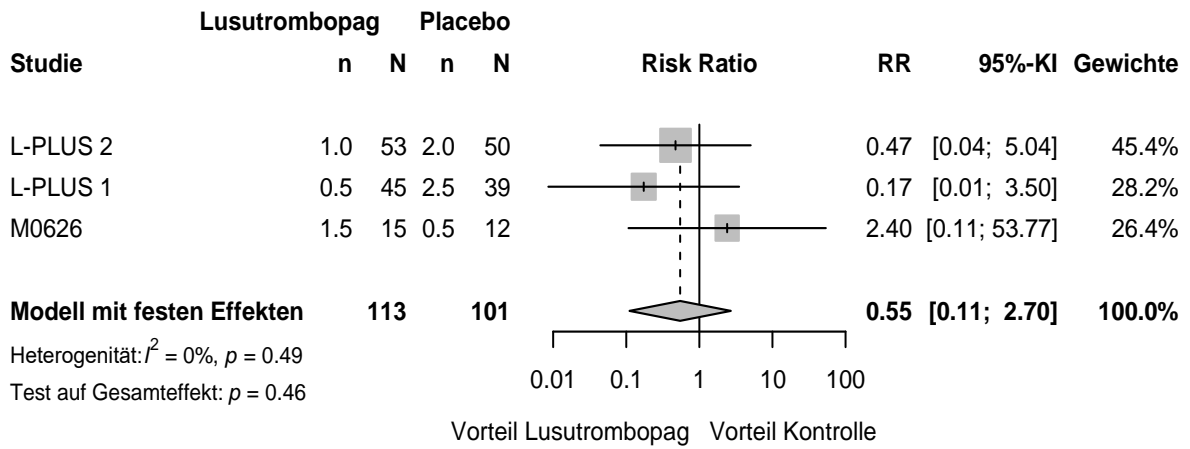
91 SUE unter Ausschluss Morbidität_RR Child-Pugh class - B



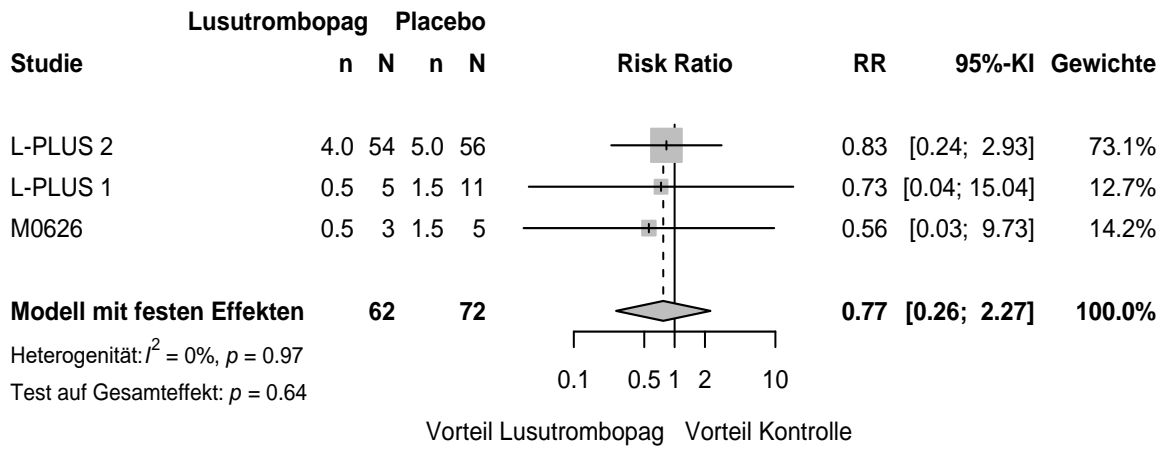
92 SUE unter Ausschluss Morbidität_RR Invasive procedure liver-related



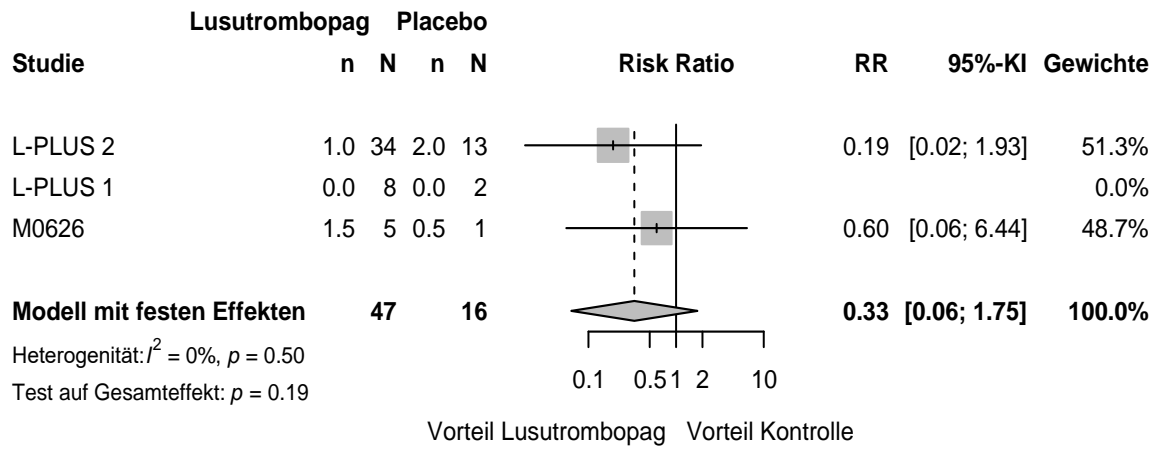
93 SUE unter Ausschluss Morbidität_RR Baseline body weight (kg) - < 75



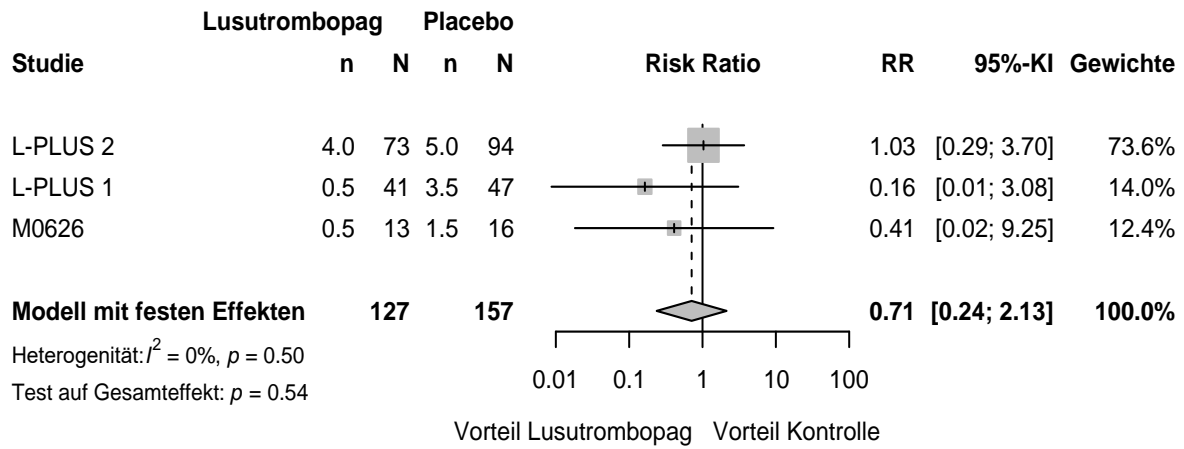
94 SUE unter Ausschluss Morbidität_RR Baseline body weight (kg) - >= 75



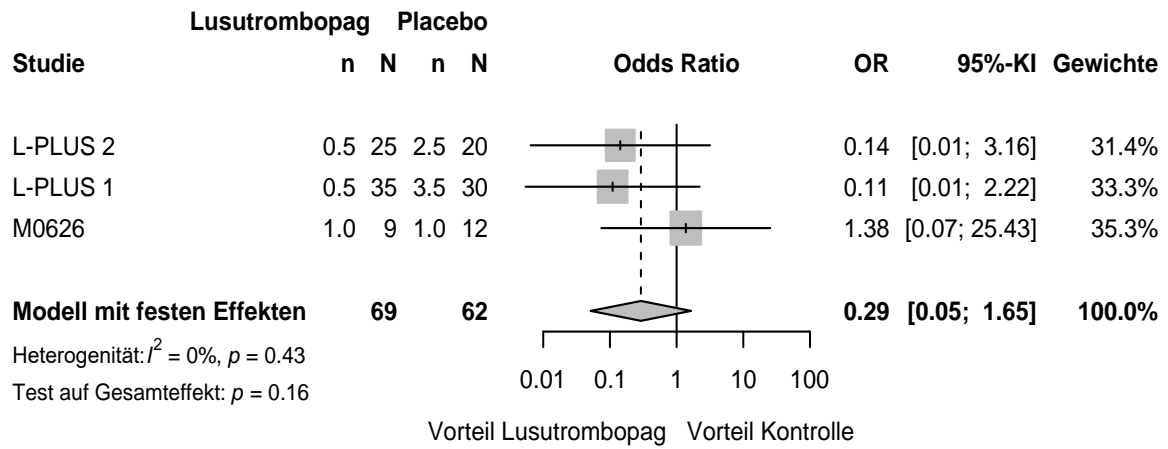
95 SUE unter Ausschluss Morbidität_RR Treatment duration (days) - < 7



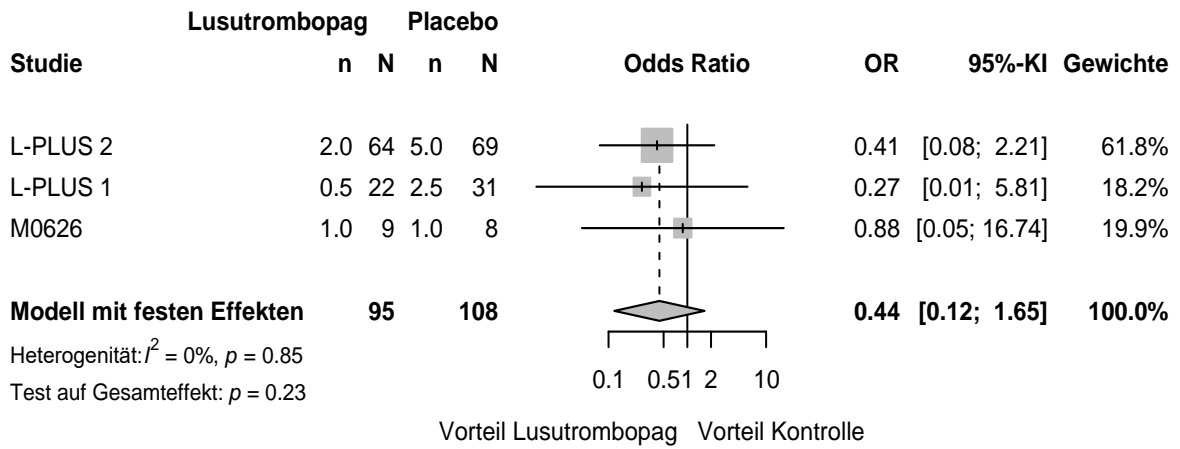
96 SUE unter Ausschluss Morbidität_RR Treatment duration (days) -7



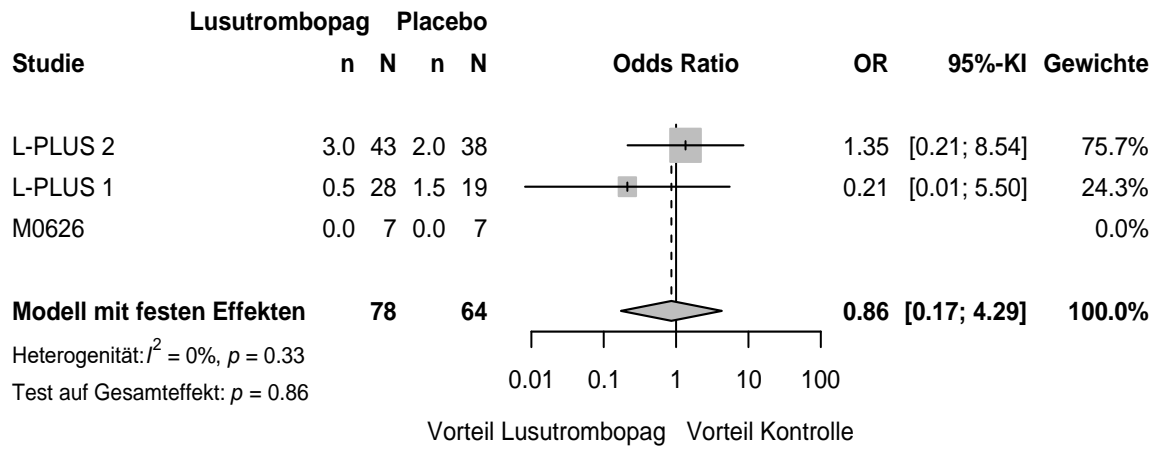
97 SUE unter Ausschluss Morbidität_OR Age (years) - >=65



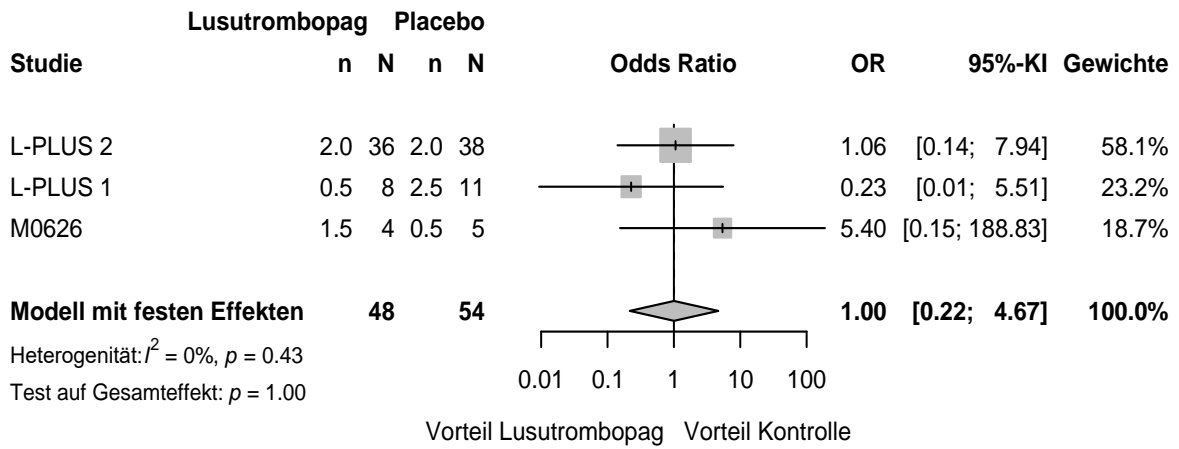
98 SUE unter Ausschluss Morbidität_OR Gender - Male



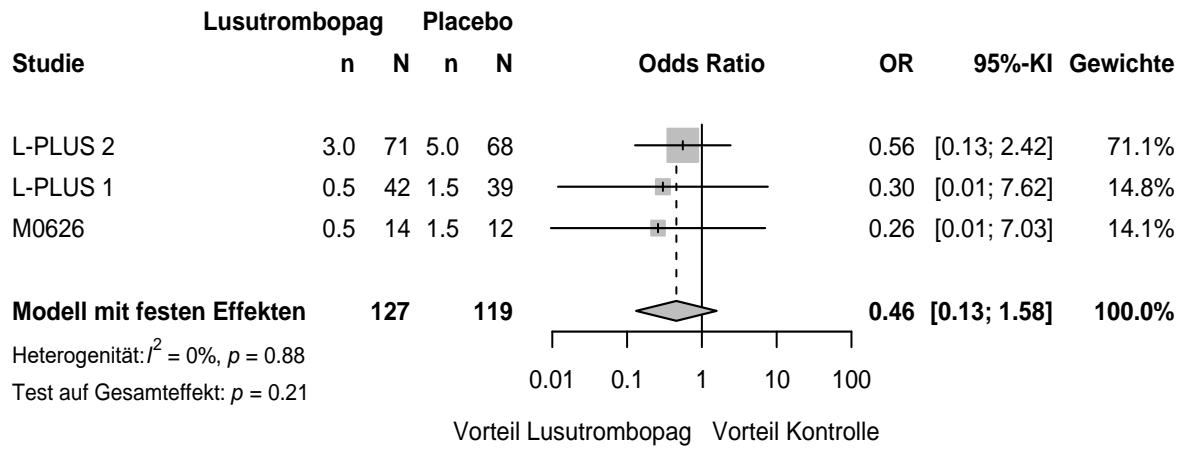
99 SUE unter Ausschluss Morbidität_OR Gender - Female



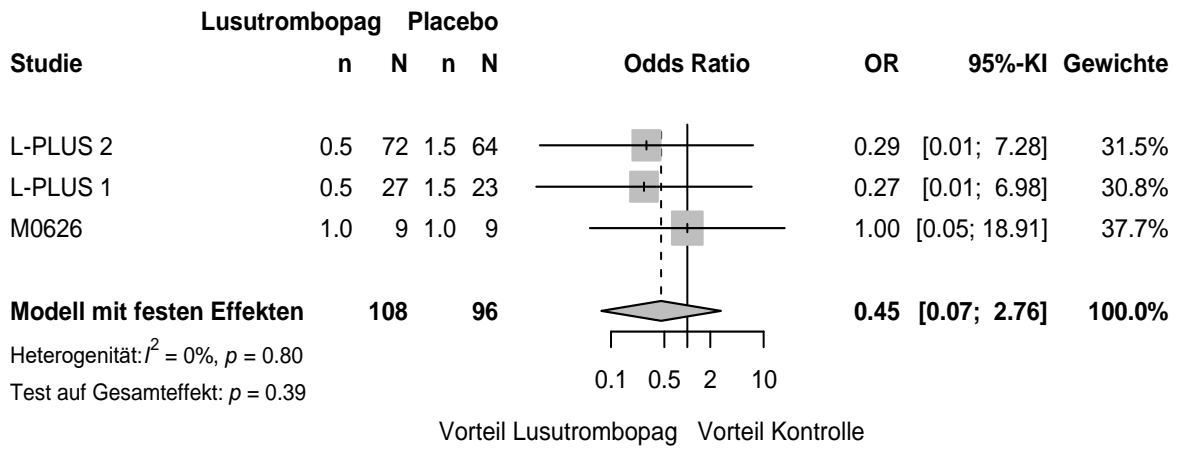
100 SUE unter Ausschluss Morbidität_OR Baseline platelet count ($\cdot 10^4/uL$) - < 3.5



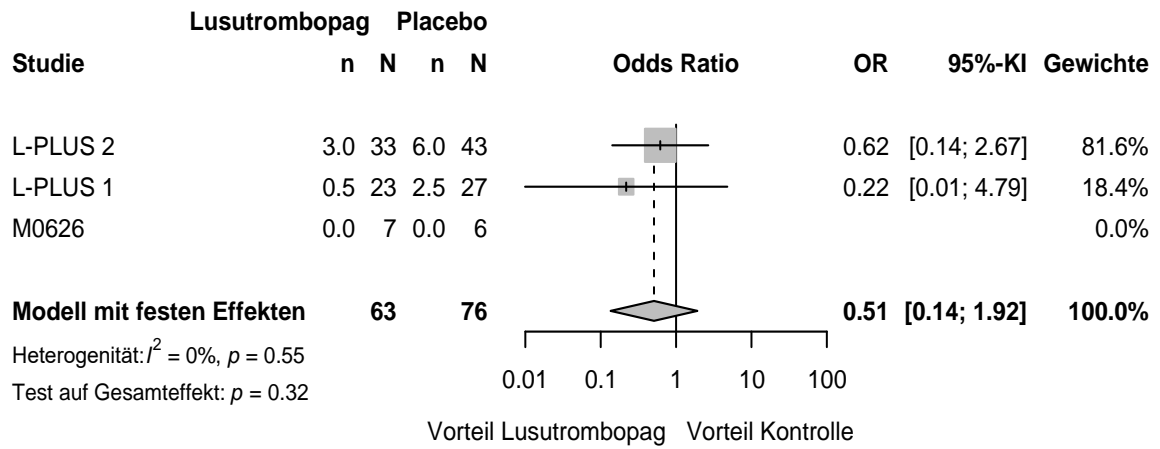
101 SUE unter Ausschluss Morbidität_OR Baseline platelet count (*10⁴/uL) - >= 3.5



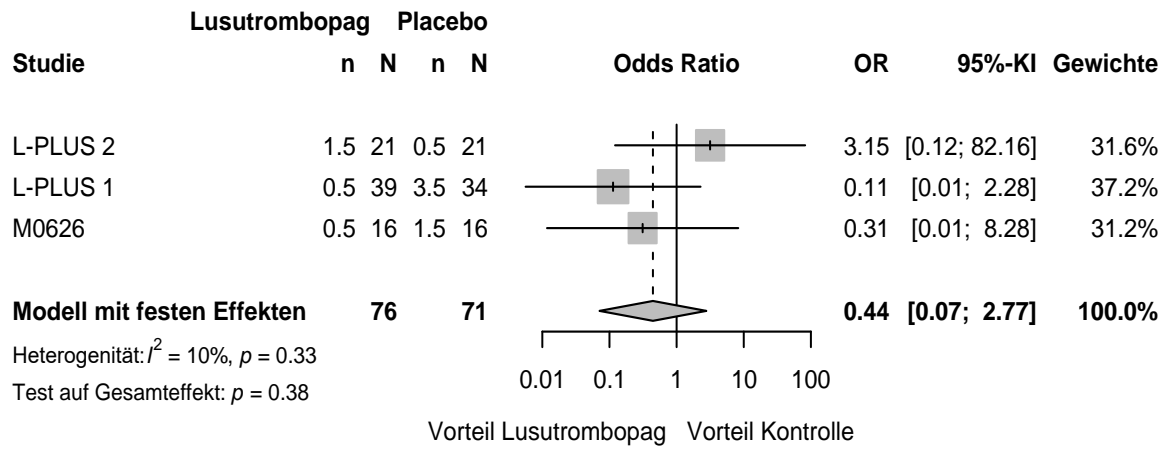
102 SUE unter Ausschluss Morbidität_OR Child-Pugh class - A



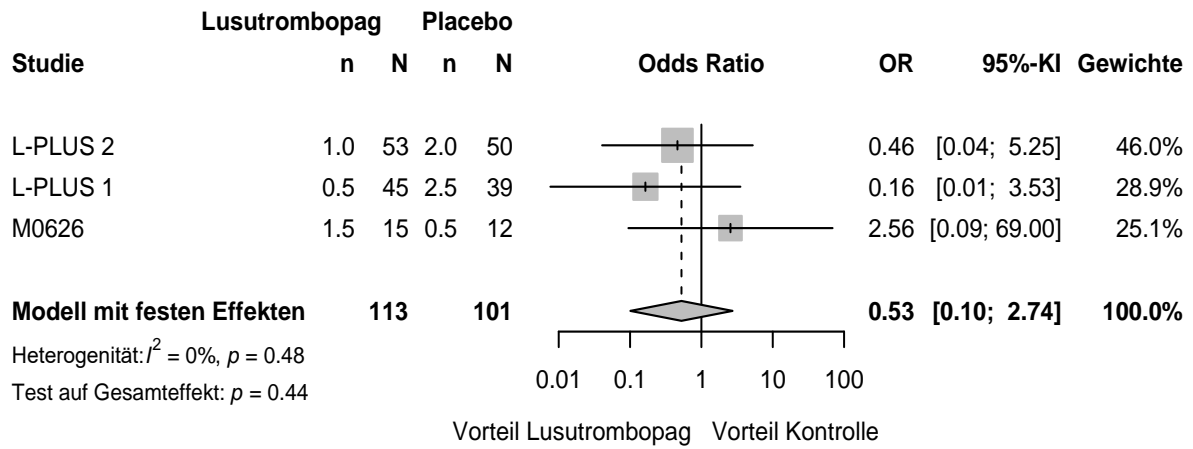
103 SUE unter Ausschluss Morbidität_OR Child-Pugh class - B



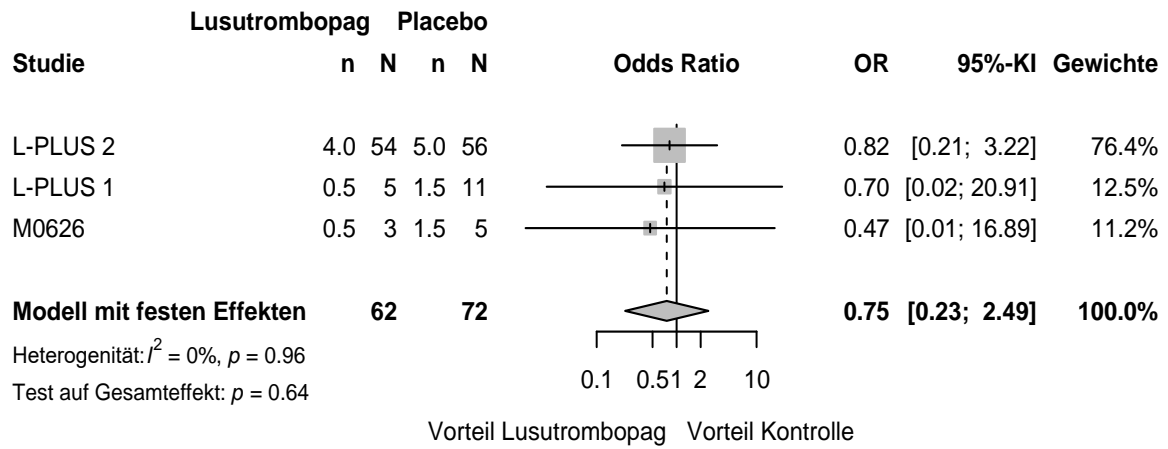
104 SUE unter Ausschluss Morbidität_OR Invasive procedure liver-related



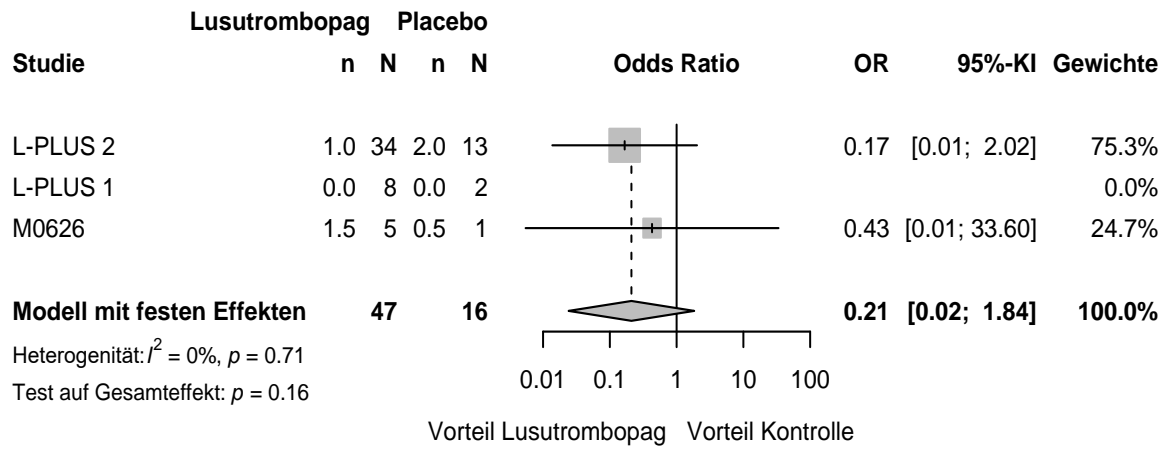
105 SUE unter Ausschluss Morbidität_OR Baseline body weight (kg) - < 75



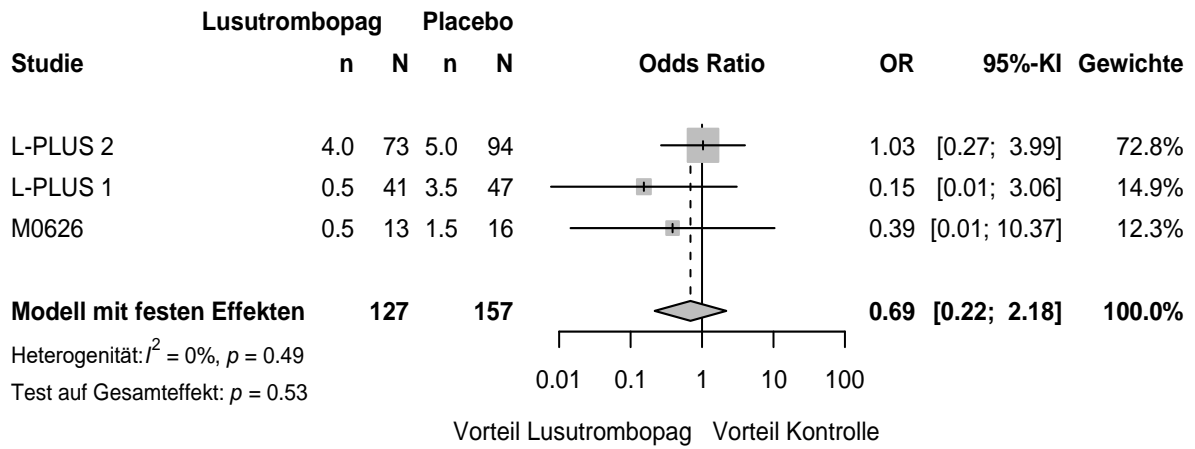
106 SUE unter Ausschluss Morbidität_OR Baseline body weight (kg) - >= 75



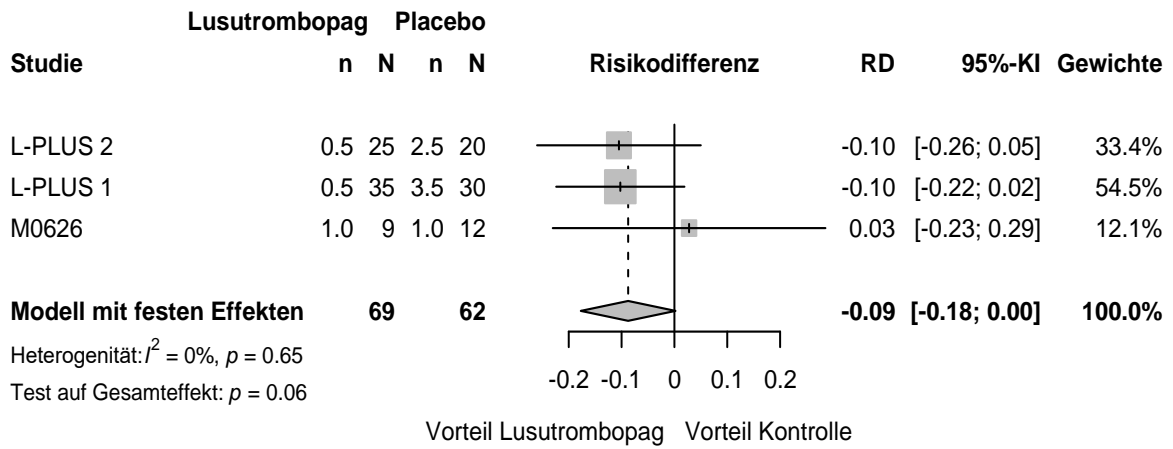
107 SUE unter Ausschluss Morbidität_OR Treatment duration (days) - < 7



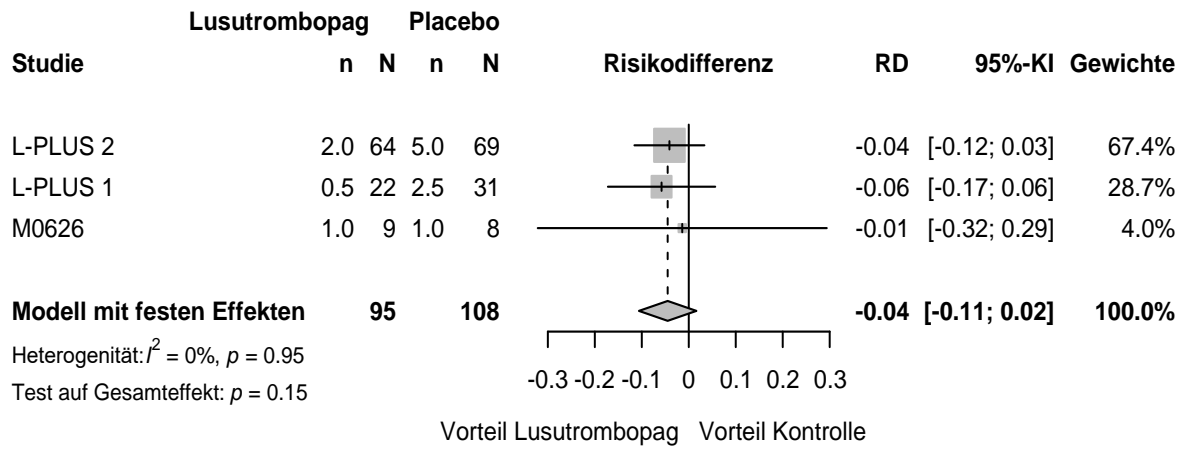
108 SUE unter Ausschluss Morbidität_OR Treatment duration (days) -7



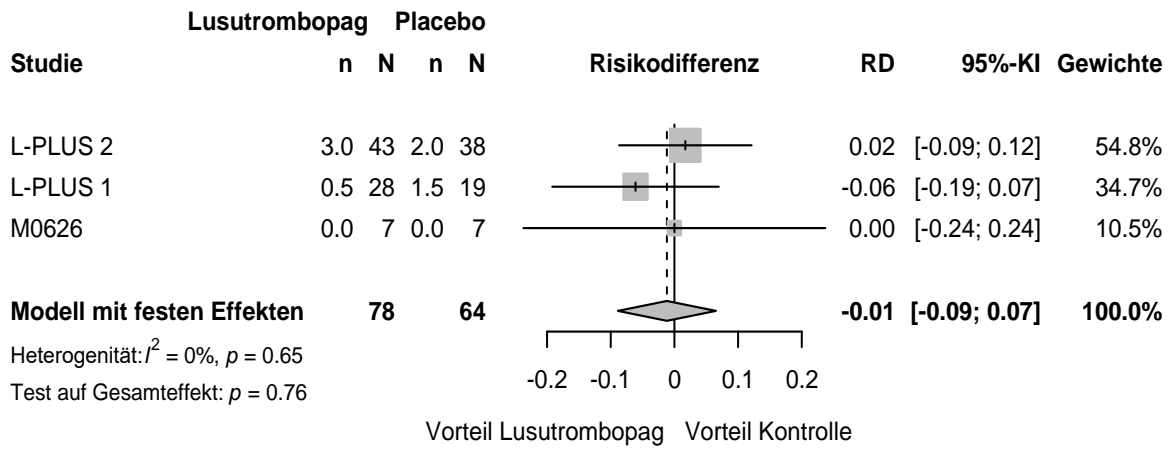
109 SUE unter Ausschluss Morbidität_RD Age (years) - >=65



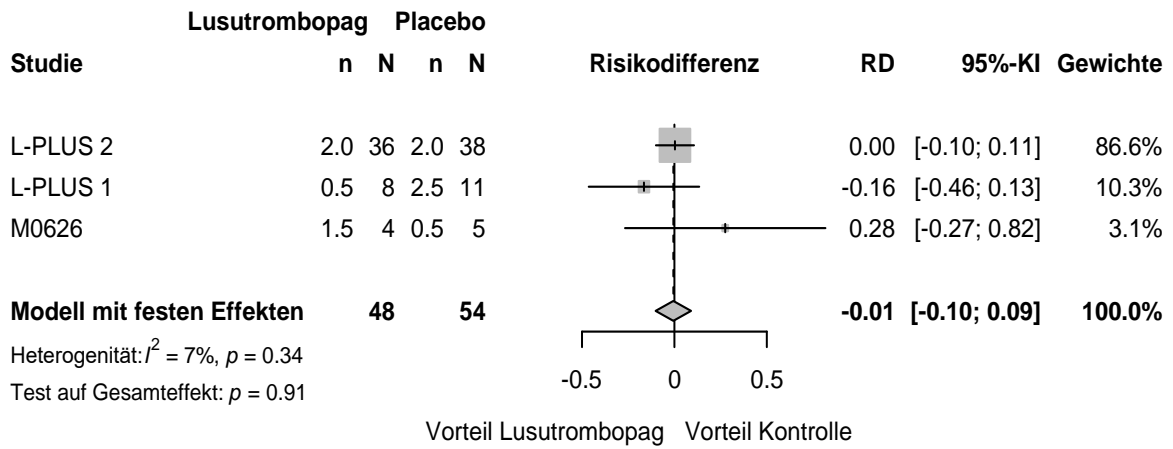
110 SUE unter Ausschluss Morbidität_RD Gender - Male



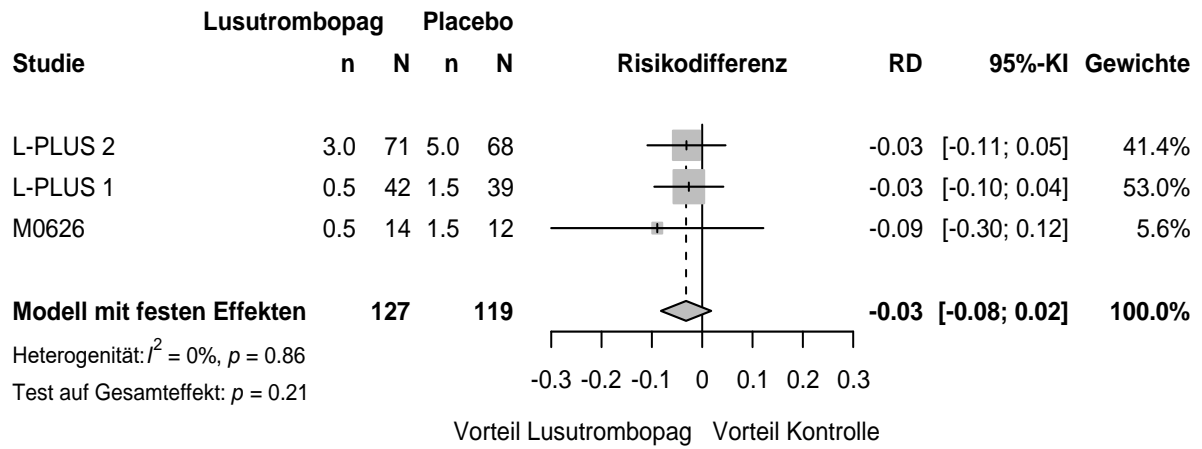
111 SUE unter Ausschluss Morbidität_RD Gender - Female



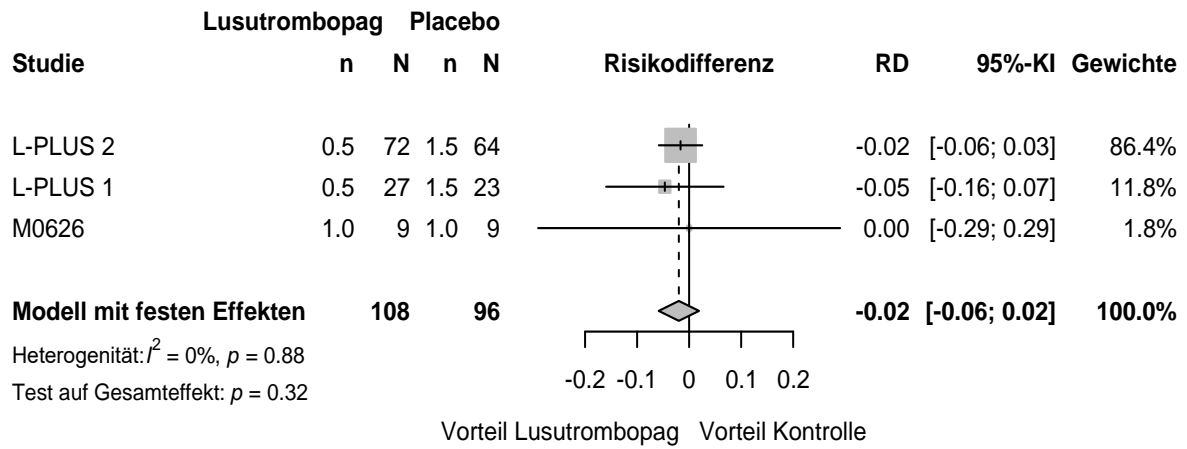
112 SUE unter Ausschluss Morbidität_RD Baseline platelet count (*10⁴/uL) - < 3.5



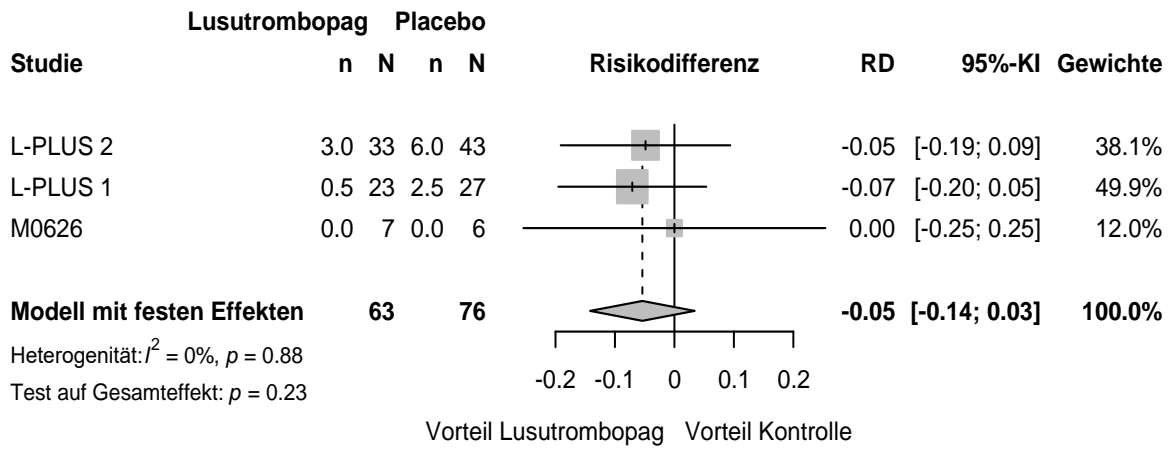
113 SUE unter Ausschluss Morbidität_RD Baseline platelet count (*10⁴/uL) - >= 3.5



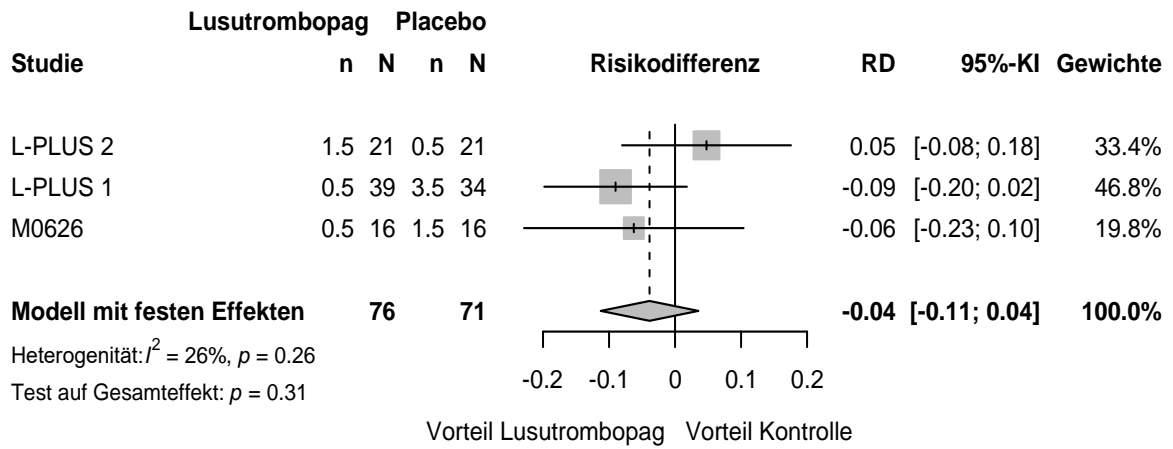
114 SUE unter Ausschluss Morbidität_RD Child-Pugh class - A



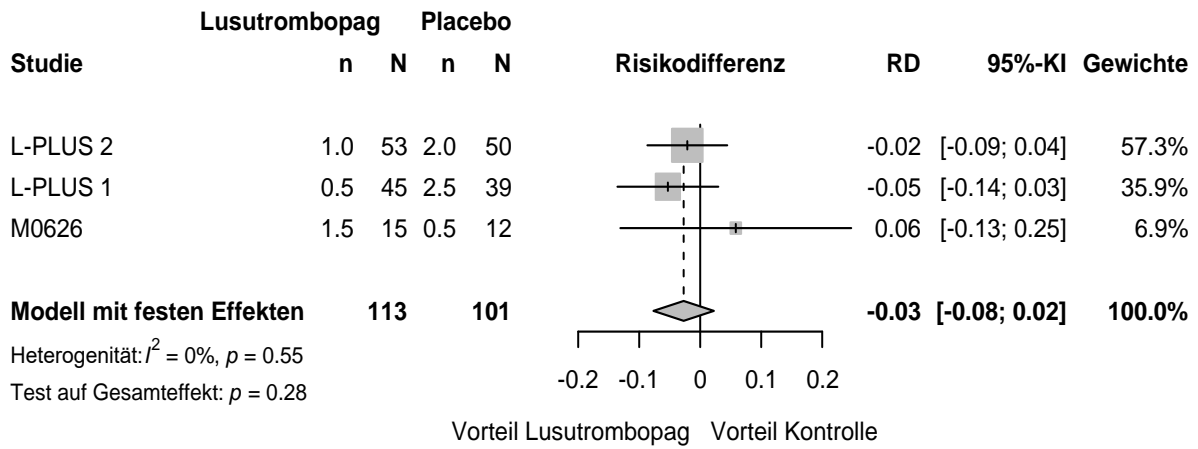
115 SUE unter Ausschluss Morbidität_RD Child-Pugh class - B



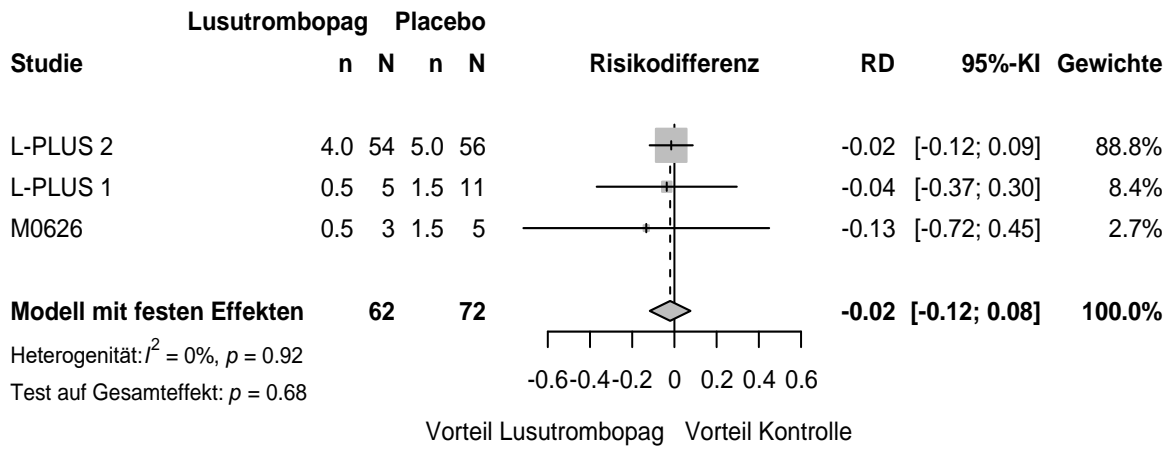
116 SUE unter Ausschluss Morbidität_RD Invasive procedure liver-related



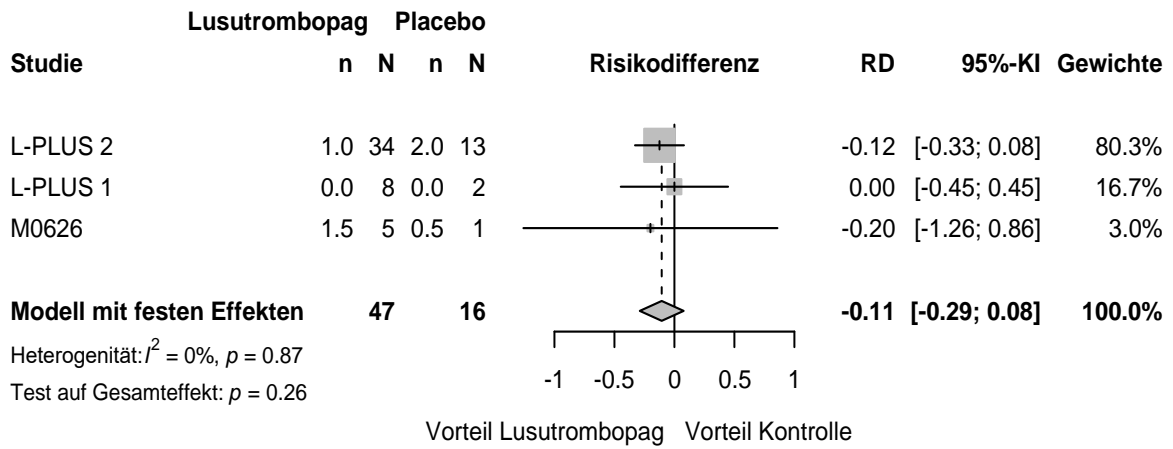
117 SUE unter Ausschluss Morbidität_RD Baseline body weight (kg) - < 75



118 SUE unter Ausschluss Morbidität_RD Baseline body weight (kg) - >= 75



119 SUE unter Ausschluss Morbidität_RD Treatment duration (days) - < 7



120 SUE unter Ausschluss Morbidität_RD Treatment duration (days) -7

