

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

Abaloparatid (Eladynos[®])

Theramex Ireland Limited

Anhang 4-G zu Modul 4 A

*Behandlung der Osteoporose bei postmenopausalen
Frauen mit erhöhtem Frakturrisiko*

Ergänzende Unterlagen zu
medizinischem Nutzen und
medizinischer Zusatznutzen,
Patientengruppen mit therapeutisch
bedeutsamem Zusatznutzen

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Es konnten keine Einträge für ein Abbildungsverzeichnis gefunden werden.

Abkürzungsverzeichnis

Abkürzung	Bedeutung
NVF	Nicht-vertebrale Fraktur
PT	Bevorzugter Begriff (<i>Preferred Term</i>) nach MedDRA
SOC	Systemorganklasse (<i>System Organ Class</i>) nach MedDRA
sUE	Schweres UE
SUE	Schwerwiegendes UE
UE	Unerwünschtes Ereignis
UESI	UE von speziellem Interesse

4.1 Ergänzende Unterlagen zu Modul 4

4.1.1 Subgruppenanalysen für den Endpunkt Morbidität – Klinische und nicht-vertebrale Frakturen

4.1.1.1 Ergebnisse der Interaktionsterme

Tabelle 4-1: Ergebnisse der Interaktionsterme für den Endpunkt Morbidität – Klinische und nicht-vertebrale Frakturen

Category	Age	Years Since Menopause	Ethnicity	Region	Any Prior Fracture	Any Prior Vertebral Fracture	Any Prior Non-vertebral Fracture	Any Prior Clinical MOF	Num of Prevalence of VF	Severity of VF (SQ Score)	Severe Disease at Baseline	Lumbar Spine BMD T-score Cutoff - 2.5	Lumbar Spine BMD T-score Cutoff - 3	Total Hip BMD T-score Cutoff - 2.5	Total Hip BMD T-score Cutoff - 3	Femoral Neck BMD T-score Cutoff - 2.5	Femoral Neck BMD T-score Cutoff - 3
NON-VERTEBRAL FRACTURE (NVF)	0,2601	0,8361	0,9961	0,9978	0,4105	0,6382	0,2234	0,6667	0,8242	0,8002	0,6417	0,7554	0,2313	0,8269	0,3995	0,9983	0,8423
CLINICAL FRACTURE	0,1931	0,6716	0,8455	0,8435	0,8026	0,6322	0,3615	0,4943	0,8278	0,8882	0,6389	0,7962	0,8357	0,8476	0,2858	0,9980	0,7608
MAJOR OSTEOPOROTIC FRACTURES	0,4309	0,2950	1,0000	1,0000	0,3285	0,9905	0,6630	0,3947	0,9999	0,9999	0,9872	0,5607	0,4288	0,2732	0,9903	0,3138	0,5132
WRIST FRACTURE	0,5498	0,3207	0,8960	0,8159	0,7411	0,9920	0,1893	0,8400	0,9999	1,0000	0,9891	0,5551	0,2245	0,3933	0,9894	0,4408	0,7322
NVF INCLUDING ALL TRAUMA LEVEL	0,4558	0,6416	0,9973	0,9887	0,4435	0,6171	0,2762	0,9995	0,8091	0,7895	0,6218	0,7407	0,4296	0,8093	0,4099	0,9782	0,8622
CLINICAL SPINE FRACTURE	1,0000	1,0000	1,0000	1,0000	0,9981	0,9999	1,0000	0,9998	1,0000	1,0000	0,9999	0,9988	0,9982	0,9999	0,9999	1,0000	1,0000
HIP FRACTURES
MAJOR NON-VERTEBRAL FRACTURE	0,7689	0,4653	0,9998	0,9942	0,8389	0,4771	0,4067	0,5869	0,9839	0,9844	0,4715	0,4398	0,7501	0,3467	0,9906	0,4051	0,7617

Treatment-subgroup interactions were assessed by the Cox proportional hazards model with covariates of subgroup, treatment and subgroup and treatment interactions.

4.1.1.2 Morbidität – Klinische und nicht-vertebrale Frakturen

Tabelle 4-2: Subgruppenanalyse nicht-vertebrale Frakturen (NVF)

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Logrank Test (Aba vs TRTD)
All ITT Population	696	15	2,1552	681	97,8448	2,6917	686	12	1,7493	674	98,2507	1,9577	1,3040	0,6103	2,7859	0,4919
Age (Years)
<65	102	1	0,9804	101	99,0196	1,2195	99	2	2,0202	97	97,9798	2,1412	0,5333	0,0484	5,8813	0,6017
65 to <75	455	11	2,4176	444	97,5824	3,0818	443	5	1,1287	438	98,8713	1,2546	2,3196	0,8059	6,6769	0,1081
>=75	139	3	2,1583	136	97,8417	2,5161	144	5	3,4722	139	96,5278	4,1460	0,6211	0,1484	2,5990	0,5103
Years Since Menopause
<15	138	3	2,1739	135	97,8261	2,6019	154	2	1,2987	152	98,7013	1,4795	1,7823	0,2978	10,6666	0,5209
15 to <25	338	6	1,7751	332	98,2249	2,3423	324	6	1,8519	318	98,1481	1,9955	1,0138	0,3269	3,1439	0,9811
>=25	220	6	2,7273	214	97,2727	3,3121	208	4	1,9231	204	98,0769	2,3045	1,5044	0,4245	5,3314	0,5241
Ethnicity
White	535	13	2,4299	522	97,5701	3,1753	513	9	1,7544	504	98,2456	2,0525	1,5026	0,6423	3,5154	0,3444
Black/African-American	26	0	0,0000	26	100,0000	.	24	1	4,1667	23	95,8333	4,3478	0,0000	0,0000	.	0,2971
Asian	128	2	1,5625	126	98,4375	1,5811	137	2	1,4599	135	98,5401	1,4599	1,0590	0,1492	7,5181	0,9543
Other	7	0	0,0000	7	100,0000	.	12	0	0,0000	12	100,0000
Region
North America	17	0	0,0000	17	100,0000	.	9	0	0,0000	9	100,0000
South America	222	5	2,2523	217	97,7477	3,0896	222	4	1,8018	218	98,1982	2,1710	1,2964	0,3481	4,8279	0,6980
Europe	332	8	2,4096	324	97,5904	3,0285	323	6	1,8576	317	98,1424	2,1072	1,4100	0,4892	4,0638	0,5226
Asia	125	2	1,6000	123	98,4000	1,6195	132	2	1,5152	130	98,4848	1,5152	1,0443	0,1471	7,4136	0,9654
Any Prior Fracture
Yes	407	10	2,4570	397	97,5430	3,0739	397	6	1,5113	391	98,4887	1,6472	1,7158	0,6235	4,7211	0,2900
No	289	5	1,7301	284	98,2699	2,1133	289	6	2,0761	283	97,9239	2,3944	0,8817	0,2691	2,8893	0,8347
Any Prior Vertebral Fracture
Yes	145	4	2,7586	141	97,2414	3,5206	182	3	1,6484	179	98,3516	1,8257	1,8036	0,4037	8,0587	0,4334

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Logrank Test (Aba vs TRTD)
No	551	11	1,9964	540	98,0036	2,4630	504	9	1,7857	495	98,2143	2,0062	1,1748	0,4868	2,8351	0,7198
Any Prior Nonvertebral Fracture
Yes	308	8	2,5974	300	97,4026	3,2009	271	3	1,1070	268	98,8930	1,1768	2,4669	0,6544	9,2995	0,1678
No	388	7	1,8041	381	98,1959	2,2733	415	9	2,1687	406	97,8313	2,4682	0,8823	0,3285	2,3692	0,8036
Any Prior Clinical Major Osteoporotic Fracture
Yes	238	7	2,9412	231	97,0588	3,4762	208	4	1,9231	204	98,0769	2,1008	1,5762	0,4614	5,3846	0,4640
No	458	8	1,7467	450	98,2533	2,2530	478	8	1,6736	470	98,3264	1,8951	1,1189	0,4199	2,9816	0,8225
Prevalence of Vertebral Fracture at Baseline
Yes	145	4	2,7586	141	97,2414	3,5206	182	3	1,6484	179	98,3516	1,8257	1,8036	0,4037	8,0587	0,4334
No	551	11	1,9964	540	98,0036	2,4630	504	9	1,7857	495	98,2143	2,0062	1,1748	0,4868	2,8351	0,7198
Number of Prevalence of Vertebral Fracture at Baseline
0	551	11	1,9964	540	98,0036	2,4630	504	9	1,7857	495	98,2143	2,0062	1,1748	0,4868	2,8351	0,7198
1	111	2	1,8018	109	98,1982	2,3007	126	1	0,7937	125	99,2063	0,8264	2,4794	0,2248	27,3436	0,4430
>=2	34	2	5,8824	32	94,1176	7,3103	56	2	3,5714	54	96,4286	4,1026	1,6888	0,2375	12,0084	0,5964
Severity of Vertebral Fracture (SQ Score) at Baseline
0	551	11	1,9964	540	98,0036	2,4630	505	9	1,7822	496	98,2178	2,0035	1,1761	0,4873	2,8384	0,7179
1	89	2	2,2472	87	97,7528	2,7719	106	2	1,8868	104	98,1132	1,9814	1,2908	0,1818	9,1638	0,7980
>=2	56	2	3,5714	54	96,4286	4,4147	75	1	1,3333	74	98,6667	1,5625	2,7643	0,2506	30,4968	0,3864

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Logrank Test (Aba vs TRTD)
Severe Disease (least BMD T-score <= -2.5 and Prevalent Vertebral Fracture) at Baseline
Yes	113	4	3,5398	109	96,4602	4,5718	142	3	2,1127	139	97,8873	2,3047	1,8355	0,4108	8,2015	0,4194
No	582	11	1,8900	571	98,1100	2,3227	544	9	1,6544	535	98,3456	1,8584	1,1968	0,4959	2,8882	0,6891
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	530	12	2,2642	518	97,7358	2,8111	511	10	1,9569	501	98,0431	2,2176	1,2223	0,5281	2,8290	0,6379
> -2.5	165	3	1,8182	162	98,1818	2,3284	175	2	1,1429	173	98,8571	1,2321	1,6778	0,2803	10,0433	0,5666
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	395	7	1,7722	388	98,2278	2,2866	365	8	2,1918	357	97,8082	2,4967	0,8595	0,3117	2,3703	0,7694
> -3	300	8	2,6667	292	97,3333	3,2086	321	4	1,2461	317	98,7539	1,3627	2,2380	0,6739	7,4329	0,1766
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	6	3,5294	164	96,4706	4,5059	154	4	2,5974	150	97,4026	2,7589	1,4229	0,4015	5,0436	0,5829
> -2.5	524	9	1,7176	515	98,2824	2,1181	532	8	1,5038	524	98,4962	1,7272	1,2073	0,4658	3,1294	0,6979
Total Hip BMD T-score Group 2 at Baseline
<= -3	52	1	1,9231	51	98,0769	2,0408	51	2	3,9216	49	96,0784	4,3902	0,4832	0,0438	5,3298	0,5438
> -3	642	14	2,1807	628	97,8193	2,7354	635	10	1,5748	625	98,4252	1,7645	1,4699	0,6529	3,3095	0,3492
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	5	2,3585	207	97,6415	3,1015	207	4	1,9324	203	98,0676	2,0578	1,2929	0,3470	4,8170	0,7011

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Logrank Test (Aba vs TRTD)
> -2.5	482	10	2,0747	472	97,9253	2,5651	479	8	1,6701	471	98,3299	1,9203	1,3086	0,5165	3,3158	0,5695
Femoral Neck BMD T-score Group 2 at Baseline
<= -3	73	3	4,1096	70	95,8904	5,9732	78	3	3,8462	75	96,1538	4,0959	1,1461	0,2309	5,6887	0,8678
> -3	621	12	1,9324	609	98,0676	2,3777	608	9	1,4803	599	98,5197	1,6819	1,3801	0,5815	3,2754	0,4631

Cox proportional hazard model was used to calculate the hazard ratio with Teriparatide as reference.

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Tabelle 4-3: Subgruppenanalyse jegliche klinische Frakturen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Logrank Test (Aba vs TRTD)
All ITT Population	696	21	3,0172	675	96,9828	3,7537	686	21	3,0612	665	96,9388	3,4267	1,0381	0,5669	1,9008	0,9037
Age (Years)
<65	102	1	0,9804	101	99,0196	1,2195	99	5	5,0505	94	94,9495	5,6696	0,2104	0,0246	1,8011	0,1161
65 to <75	455	14	3,0769	441	96,9231	3,9071	443	9	2,0316	434	97,9684	2,2383	1,6254	0,7034	3,7559	0,2510
>=75	139	6	4,3165	133	95,6835	5,1796	144	7	4,8611	137	95,1389	5,6042	0,8865	0,2979	2,6381	0,8281
Years Since Menopause
<15	138	3	2,1739	135	97,8261	2,6019	154	5	3,2468	149	96,7532	3,7221	0,7099	0,1696	2,9704	0,6373
15 to <25	338	8	2,3669	330	97,6331	3,0466	324	9	2,7778	315	97,2222	2,9993	0,8929	0,3444	2,3146	0,8154
>=25	220	10	4,5455	210	95,4545	5,6472	208	7	3,3654	201	96,6346	3,8963	1,4243	0,5421	3,7421	0,4707
Ethnicity
White	535	19	3,5514	516	96,4486	4,5901	513	15	2,9240	498	97,0760	3,3909	1,3126	0,6670	2,5831	0,4296
Black/African-American	26	0	0,0000	26	#####	.	24	1	4,1667	23	95,8333	4,3478	0,0000	0,0000	.	0,2971
Asian	128	2	1,5625	126	98,4375	1,5811	137	4	2,9197	133	97,0803	2,9197	0,5261	0,0964	2,8725	0,4503
Other	7	0	0,0000	7	#####	.	12	1	8,3333	11	91,6667	8,3333	0,0000	0,0000	.	0,4795
Region
North America	17	0	0,0000	17	#####	.	9	0	0,0000	9	#####
South America	222	8	3,6036	214	96,3964	4,7037	222	6	2,7027	216	97,2973	3,3815	1,3864	0,4810	3,9958	0,5434
Europe	332	11	3,3133	321	96,6867	4,1945	323	11	3,4056	312	96,5944	3,8223	1,0491	0,4548	2,4200	0,9104
Asia	125	2	1,6000	123	98,4000	1,6195	132	4	3,0303	128	96,9697	3,0303	0,5187	0,0950	2,8320	0,4400
Any Prior Fracture
Yes	407	14	3,4398	393	96,5602	4,2807	397	13	3,2746	384	96,7254	3,5848	1,0970	0,5156	2,3339	0,8100
No	289	7	2,4221	282	97,5779	2,9570	289	8	2,7682	281	97,2318	3,2183	0,9304	0,3373	2,5658	0,8889
Any Prior Vertebral Fracture
Yes	145	6	4,1379	139	95,8621	5,2827	182	6	3,2967	176	96,7033	3,5472	1,3349	0,4305	4,1395	0,6156
No	551	15	2,7223	536	97,2777	3,3376	504	15	2,9762	489	97,0238	3,3858	0,9596	0,4691	1,9630	0,9101
Any Prior Nonvertebral Fracture
Yes	308	11	3,5714	297	96,4286	4,4049	271	7	2,5830	264	97,4170	2,8524	1,4491	0,5617	3,7383	0,4404
No	388	10	2,5773	378	97,4227	3,2234	415	14	3,3735	401	96,6265	3,7992	0,8078	0,3588	1,8187	0,6055

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Logrank Test (Aba vs TRTD)
Any Prior Clinical Major Osteoporotic Fracture
Yes	238	8	3,3613	230	96,6387	4,0155	208	9	4,3269	199	95,6731	4,7586	0,7892	0,3045	2,0455	0,6253
No	458	13	2,8384	445	97,1616	3,6032	478	12	2,5105	466	97,4895	2,8428	1,2171	0,5553	2,6676	0,6240
Prevalence of Vertebral Fracture at Baseline
Yes	145	6	4,1379	139	95,8621	5,2827	182	6	3,2967	176	96,7033	3,5472	1,3349	0,4305	4,1395	0,6156
No	551	15	2,7223	536	97,2777	3,3376	504	15	2,9762	489	97,0238	3,3858	0,9596	0,4691	1,9630	0,9101
Number of Prevalence of Vertebral Fracture at Baseline
0	551	15	2,7223	536	97,2777	3,3376	504	15	2,9762	489	97,0238	3,3858	0,9596	0,4691	1,9630	0,9101
1	111	4	3,6036	107	96,3964	4,6172	126	3	2,3810	123	97,6190	2,4269	1,5976	0,3575	7,1402	0,5357
>=2	34	2	5,8824	32	94,1176	7,3103	56	3	5,3571	53	94,6429	5,9829	1,1424	0,1906	6,8457	0,8841
Severity of Vertebral Fracture (SQ Score) at Baseline
0	551	15	2,7223	536	97,2777	3,3376	505	15	2,9703	490	97,0297	3,3818	0,9608	0,4697	1,9655	0,9128
1	89	3	3,3708	86	96,6292	4,2910	106	3	2,8302	103	97,1698	3,0468	1,3014	0,2627	6,4482	0,7462
>=2	56	3	5,3571	53	94,6429	6,5041	75	3	4,0000	72	96,0000	4,2720	1,3614	0,2747	6,7463	0,7041
Severe Disease (least BMD T-score <= -2.5 and Prevalent Vertebral Fracture) at Baseline
Yes	113	6	5,3097	107	94,6903	6,8610	142	6	4,2254	136	95,7746	4,5087	1,3514	0,4358	4,1913	0,6005
No	582	15	2,5773	567	97,4227	3,1478	544	15	2,7574	529	97,2426	3,1379	0,9776	0,4779	1,9998	0,9505
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	530	17	3,2075	513	96,7925	3,9867	511	16	3,1311	495	96,8689	3,5334	1,0767	0,5440	2,1312	0,8319
> -2.5	165	4	2,4242	161	97,5758	3,0296	175	5	2,8571	170	97,1429	3,1619	0,8851	0,2376	3,2964	0,8555
Lumbar Spine BMD T-score Group 2 at Baseline

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Logrank Test (Aba vs TRTD)
<= -3	395	11	2,7848	384	97,2152	3,5451	365	11	3,0137	354	96,9863	3,3989	0,9773	0,4237	2,2544	0,9571
> -3	300	10	3,3333	290	96,6667	4,0212	321	10	3,1153	311	96,8847	3,4553	1,1144	0,4638	2,6775	0,8089
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	6	3,5294	164	96,4706	4,5059	154	5	3,2468	149	96,7532	3,4178	1,1246	0,3431	3,6857	0,8457
> -2.5	524	15	2,8626	509	97,1374	3,5275	532	16	3,0075	516	96,9925	3,4407	1,0013	0,4950	2,0253	0,9971
Total Hip BMD T-score Group 2 at Baseline
<= -3	52	1	1,9231	51	98,0769	2,0408	51	3	5,8824	48	94,1176	6,4000	0,3164	0,0329	3,0417	0,2926
> -3	642	20	3,1153	622	96,8847	3,8874	635	18	2,8346	617	97,1654	3,1916	1,1630	0,6152	2,1987	0,6417
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	5	2,3585	207	97,6415	3,1015	207	5	2,4155	202	97,5845	2,5462	1,0225	0,2959	3,5337	0,9719
> -2.5	482	16	3,3195	466	96,6805	4,0888	479	16	3,3403	463	96,6597	3,8242	1,0412	0,5207	2,0820	0,9091
Femoral Neck BMD T-score Group 2 at Baseline
<= -3	73	3	4,1096	70	95,8904	5,9732	78	4	5,1282	74	94,8718	5,3977	0,8375	0,1872	3,7474	0,8164
> -3	621	18	2,8986	603	97,1014	3,5643	608	17	2,7961	591	97,2039	3,1776	1,0918	0,5626	2,1184	0,7951

Cox proportional hazard model was used to calculate the hazard ratio with Teriparatide as reference.

Tabelle 4-4: Subgruppenanalyse Major osteoporotische Frakturen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Log-rank Test (Aba vs TRTD)
All ITT Population	696	7	1,0057	689	98,9943	1,1971	686	14	2,0408	672	97,9592	2,2325	0,5112	0,2063	1,2665	0,1396
Age (Years)
<65	102	1	0,9804	101	99,0196	1,2195	99	2	2,0202	97	97,9798	2,2485	0,5322	0,0483	5,8684	0,6005
65 to <75	455	5	1,0989	450	98,9011	1,3207	443	6	1,3544	437	98,6456	1,4383	0,8466	0,2583	2,7745	0,7825
>=75	139	1	0,7194	138	99,2806	0,7407	144	6	4,1667	138	95,8333	4,8517	0,1695	0,0204	1,4073	0,0617
Years Since Menopause
<15	138	2	1,4493	136	98,5507	1,6654	154	2	1,2987	152	98,7013	1,4669	1,1866	0,1671	8,4240	0,8640
15 to <25	338	1	0,2959	337	99,7041	0,3937	324	7	2,1605	317	97,8395	2,2778	0,1396	0,0172	1,1344	0,0312
>=25	220	4	1,8182	216	98,1818	2,1824	208	5	2,4038	203	97,5962	2,7923	0,7882	0,2116	2,9354	0,7221
Ethnicity
White	535	5	0,9346	530	99,0654	1,1990	513	9	1,7544	504	98,2456	2,0209	0,5708	0,1913	1,7033	0,3084
Black/African-American	26	0	0,0000	26	100,0000	.	24	1	4,1667	23	95,8333	4,3478	0,0000	0,0000	.	0,2971
Asian	128	2	1,5625	126	98,4375	1,5811	137	4	2,9197	133	97,0803	2,9197	0,5261	0,0964	2,8725	0,4503
Other	7	0	0,0000	7	100,0000	.	12	0	0,0000	12	100,0000
Region
North America	17	0	0,0000	17	100,0000	.	9	0	0,0000	9	100,0000
South America	222	2	0,9009	220	99,0991	1,2129	222	4	1,8018	218	98,1982	2,1710	0,5182	0,0949	2,8289	0,4395
Europe	332	3	0,9036	329	99,0964	1,1185	323	6	1,8576	317	98,1424	2,0640	0,5194	0,1299	2,0769	0,3456
Asia	125	2	1,6000	123	98,4000	1,6195	132	4	3,0303	128	96,9697	3,0303	0,5187	0,0950	2,8320	0,4400
Any Prior Fracture
Yes	407	3	0,7371	404	99,2629	0,8912	397	9	2,2670	388	97,7330	2,4376	0,3337	0,0903	1,2327	0,0836
No	289	4	1,3841	285	98,6159	1,6358	289	5	1,7301	284	98,2699	1,9507	0,8439	0,2266	3,1430	0,8000

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Log-rank Test (Aba vs TRTD)
Any Prior Vertebral Fracture
Yes	145	0	0,0000	145	100,0000	.	182	5	2,7473	177	97,2527	2,9328	0,0000	0,0000	.	0,0494
No	551	7	1,2704	544	98,7296	1,5170	504	9	1,7857	495	98,2143	1,9755	0,7389	0,2752	1,9842	0,5467
Any Prior Nonvertebral Fracture
Yes	308	3	0,9740	305	99,0260	1,1770	271	4	1,4760	267	98,5240	1,5837	0,6817	0,1526	3,0463	0,6138
No	388	4	1,0309	384	98,9691	1,2039	415	10	2,4096	405	97,5904	2,6513	0,4459	0,1398	1,4219	0,1607
Any Prior Clinical Major Osteoporotic Fracture
Yes	238	2	0,8403	236	99,1597	0,9473	208	6	2,8846	202	97,1154	3,1246	0,2941	0,0593	1,4570	0,1109
No	458	5	1,0917	453	98,9083	1,3328	478	8	1,6736	470	98,3264	1,8403	0,6891	0,2254	2,1069	0,5113
Prevalence of Vertebral Fracture at Baseline
Yes	145	0	0,0000	145	100,0000	.	182	5	2,7473	177	97,2527	2,9328	0,0000	0,0000	.	0,0494
No	551	7	1,2704	544	98,7296	1,5170	504	9	1,7857	495	98,2143	1,9755	0,7389	0,2752	1,9842	0,5467
Number of Prevalence of Vertebral Fracture at Baseline
0	551	7	1,2704	544	98,7296	1,5170	504	9	1,7857	495	98,2143	1,9755	0,7389	0,2752	1,9842	0,5467
1	111	0	0,0000	111	100,0000	.	126	3	2,3810	123	97,6190	2,4269	0,0000	0,0000	.	0,1059
>=2	34	0	0,0000	34	100,0000	.	56	2	3,5714	54	96,4286	4,1026	0,0000	0,0000	.	0,2731
Severity of Vertebral Fracture (SQ Score) at Baseline
0	551	7	1,2704	544	98,7296	1,5170	505	9	1,7822	496	98,2178	1,9730	0,7399	0,2755	1,9868	0,5485

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Log-rank Test (Aba vs TRTD)
1	89	0	0,0000	89	100,0000	.	106	2	1,8868	104	98,1132	1,9814	0,0000	0,0000	.	0,2128
>=2	56	0	0,0000	56	100,0000	.	75	3	4,0000	72	96,0000	4,2720	0,0000	0,0000	.	0,1359
Severe Disease (least BMD T-score <= -2.5 and Prevalent Vertebral Fracture) at Baseline
Yes	113	0	0,0000	113	100,0000	.	142	5	3,5211	137	96,4789	3,7260	0,0000	0,0000	.	0,0496
No	582	7	1,2027	575	98,7973	1,4317	544	9	1,6544	535	98,3456	1,8301	0,7532	0,2805	2,0227	0,5727
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	530	6	1,1321	524	98,8679	1,3329	511	13	2,5440	498	97,4560	2,8107	0,4608	0,1751	1,2122	0,1074
> -2.5	165	1	0,6061	164	99,3939	0,7692	175	1	0,5714	174	99,4286	0,5780	1,0960	0,0685	17,5313	0,9484
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	395	4	1,0127	391	98,9873	1,2157	365	10	2,7397	355	97,2603	3,0450	0,3860	0,1211	1,2309	0,0948
> -3	300	3	1,0000	297	99,0000	1,1762	321	4	1,2461	317	98,7539	1,3269	0,8230	0,1842	3,6778	0,7984
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	1	0,5882	169	99,4118	0,6250	154	5	3,2468	149	96,7532	3,4178	0,1829	0,0214	1,5659	0,0812
> -2.5	524	6	1,1450	518	98,8550	1,3884	532	9	1,6917	523	98,3083	1,8887	0,7061	0,2513	1,9840	0,5070
Total Hip BMD T-score Group 2 at Baseline
<= -3	52	0	0,0000	52	100,0000	.	51	3	5,8824	48	94,1176	6,4000	0,0000	0,0000	.	0,0759
> -3	642	7	1,0903	635	98,9097	1,2994	635	11	1,7323	624	98,2677	1,9007	0,6569	0,2546	1,6947	0,3814

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Log-rank Test (Aba vs TRTD)
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	1	0,4717	211	99,5283	0,5000	207	5	2,4155	202	97,5845	2,5462	0,1983	0,0232	1,6970	0,1002
> -2.5	482	6	1,2448	476	98,7552	1,5065	479	9	1,8789	470	98,1211	2,0990	0,6889	0,2452	1,9356	0,4770
Femoral Neck BMD T-score Group 2 at Baseline
<= -3	73	1	1,3699	72	98,6301	1,4286	78	4	5,1282	74	94,8718	5,3977	0,2672	0,0298	2,3917	0,2049
> -3	621	6	0,9662	615	99,0338	1,1681	608	10	1,6447	598	98,3553	1,8235	0,6122	0,2225	1,6845	0,3372

Cox proportional hazard model was used to calculate the hazard ratio with Teriparatide as reference.

Major Osteoporotic fractures included clinical fractures of the upper arm, the forearm, the wrist, the hip, the shoulder, and/or the spine.

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Tabelle 4-5: Subgruppenanalyse Handgelenksfrakturen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Log-rank Test (Aba vs TRTD)
All ITT Population	696	5	0,7184	691	99,2816	0,8582	686	10	1,4577	676	98,5423	1,6083	0,5140	0,1757	1,5040	0,2159
Age (Years)
<65	102	1	0,9804	101	99,0196	1,2195	99	1	1,0101	98	98,9899	1,0417	1,0639	0,0665	17,0085	0,9651
65 to <75	455	3	0,6593	452	99,3407	0,8077	443	4	0,9029	439	99,0971	0,9787	0,7711	0,1725	3,4459	0,7329
>=75	139	1	0,7194	138	99,2806	0,7407	144	5	3,4722	139	96,5278	4,1460	0,2041	0,0238	1,7470	0,1078
Years Since Menopause
<15	138	2	1,4493	136	98,5507	1,6654	154	1	0,6494	153	99,3506	0,6849	2,3579	0,2138	26,0033	0,4702
15 to <25	338	1	0,2959	337	99,7041	0,3937	324	5	1,5432	319	98,4568	1,6502	0,1985	0,0232	1,6988	0,1005
>=25	220	2	0,9091	218	99,0909	1,0749	208	4	1,9231	204	98,0769	2,3045	0,4919	0,0901	2,6855	0,4028
Ethnicity
White	535	3	0,5607	532	99,4393	0,7469	513	7	1,3645	506	98,6355	1,5777	0,4418	0,1142	1,7081	0,2233
Black/African-American	26	0	0,0000	26	100,0000	.	24	1	4,1667	23	95,8333	4,3478	0,0000	0,0000	.	0,2971
Asian	128	2	1,5625	126	98,4375	1,5811	137	2	1,4599	135	98,5401	1,4599	1,0590	0,1492	7,5181	0,9543
Other	7	0	0,0000	7	100,0000	.	12	0	0,0000	12	100,0000
Region
North America	17	0	0,0000	17	100,0000	.	9	0	0,0000	9	100,0000
South America	222	1	0,4505	221	99,5495	0,6536	222	4	1,8018	218	98,1982	2,1710	0,2582	0,0289	2,3099	0,1916
Europe	332	2	0,6024	330	99,3976	0,7649	323	4	1,2384	319	98,7616	1,3767	0,5223	0,0957	2,8518	0,4453
Asia	125	2	1,6000	123	98,4000	1,6195	132	2	1,5152	130	98,4848	1,5152	1,0443	0,1471	7,4136	0,9654
Any Prior Fracture
Yes	407	3	0,7371	404	99,2629	0,8912	397	5	1,2594	392	98,7406	1,3628	0,6098	0,1457	2,5520	0,4939
No	289	2	0,6920	287	99,3080	0,8078	289	5	1,7301	284	98,2699	1,9507	0,4184	0,0812	2,1567	0,2825
Any Prior Vertebral Fracture
Yes	145	0	0,0000	145	100,0000	.	182	3	1,6484	179	98,3516	1,8257	0,0000	0,0000	.	0,1346
No	551	5	0,9074	546	99,0926	1,0885	504	7	1,3889	497	98,6111	1,5261	0,6778	0,2151	2,1359	0,5040
Any Prior Nonvertebral Fracture
Yes	308	3	0,9740	305	99,0260	1,1770	271	2	0,7380	269	99,2620	0,7562	1,3687	0,2287	8,1923	0,7299

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Log-rank Test (Aba vs TRTD)
No	388	2	0,5155	386	99,4845	0,5951	415	8	1,9277	407	98,0723	2,1634	0,2803	0,0595	1,3200	0,0855
Any Prior Clinical Major Osteoporotic Fracture
Yes	238	2	0,8403	236	99,1597	0,9473	208	3	1,4423	205	98,5577	1,5595	0,5957	0,0995	3,5653	0,5661
No	458	3	0,6550	455	99,3450	0,8090	478	7	1,4644	471	98,5356	1,6285	0,4734	0,1224	1,8307	0,2672
Prevalence of Vertebral Fracture at Baseline
Yes	145	0	0,0000	145	100,0000	.	182	3	1,6484	179	98,3516	1,8257	0,0000	0,0000	.	0,1346
No	551	5	0,9074	546	99,0926	1,0885	504	7	1,3889	497	98,6111	1,5261	0,6778	0,2151	2,1359	0,5040
Number of Prevalence of Vertebral Fracture at Baseline
0	551	5	0,9074	546	99,0926	1,0885	504	7	1,3889	497	98,6111	1,5261	0,6778	0,2151	2,1359	0,5040
1	111	0	0,0000	111	100,0000	.	126	1	0,7937	125	99,2063	0,8264	0,0000	0,0000	.	0,3657
>=2	34	0	0,0000	34	100,0000	.	56	2	3,5714	54	96,4286	4,1026	0,0000	0,0000	.	0,2731
Severity of Vertebral Fracture (SQ Score) at Baseline
0	551	5	0,9074	546	99,0926	1,0885	505	7	1,3861	498	98,6139	1,5240	0,6786	0,2154	2,1384	0,5053
1	89	0	0,0000	89	100,0000	.	106	2	1,8868	104	98,1132	1,9814	0,0000	0,0000	.	0,2128
>=2	56	0	0,0000	56	100,0000	.	75	1	1,3333	74	98,6667	1,5625	0,0000	0,0000	.	0,4017
Severe Disease (least BMD T-score <= -2.5 and Prevalent Vertebral Fracture) at Baseline
Yes	113	0	0,0000	113	100,0000	.	142	3	2,1127	139	97,8873	2,3047	0,0000	0,0000	.	0,1369
No	582	5	0,8591	577	99,1409	1,0266	544	7	1,2868	537	98,7132	1,4134	0,6909	0,2193	2,1771	0,5255
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	530	4	0,7547	526	99,2453	0,8868	511	9	1,7613	502	98,2387	1,9681	0,4468	0,1376	1,4510	0,1683
> -2.5	165	1	0,6061	164	99,3939	0,7692	175	1	0,5714	174	99,4286	0,5780	1,0960	0,0685	17,5313	0,9484

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Log-rank Test (Aba vs TRTD)
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	395	2	0,5063	393	99,4937	0,6105	365	7	1,9178	358	98,0822	2,1434	0,2771	0,0576	1,3337	0,0867
> -3	300	3	1,0000	297	99,0000	1,1762	321	3	0,9346	318	99,0654	1,0102	1,1065	0,2233	5,4831	0,9015
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	1	0,5882	169	99,4118	0,6250	154	4	2,5974	150	97,4026	2,7589	0,2310	0,0258	2,0673	0,1525
> -2.5	524	4	0,7634	520	99,2366	0,9348	532	6	1,1278	526	98,8722	1,2725	0,7091	0,2001	2,5131	0,5926
Total Hip BMD T-score Group 2 at Baseline
<= -3	52	0	0,0000	52	100,0000	.	51	2	3,9216	49	96,0784	4,3902	0,0000	0,0000	.	0,1508
> -3	642	5	0,7788	637	99,2212	0,9302	635	8	1,2598	627	98,7402	1,3863	0,6473	0,2117	1,9788	0,4419
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	1	0,4717	211	99,5283	0,5000	207	4	1,9324	203	98,0676	2,0578	0,2501	0,0279	2,2379	0,1799
> -2.5	482	4	0,8299	478	99,1701	1,0114	479	6	1,2526	473	98,7474	1,4146	0,6915	0,1951	2,4507	0,5656
Femoral Neck BMD T-score Group 2 at Baseline
<= -3	73	1	1,3699	72	98,6301	1,4286	78	3	3,8462	75	96,1538	4,0959	0,3624	0,0377	3,4877	0,3593
> -3	621	4	0,6441	617	99,3559	0,7859	608	7	1,1513	601	98,8487	1,2851	0,5853	0,1713	1,9996	0,3872

Cox proportional hazard model was used to calculate the hazard ratio with Teriparatide as reference.

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Tabelle 4-6: Subgruppenanalyse NVF unabhängig von der Trauma-Intensität

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Log-rank Test (Aba vs TRTD)
All ITT Population	696	16	2,2989	680	97,7011	2,8677	686	13	1,8950	673	98,1050	2,1064	1,2802	0,6158	2,6617	0,5072
Age (Years)
<65	102	1	0,9804	101	99,0196	1,2195	99	2	2,0202	97	97,9798	2,1412	0,5333	0,0484	5,8813	0,6017
65 to <75	455	11	2,4176	444	97,5824	3,0818	443	6	1,3544	437	98,6456	1,4853	1,9190	0,7096	5,1900	0,1912
>=75	139	4	2,8777	135	97,1223	3,4190	144	5	3,4722	139	96,5278	4,1460	0,8315	0,2233	3,0968	0,7830
Years Since Menopause
<15	138	3	2,1739	135	97,8261	2,6019	154	2	1,2987	152	98,7013	1,4795	1,7823	0,2978	10,6666	0,5209
15 to <25	338	6	1,7751	332	98,2249	2,3423	324	7	2,1605	317	97,8395	2,3104	0,8621	0,2897	2,5657	0,7891
>=25	220	7	3,1818	213	96,8182	3,8945	208	4	1,9231	204	98,0769	2,3045	1,7613	0,5156	6,0170	0,3601
Ethnicity
White	535	14	2,6168	521	97,3832	3,4087	513	10	1,9493	503	98,0507	2,2516	1,4490	0,6436	3,2621	0,3677
Black/African-American	26	0	0,0000	26	100,0000	.	24	1	4,1667	23	95,8333	4,3478	0,0000	0,0000	.	0,2971
Asian	128	2	1,5625	126	98,4375	1,5811	137	2	1,4599	135	98,5401	1,4599	1,0590	0,1492	7,5181	0,9543
Other	7	0	0,0000	7	100,0000	.	12	0	0,0000	12	100,0000
Region
North America	17	0	0,0000	17	100,0000	.	9	0	0,0000	9	100,0000
South America	222	6	2,7027	216	97,2973	3,6498	222	4	1,8018	218	98,1982	2,1710	1,5536	0,4384	5,5055	0,4914
Europe	332	8	2,4096	324	97,5904	3,0285	323	7	2,1672	316	97,8328	2,4225	1,1982	0,4345	3,3044	0,7264
Asia	125	2	1,6000	123	98,4000	1,6195	132	2	1,5152	130	98,4848	1,5152	1,0443	0,1471	7,4136	0,9654
Any Prior Fracture
Yes	407	11	2,7027	396	97,2973	3,3677	397	7	1,7632	390	98,2368	1,9032	1,6090	0,6237	4,1509	0,3207
No	289	5	1,7301	284	98,2699	2,1133	289	6	2,0761	283	97,9239	2,3944	0,8817	0,2691	2,8893	0,8347
Any Prior Vertebral Fracture
Yes	145	4	2,7586	141	97,2414	3,5206	182	3	1,6484	179	98,3516	1,8257	1,8036	0,4037	8,0587	0,4334
No	551	12	2,1779	539	97,8221	2,6862	504	10	1,9841	494	98,0159	2,2095	1,1487	0,4963	2,6588	0,7452
Any Prior Nonvertebral Fracture
Yes	308	9	2,9221	299	97,0779	3,5897	271	4	1,4760	267	98,5240	1,5529	2,0660	0,6362	6,7089	0,2170
No	388	7	1,8041	381	98,1959	2,2733	415	9	2,1687	406	97,8313	2,4682	0,8823	0,3285	2,3692	0,8036
Any Prior Clinical Major

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Log-rank Test (Aba vs TRTD)
Osteoporotic Fracture ##																
Yes	238	7	2,9412	231	97,0588	3,4762	208	5	2,4038	203	97,5962	2,5918	1,2513	0,3971	3,9426	0,7013
No	458	9	1,9651	449	98,0349	2,5284	478	8	1,6736	470	98,3264	1,8951	1,2610	0,4865	3,2687	0,6332
Prevalence of Vertebral Fracture at Baseline
Yes	145	4	2,7586	141	97,2414	3,5206	182	3	1,6484	179	98,3516	1,8257	1,8036	0,4037	8,0587	0,4334
No	551	12	2,1779	539	97,8221	2,6862	504	10	1,9841	494	98,0159	2,2095	1,1487	0,4963	2,6588	0,7452
Number of Prevalence of Vertebral Fracture at Baseline
0	551	12	2,1779	539	97,8221	2,6862	504	10	1,9841	494	98,0159	2,2095	1,1487	0,4963	2,6588	0,7452
1	111	2	1,8018	109	98,1982	2,3007	126	1	0,7937	125	99,2063	0,8264	2,4794	0,2248	27,3436	0,4430
>=2	34	2	5,8824	32	94,1176	7,3103	56	2	3,5714	54	96,4286	4,1026	1,6888	0,2375	12,0084	0,5964
Severity of Vertebral Fracture (SQ Score) at Baseline
0	551	12	2,1779	539	97,8221	2,6862	505	10	1,9802	495	98,0198	2,2064	1,1501	0,4969	2,6622	0,7429
1	89	2	2,2472	87	97,7528	2,7719	106	2	1,8868	104	98,1132	1,9814	1,2908	0,1818	9,1638	0,7980
>=2	56	2	3,5714	54	96,4286	4,4147	75	1	1,3333	74	98,6667	1,5625	2,7643	0,2506	30,4968	0,3864
Severe Disease (least BMD T-score <= -2.5 and Prevalent Vertebral Fracture) at Baseline
Yes	113	4	3,5398	109	96,4602	4,5718	142	3	2,1127	139	97,8873	2,3047	1,8355	0,4108	8,2015	0,4194
No	582	12	2,0619	570	97,9381	2,5337	544	10	1,8382	534	98,1618	2,0464	1,1707	0,5058	2,7096	0,7118
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	530	13	2,4528	517	97,5472	3,0425	511	11	2,1526	500	97,8474	2,4177	1,1995	0,5374	2,6776	0,6559
> -2.5	165	3	1,8182	162	98,1818	2,3284	175	2	1,1429	173	98,8571	1,2321	1,6778	0,2803	10,0433	0,5666
Lumbar Spine BMD T-score Group 2 at Baseline

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Log-rank Test (Aba vs TRTD)
<= -3	395	8	2,0253	387	97,9747	2,6028	365	8	2,1918	357	97,8082	2,4967	0,9830	0,3689	2,6193	0,9727
> -3	300	8	2,6667	292	97,3333	3,2086	321	5	1,5576	316	98,4424	1,6795	1,7782	0,5817	5,4362	0,3060
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	6	3,5294	164	96,4706	4,5059	154	4	2,5974	150	97,4026	2,7589	1,4229	0,4015	5,0436	0,5829
> -2.5	524	10	1,9084	514	98,0916	2,3529	532	9	1,6917	523	98,3083	1,9192	1,1873	0,4825	2,9221	0,7084
Total Hip BMD T-score Group 2 at Baseline
<= -3	52	1	1,9231	51	98,0769	2,0408	51	2	3,9216	49	96,0784	4,3902	0,4832	0,0438	5,3298	0,5438
> -3	642	15	2,3364	627	97,6636	2,9265	635	11	1,7323	624	98,2677	1,9250	1,4271	0,6554	3,1072	0,3678
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	5	2,3585	207	97,6415	3,1015	207	4	1,9324	203	98,0676	2,0578	1,2929	0,3470	4,8170	0,7011
> -2.5	482	11	2,2822	471	97,7178	2,8189	479	9	1,8789	470	98,1211	2,1337	1,2743	0,5280	3,0751	0,5888
Femoral Neck BMD T-score Group 2 at Baseline
<= -3	73	3	4,1096	70	95,8904	5,9732	78	3	3,8462	75	96,1538	4,0959	1,1461	0,2309	5,6887	0,8678
> -3	621	13	2,0934	608	97,9066	2,5749	608	10	1,6447	598	98,3553	1,8495	1,3409	0,5879	3,0580	0,4840

Cox proportional hazard model was used to calculate the hazard ratio with Teriparatide as reference.

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Tabelle 4-7: Subgruppenanalyse Klinische Wirbelkörperfrakturen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Log-rank Test (Aba vs TRTD)
All ITT Population	696	0	0,0000	696	100,0000	.	686	3	0,4373	683	99,5627	0,4747	0,0000	0,0000	.	0,0854
Age (Years)
<65	102	0	0,0000	102	100,0000	.	99	1	1,0101	98	98,9899	1,2048	0,0000	0,0000	.	0,3323
65 to <75	455	0	0,0000	455	100,0000	.	443	1	0,2257	442	99,7743	0,2288	0,0000	0,0000	.	0,3113
>=75	139	0	0,0000	139	100,0000	.	144	1	0,6944	143	99,3056	0,6993	0,0000	0,0000	.	0,3277
Years Since Menopause
<15	138	0	0,0000	138	100,0000	.	154	1	0,6494	153	99,3506	0,7813	0,0000	0,0000	.	0,3606
15 to <25	338	0	0,0000	338	100,0000	.	324	1	0,3086	323	99,6914	0,3125	0,0000	0,0000	.	0,3062
>=25	220	0	0,0000	220	100,0000	.	208	1	0,4808	207	99,5192	0,4854	0,0000	0,0000	.	0,3081
Ethnicity
White	535	0	0,0000	535	100,0000	.	513	1	0,1949	512	99,8051	0,2439	0,0000	0,0000	.	0,3313
Black/African-American	26	0	0,0000	26	100,0000	.	24	0	0,0000	24	100,0000
Asian	128	0	0,0000	128	100,0000	.	137	2	1,4599	135	98,5401	1,4599	0,0000	0,0000	.	0,1708
Other	7	0	0,0000	7	100,0000	.	12	0	0,0000	12	100,0000
Region
North America	17	0	0,0000	17	100,0000	.	9	0	0,0000	9	100,0000
South America	222	0	0,0000	222	100,0000	.	222	0	0,0000	222	100,0000
Europe	332	0	0,0000	332	100,0000	.	323	1	0,3096	322	99,6904	0,3717	0,0000	0,0000	.	0,3350
Asia	125	0	0,0000	125	100,0000	.	132	2	1,5152	130	98,4848	1,5152	0,0000	0,0000	.	0,1679
Any Prior Fracture
Yes	407	0	0,0000	407	100,0000	.	397	3	0,7557	394	99,2443	0,8176	0,0000	0,0000	.	0,0830
No	289	0	0,0000	289	100,0000	.	289	0	0,0000	289	100,0000
Any Prior Vertebral Fracture

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Log-rank Test (Aba vs TRTD)
Yes	145	0	0,0000	145	100,0000	.	182	2	1,0989	180	98,9011	1,1050	0,0000	0,0000	.	0,2065
No	551	0	0,0000	551	100,0000	.	504	1	0,1984	503	99,8016	0,2457	0,0000	0,0000	.	0,3149
Any Prior Nonvertebral Fracture
Yes	308	0	0,0000	308	100,0000	.	271	1	0,3690	270	99,6310	0,4505	0,0000	0,0000	.	0,3046
No	388	0	0,0000	388	100,0000	.	415	2	0,4819	413	99,5181	0,4866	0,0000	0,0000	.	0,1730
Any Prior Clinical Major Osteoporotic Fracture
Yes	238	0	0,0000	238	100,0000	.	208	2	0,9615	206	99,0385	1,0721	0,0000	0,0000	.	0,1339
No	458	0	0,0000	458	100,0000	.	478	1	0,2092	477	99,7908	0,2114	0,0000	0,0000	.	0,3294
Prevalence of Vertebral Fracture at Baseline
Yes	145	0	0,0000	145	100,0000	.	182	2	1,0989	180	98,9011	1,1050	0,0000	0,0000	.	0,2065
No	551	0	0,0000	551	100,0000	.	504	1	0,1984	503	99,8016	0,2457	0,0000	0,0000	.	0,3149
Number of Prevalence of Vertebral Fracture at Baseline
0	551	0	0,0000	551	100,0000	.	504	1	0,1984	503	99,8016	0,2457	0,0000	0,0000	.	0,3149
1	111	0	0,0000	111	100,0000	.	126	2	1,5873	124	98,4127	1,6000	0,0000	0,0000	.	0,1817
>=2	34	0	0,0000	34	100,0000	.	56	0	0,0000	56	100,0000
Severity of Vertebral Fracture (SQ Score) at Baseline
0	551	0	0,0000	551	100,0000	.	505	1	0,1980	504	99,8020	0,2457	0,0000	0,0000	.	0,3149
1	89	0	0,0000	89	100,0000	.	106	0	0,0000	106	100,0000
>=2	56	0	0,0000	56	100,0000	.	75	2	2,6667	73	97,3333	2,7027	0,0000	0,0000	.	0,2209

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Log-rank Test (Aba vs TRTD)
Severe Disease (least BMD T-score <= -2.5 and Prevalent Vertebral Fracture) at Baseline
Yes	113	0	0,0000	113	100,0000	.	142	2	1,4085	140	98,5915	1,4184	0,0000	0,0000	.	0,2046
No	582	0	0,0000	582	100,0000	.	544	1	0,1838	543	99,8162	0,2283	0,0000	0,0000	.	0,3179
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	530	0	0,0000	530	100,0000	.	511	3	0,5871	508	99,4129	0,6410	0,0000	0,0000	.	0,0815
> -2.5	165	0	0,0000	165	100,0000	.	175	0	0,0000	175	100,0000
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	395	0	0,0000	395	100,0000	.	365	3	0,8219	362	99,1781	0,8993	0,0000	0,0000	.	0,0765
> -3	300	0	0,0000	300	100,0000	.	321	0	0,0000	321	100,0000
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	0	0,0000	170	100,0000	.	154	1	0,6494	153	99,3506	0,6579	0,0000	0,0000	.	0,2917
> -2.5	524	0	0,0000	524	100,0000	.	532	2	0,3759	530	99,6241	0,4237	0,0000	0,0000	.	0,1679
Total Hip BMD T-score Group 2 at Baseline
<= -3	52	0	0,0000	52	100,0000	.	51	1	1,9608	50	98,0392	2,0000	0,0000	0,0000	.	0,3078
> -3	642	0	0,0000	642	100,0000	.	635	2	0,3150	633	99,6850	0,3534	0,0000	0,0000	.	0,1635
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	0	0,0000	212	100,0000	.	207	1	0,4831	206	99,5169	0,4878	0,0000	0,0000	.	0,3103
> -2.5	482	0	0,0000	482	100,0000	.	479	2	0,4175	477	99,5825	0,4704	0,0000	0,0000	.	0,1625

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Log-rank Test (Aba vs TRTD)
Femoral Neck BMD T-score Group 2 at Baseline
<= -3	73	0	0,0000	73	100,0000	.	78	1	1,2821	77	98,7179	1,2987	0,0000	0,0000	.	0,3302
> -3	621	0	0,0000	621	100,0000	.	608	2	0,3289	606	99,6711	0,3704	0,0000	0,0000	.	0,1603

Cox proportional hazard model was used to calculate the hazard ratio with Teriparatide as reference.

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Tabelle 4-8: Subgruppenanalyse Hüftfrakturen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Log-rank Test (Aba vs TRTD)
All ITT Population	696	0	0,0000	696	100,0000	.	686	0	0,0000	686	100,0000
Age (Years)
<65	102	0	0,0000	102	100,0000	.	99	0	0,0000	99	100,0000
65 to <75	455	0	0,0000	455	100,0000	.	443	0	0,0000	443	100,0000
>=75	139	0	0,0000	139	100,0000	.	144	0	0,0000	144	100,0000
Years Since Menopause
<15	138	0	0,0000	138	100,0000	.	154	0	0,0000	154	100,0000
15 to <25	338	0	0,0000	338	100,0000	.	324	0	0,0000	324	100,0000
>=25	220	0	0,0000	220	100,0000	.	208	0	0,0000	208	100,0000
Ethnicity
White	535	0	0,0000	535	100,0000	.	513	0	0,0000	513	100,0000
Black/African-American	26	0	0,0000	26	100,0000	.	24	0	0,0000	24	100,0000
Asian	128	0	0,0000	128	100,0000	.	137	0	0,0000	137	100,0000
Other	7	0	0,0000	7	100,0000	.	12	0	0,0000	12	100,0000
Region
North America	17	0	0,0000	17	100,0000	.	9	0	0,0000	9	100,0000
South America	222	0	0,0000	222	100,0000	.	222	0	0,0000	222	100,0000
Europe	332	0	0,0000	332	100,0000	.	323	0	0,0000	323	100,0000
Asia	125	0	0,0000	125	100,0000	.	132	0	0,0000	132	100,0000
Any Prior Fracture
Yes	407	0	0,0000	407	100,0000	.	397	0	0,0000	397	100,0000
No	289	0	0,0000	289	100,0000	.	289	0	0,0000	289	100,0000

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Log-rank Test (Aba vs TRTD)
Any Prior Vertebral Fracture
Yes	145	0	0,0000	145	100,0000	.	182	0	0,0000	182	100,0000
No	551	0	0,0000	551	100,0000	.	504	0	0,0000	504	100,0000
Any Prior Nonvertebral Fracture
Yes	308	0	0,0000	308	100,0000	.	271	0	0,0000	271	100,0000
No	388	0	0,0000	388	100,0000	.	415	0	0,0000	415	100,0000
Any Prior Clinical Major Osteoporotic Fracture
Yes	238	0	0,0000	238	100,0000	.	208	0	0,0000	208	100,0000
No	458	0	0,0000	458	100,0000	.	478	0	0,0000	478	100,0000
Prevalence of Vertebral Fracture at Baseline
Yes	145	0	0,0000	145	100,0000	.	182	0	0,0000	182	100,0000
No	551	0	0,0000	551	100,0000	.	504	0	0,0000	504	100,0000
Number of Prevalence of Vertebral Fracture at Baseline
0	551	0	0,0000	551	100,0000	.	504	0	0,0000	504	100,0000
1	111	0	0,0000	111	100,0000	.	126	0	0,0000	126	100,0000
>=2	34	0	0,0000	34	100,0000	.	56	0	0,0000	56	100,0000
Severity of Vertebral Fracture (SQ Score) at Baseline
0	551	0	0,0000	551	100,0000	.	505	0	0,0000	505	100,0000
1	89	0	0,0000	89	100,0000	.	106	0	0,0000	106	100,0000

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Log-rank Test (Aba vs TRTD)
>=2	56	0	0,0000	56	100,0000	.	75	0	0,0000	75	100,0000
Severe Disease (least BMD T-score <= -2.5 and Prevalent Vertebral Fracture) at Baseline
Yes	113	0	0,0000	113	100,0000	.	142	0	0,0000	142	100,0000
No	582	0	0,0000	582	100,0000	.	544	0	0,0000	544	100,0000
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	530	0	0,0000	530	100,0000	.	511	0	0,0000	511	100,0000
> -2.5	165	0	0,0000	165	100,0000	.	175	0	0,0000	175	100,0000
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	395	0	0,0000	395	100,0000	.	365	0	0,0000	365	100,0000
> -3	300	0	0,0000	300	100,0000	.	321	0	0,0000	321	100,0000
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	0	0,0000	170	100,0000	.	154	0	0,0000	154	100,0000
> -2.5	524	0	0,0000	524	100,0000	.	532	0	0,0000	532	100,0000
Total Hip BMD T-score Group 2 at Baseline
<= -3	52	0	0,0000	52	100,0000	.	51	0	0,0000	51	100,0000
> -3	642	0	0,0000	642	100,0000	.	635	0	0,0000	635	100,0000

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Log-rank Test (Aba vs TRTD)
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	0	0,0000	212	100,0000	.	207	0	0,0000	207	100,0000
> -2.5	482	0	0,0000	482	100,0000	.	479	0	0,0000	479	100,0000
Femoral Neck BMD T-score Group 2 at Baseline
<= -3	73	0	0,0000	73	100,0000	.	78	0	0,0000	78	100,0000
> -3	621	0	0,0000	621	100,0000	.	608	0	0,0000	608	100,0000

Cox proportional hazard model was used to calculate the hazard ratio with Teriparatide as reference.

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Tabelle 4-9: Subgruppenanalyse Major NVF

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P- Value Log-rank Test (Aba vs TRTD)
All ITT Population	696	10	1,4368	686	98,5632	1,7711	686	11	1,6035	675	98,3965	1,7569	0,9388	0,3987	2,2106	0,8849
Age (Years)
<65	102	1	0,9804	101	99,0196	1,2195	99	1	1,0101	98	98,9899	1,0417	1,0639	0,0665	17,0085	0,9651
65 to <75	455	6	1,3187	449	98,6813	1,6621	443	5	1,1287	438	98,8713	1,2093	1,2347	0,3767	4,0465	0,7267
>=75	139	3	2,1583	136	97,8417	2,5623	144	5	3,4722	139	96,5278	4,1460	0,6203	0,1482	2,5960	0,5092
Years Since Menopause
<15	138	2	1,4493	136	98,5507	1,6654	154	1	0,6494	153	99,3506	0,6849	2,3579	0,2138	26,0033	0,4702
15 to <25	338	3	0,8876	335	99,1124	1,2099	324	6	1,8519	318	98,1481	1,9650	0,4996	0,1249	1,9981	0,3167
>=25	220	5	2,2727	215	97,7273	2,7647	208	4	1,9231	204	98,0769	2,3045	1,2472	0,3349	4,6447	0,7415
Ethnicity
White	535	8	1,4953	527	98,5047	1,9442	513	8	1,5595	505	98,4405	1,7765	1,0298	0,3865	2,7439	0,9532
Black/African-American	26	0	0,0000	26	100,0000	.	24	1	4,1667	23	95,8333	4,3478	0,0000	0,0000	.	0,2971
Asian	128	2	1,5625	126	98,4375	1,5811	137	2	1,4599	135	98,5401	1,4599	1,0590	0,1492	7,5181	0,9543
Other	7	0	0,0000	7	100,0000	.	12	0	0,0000	12	100,0000
Region
North America	17	0	0,0000	17	100,0000	.	9	0	0,0000	9	100,0000
South America	222	4	1,8018	218	98,1982	2,4475	222	4	1,8018	218	98,1982	2,1710	1,0360	0,2591	4,1423	0,9602
Europe	332	4	1,2048	328	98,7952	1,4946	323	5	1,5480	318	98,4520	1,6916	0,8303	0,2230	3,0925	0,7814
Asia	125	2	1,6000	123	98,4000	1,6195	132	2	1,5152	130	98,4848	1,5152	1,0443	0,1471	7,4136	0,9654
Any Prior Fracture
Yes	407	6	1,4742	401	98,5258	1,8524	397	6	1,5113	391	98,4887	1,6188	1,0179	0,3283	3,1563	0,9755

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Log-rank Test (Aba vs TRTD)
No	289	4	1,3841	285	98,6159	1,6358	289	5	1,7301	284	98,2699	1,9507	0,8439	0,2266	3,1430	0,8000
Any Prior Vertebral Fracture
Yes	145	1	0,6897	144	99,3103	1,0000	182	3	1,6484	179	98,3516	1,8257	0,4467	0,0465	4,2943	0,4734
No	551	9	1,6334	542	98,3666	1,9684	504	8	1,5873	496	98,4127	1,7292	1,0702	0,4129	2,7740	0,8888
Any Prior Nonvertebral Fracture
Yes	308	5	1,6234	303	98,3766	1,9680	271	3	1,1070	268	98,8930	1,1322	1,5167	0,3624	6,3471	0,5657
No	388	5	1,2887	383	98,7113	1,6007	415	8	1,9277	407	98,0723	2,1634	0,7061	0,2310	2,1584	0,5395
Any Prior Clinical Major Osteoporotic Fracture
Yes	238	3	1,2605	235	98,7395	1,4451	208	4	1,9231	204	98,0769	2,0502	0,6665	0,1492	2,9779	0,5927
No	458	7	1,5284	451	98,4716	1,9512	478	7	1,4644	471	98,5356	1,6285	1,1154	0,3912	3,1803	0,8384
Prevalence of Vertebral Fracture at Baseline
Yes	145	1	0,6897	144	99,3103	1,0000	182	3	1,6484	179	98,3516	1,8257	0,4467	0,0465	4,2943	0,4734
No	551	9	1,6334	542	98,3666	1,9684	504	8	1,5873	496	98,4127	1,7292	1,0702	0,4129	2,7740	0,8888
Number of Prevalence of Vertebral Fracture at Baseline
0	551	9	1,6334	542	98,3666	1,9684	504	8	1,5873	496	98,4127	1,7292	1,0702	0,4129	2,7740	0,8888
1	111	0	0,0000	111	100,0000	.	126	1	0,7937	125	99,2063	0,8264	0,0000	0,0000	.	0,3657
>=2	34	1	2,9412	33	97,0588	3,8462	56	2	3,5714	54	96,4286	4,1026	0,7971	0,0721	8,8075	0,8529
Severity of Vertebral Fracture (SQ Score) at Baseline

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Log-rank Test (Aba vs TRTD)
0	551	9	1,6334	542	98,3666	1,9684	505	8	1,5842	497	98,4158	1,7267	1,0717	0,4134	2,7778	0,8866
1	89	0	0,0000	89	100,0000	.	106	2	1,8868	104	98,1132	1,9814	0,0000	0,0000	.	0,2128
>=2	56	1	1,7857	55	98,2143	2,3810	75	1	1,3333	74	98,6667	1,5625	1,3647	0,0853	21,8312	0,8253
Severe Disease (least BMD T-score <= -2.5 and Prevalent Vertebral Fracture) at Baseline
Yes	113	1	0,8850	112	99,1150	1,3333	142	3	2,1127	139	97,8873	2,3047	0,4545	0,0473	4,3699	0,4835
No	582	9	1,5464	573	98,4536	1,8581	544	8	1,4706	536	98,5294	1,6013	1,0916	0,4211	2,8294	0,8567
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	530	8	1,5094	522	98,4906	1,8545	511	10	1,9569	501	98,0431	2,1682	0,8058	0,3180	2,0419	0,6484
> -2.5	165	2	1,2121	163	98,7879	1,5212	175	1	0,5714	174	99,4286	0,5780	2,2287	0,2020	24,5874	0,5016
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	395	6	1,5190	389	98,4810	1,9314	365	7	1,9178	358	98,0822	2,1434	0,8379	0,2816	2,4934	0,7499
> -3	300	4	1,3333	296	98,6667	1,5813	321	4	1,2461	317	98,7539	1,3269	1,1034	0,2759	4,4125	0,8895
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	2	1,1765	168	98,8235	1,5805	154	4	2,5974	150	97,4026	2,7589	0,4636	0,0849	2,5316	0,3630
> -2.5	524	8	1,5267	516	98,4733	1,8615	532	7	1,3158	525	98,6842	1,4643	1,2181	0,4417	3,3592	0,7026
Total Hip BMD T-score Group 2 at Baseline
<= -3	52	0	0,0000	52	100,0000	.	51	2	3,9216	49	96,0784	4,3902	0,0000	0,0000	.	0,1508

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Aba Total Subject	Aba Subject with Event	Aba Percent of Patients with Event	Aba Subject Censored	Aba Percent of Patients Censored	Aba KM Rate at 19 Months	TRTD Total Subject	TRTD Subject with Event	TRTD Percent of Subject with Event	TRTD Subject Censored	TRTD Percent of Subject Censored	TRTD KM Rate at 19 Months	Hazard Ratio (Aba vs TRTD)	Hazard Ratio Lower CI	Hazard Ratio Upper CI	P-Value Log-rank Test (Aba vs TRTD)
> -3	642	10	1,5576	632	98,4424	1,9203	635	9	1,4173	626	98,5827	1,5467	1,1554	0,4695	2,8436	0,7530
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	2	0,9434	210	99,0566	1,3361	207	4	1,9324	203	98,0676	2,0578	0,5095	0,0933	2,7827	0,4275
> -2.5	482	8	1,6598	474	98,3402	2,0196	479	7	1,4614	472	98,5386	1,6277	1,1890	0,4311	3,2790	0,7375
Femoral Neck BMD T-score Group 2 at Baseline
<= -3	73	2	2,7397	71	97,2603	4,0226	78	3	3,8462	75	96,1538	4,0959	0,7501	0,1251	4,4971	0,7522
> -3	621	8	1,2882	613	98,7118	1,5667	608	8	1,3158	600	98,6842	1,4525	1,0264	0,3852	2,7348	0,9585

Cox proportional hazard model was used to calculate the hazard ratio with Teriparatide as reference.

Major nonvertebral fractures included clinical fractures of the pelvis, distal femur (upper leg [not hip]), proximal tibia (lower leg [not knee or ankle]), ribs, proximal humerus (upper arm or shoulder), forearm (wrist) and hip.

4.1.2 Subgruppenanalysen für den Endpunkt Nebenwirkungen – Gesamtraten unerwünschter Ereignisse

4.1.2.1 Ergebnisse der Interaktionsterme

Tabelle 4-10: Ergebnisse der Interaktionsterme für den Endpunkt Nebenwirkungen – Gesamtraten unerwünschter Ereignisse

Category	Age	Years Since Menopause	Ethnicity	Region	Any Prior Fracture	Any Prior Vertebral Fracture	Any Prior Non-vertebral Fracture	Any Prior Clinical MOF	Num of Prevalence of VF	Severity of VF (SQ Score)	Severe Disease at Baseline	Lumbar Spine BMD T-score Cutoff - 2.5	Lumbar Spine BMD T-score Cutoff - 3	Total Hip BMD T-score Cutoff - 2.5	Total Hip BMD T-score Cutoff - 3	Femoral Neck BMD T-score Cutoff - 2.5	Femoral Neck BMD T-score Cutoff - 3
Any TEAE	0,4293	0,0291	0,7201	0,3778	0,4007	0,9937	0,1364	0,1109	0,5050	0,5325	0,9557	0,9664	0,2514	0,8799	0,1516	0,4088	0,7402
Severe TEAE	0,8144	0,2882	0,1456	0,1177	0,2583	0,8357	0,2536	0,7449	0,5390	0,8965	0,4793	0,6242	0,6747	0,2133	0,9622	0,3183	0,4623
Serious TEAE	0,3003	0,2177	0,0776	0,1231	0,2397	0,0549	0,8479	0,8648	0,1181	0,1498	0,1038	0,2689	0,7442	0,6010	0,3714	0,6334	0,0602
TEAE Lead to Study Drug Disc	0,7147	0,0596	0,1826	0,1594	0,9932	0,9413	0,7186	0,4536	0,7305	0,4442	0,6313	0,9179	0,7704	0,5296	0,5105	0,5396	0,9681

Note: Treatment-subgroup interactions were assessed by the Breslow-Day test.

4.1.2.2 Nebenwirkungen – Gesamtraten unerwünschter Ereignisse

Tabelle 4-11: Subgruppenanalyse Jegliche UE

Subgroup	Abalopar- tide Total Subject	Abalopar- tide Subject with Event	Abalopar- tide Percent of Patients with Event	Teri- para- tide Total Sub- ject	Teri- para- tide Sub- ject with Event	Teripara- tide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
All Safety Population	694	627	90,3458	686	614	89,5044	0,8414	-2,3516	4,0447	1,0974	0,7727	1,5585	1,0094	0,9744	1,0457	0,6036
Age (Years)
<65	101	88	87,1287	99	90	90,9091	-3,7804	-12,7554	5,1703	0,6769	0,2754	1,6637	0,9584	0,8694	1,0565	0,3929
65 to <75	454	412	90,7489	443	392	88,4876	2,2613	-1,7529	6,3104	1,2762	0,8292	1,9642	1,0256	0,9808	1,0723	0,2667
>=75	139	127	91,3669	144	132	91,6667	-0,2998	-7,1185	6,4283	0,9621	0,4168	2,2207	0,9967	0,9284	1,0700	0,9279
Years Since Menopause
<15	136	119	87,5000	154	139	90,2597	-2,7597	-10,3564	4,5381	0,7554	0,3618	1,5772	0,9694	0,8931	1,0523	0,4541
15 to <25	338	313	92,6036	324	283	87,3457	5,2579	0,6739	9,9447	1,8139	1,0755	3,0592	1,0602	1,0072	1,1159	0,0240
>=25	220	195	88,6364	208	192	92,3077	-3,6713	-9,3433	2,0089	0,6500	0,3365	1,2556	0,9602	0,9030	1,0211	0,1971
Ethnicity
White	533	476	89,3058	513	454	88,4990	0,8068	-3,0165	4,6571	1,0852	0,7377	1,5966	1,0091	0,9668	1,0533	0,6778
Black/African- American	26	21	80,7692	24	16	66,6667	14,1026	-10,0556	36,7612	2,1000	0,5764	7,6507	1,2115	0,8628	1,7012	0,2560
Asian	128	124	96,8750	137	134	97,8102	-0,9352	-5,7892	3,5400	0,6940	0,1523	3,1629	0,9904	0,9517	1,0308	0,6352
Other	7	6	85,7143	12	10	83,3333	2,3810	-36,5329	32,8599	1,2000	0,0887	16,2392	1,0286	0,6934	1,5258	0,8908
Region
North America	17	12	70,5882	9	8	88,8889	-18,3007	-43,7155	17,8832	0,3000	0,0293	3,0709	0,7941	0,5409	1,1660	0,2920
South America	222	187	84,2342	222	184	82,8829	1,3514	-5,5819	8,2780	1,1034	0,6677	1,8233	1,0163	0,9358	1,1037	0,7009
Europe	330	307	93,0303	323	292	90,4025	2,6278	-1,6480	6,9772	1,4171	0,8073	2,4875	1,0291	0,9826	1,0777	0,2228
Asia	125	121	96,8000	132	130	98,4848	-1,6848	-6,5499	2,6221	0,4654	0,0837	2,5869	0,9829	0,9460	1,0212	0,3713
Any Prior Fracture
Yes	405	372	91,8519	397	357	89,9244	1,9274	-2,0915	5,9873	1,2631	0,7790	2,0478	1,0214	0,9776	1,0673	0,3427
No	289	255	88,2353	289	257	88,9273	-0,6920	-5,9444	4,5549	0,9339	0,5592	1,5596	0,9922	0,9358	1,0520	0,7937

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- atid Total Subject	Abalopar- atid Subject with Event	Abalopar- atid Percent of Patients with Event	Teri- para- tid Total Sub- ject	Teri- para- tid Sub- ject with Event	Teri- para- tid Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Any Prior Vertebral Fracture
Yes	144	131	90,9722	182	164	90,1099	0,8623	-5,9383	7,2308	1,1060	0,5227	2,3401	1,0096	0,9409	1,0833	0,7921
No	550	496	90,1818	504	450	89,2857	0,8961	-2,7769	4,6281	1,1022	0,7402	1,6414	1,0100	0,9695	1,0522	0,6318
Any Prior Nonvertebral Fracture
Yes	306	282	92,1569	271	240	88,5609	3,5960	-1,2339	8,6129	1,5177	0,8669	2,6570	1,0406	0,9861	1,0982	0,1421
No	388	345	88,9175	415	374	90,1205	-1,2030	-5,5224	3,0537	0,8796	0,5596	1,3824	0,9867	0,9410	1,0346	0,5778
Any Prior Clinical Major Osteoporotic Fracture
Yes	237	221	93,2489	208	185	88,9423	4,3066	-1,0086	9,9100	1,7172	0,8811	3,3467	1,0484	0,9884	1,1120	0,1089
No	457	406	88,8403	478	429	89,7490	-0,9087	-4,9280	3,0743	0,9093	0,6005	1,3768	0,9899	0,9469	1,0348	0,6531
Prevalence of Vertebral Fracture at Baseline
Yes	144	131	90,9722	182	164	90,1099	0,8623	-5,9383	7,2308	1,1060	0,5227	2,3401	1,0096	0,9409	1,0833	0,7921
No	550	496	90,1818	504	450	89,2857	0,8961	-2,7769	4,6281	1,1022	0,7402	1,6414	1,0100	0,9695	1,0522	0,6318
Number of Prevalence of Vertebral Fracture at Baseline
0	550	496	90,1818	504	450	89,2857	0,8961	-2,7769	4,6281	1,1022	0,7402	1,6414	1,0100	0,9695	1,0522	0,6318
1	111	105	94,5946	126	116	92,0635	2,5311	-4,3541	9,2491	1,5086	0,5300	4,2938	1,0275	0,9601	1,0996	0,4384
>=2	33	26	78,7879	56	48	85,7143	-6,9264	-24,8340	8,6337	0,6190	0,2018	1,8993	0,9192	0,7475	1,1304	0,3992
Severity of Vertebral Fracture (SQ Score) at Baseline
0	550	496	90,1818	505	451	89,3069	0,8749	-2,7951	4,6025	1,0998	0,7386	1,6377	1,0098	0,9693	1,0519	0,6396
1	89	81	91,0112	106	99	93,3962	-2,3850	-10,8421	5,3641	0,7159	0,2490	2,0582	0,9745	0,8972	1,0584	0,5336
>=2	55	50	90,9091	75	64	85,3333	5,5758	-6,6449	16,5718	1,7188	0,5608	5,2676	1,0653	0,9395	1,2080	0,3391

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- atide Total Subject	Abalopar- atide Subject with Event	Abalopar- atide Percent of Patients with Event	Teri- para- atide Total Sub- ject	Teri- para- atide Sub- ject with Event	Teripara- atide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Severe Disease (least BMD T-score <= -2.5 and Prevalent Vertebral Fracture) at Baseline
Yes	113	103	91,1504	142	128	90,1408	1,0096	-6,7209	8,2131	1,1266	0,4806	2,6409	1,0112	0,9343	1,0945	0,7839
No	581	524	90,1893	544	486	89,3382	0,8511	-2,7026	4,4477	1,0971	0,7459	1,6137	1,0095	0,9704	1,0502	0,6377
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	529	476	89,9811	511	455	89,0411	0,9400	-2,8035	4,7107	1,1054	0,7432	1,6440	1,0106	0,9693	1,0535	0,6208
> -2.5	165	151	91,5152	175	159	90,8571	0,6580	-5,6189	6,8442	1,0854	0,5121	2,3001	1,0072	0,9428	1,0761	0,8307
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	394	353	89,5939	365	317	86,8493	2,7446	-1,8525	7,4174	1,3037	0,8367	2,0314	1,0316	0,9791	1,0869	0,2403
> -3	300	274	91,3333	321	297	92,5234	-1,1900	-5,6252	3,1470	0,8516	0,4775	1,5188	0,9871	0,9421	1,0343	0,5860
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	152	89,4118	154	137	88,9610	0,4507	-6,3904	7,4842	1,0479	0,5193	2,1142	1,0051	0,9315	1,0844	0,8962
> -2.5	523	474	90,6310	532	477	89,6617	0,9693	-2,6616	4,5976	1,1154	0,7436	1,6731	1,0108	0,9713	1,0520	0,5974
Total Hip BMD T-score Group 2 at Baseline
<= -3	52	48	92,3077	51	42	82,3529	9,9548	-3,2762	23,3956	2,5714	0,7379	8,9615	1,1209	0,9654	1,3014	0,1282
> -3	641	578	90,1716	635	572	90,0787	0,0929	-3,2036	3,3947	1,0105	0,6995	1,4598	1,0010	0,9653	1,0381	0,9557
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	193	91,0377	207	191	92,2705	-1,2328	-6,6879	4,2242	0,8509	0,4249	1,7041	0,9866	0,9312	1,0453	0,6484

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Subject	Teriparatide Subject with Event	Teriparatide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
> -2.5	481	433	90,0208	479	423	88,3090	1,7118	-2,2461	5,6831	1,1942	0,7940	1,7962	1,0194	0,9754	1,0654	0,3935
Femoral Neck BMD T-score Group 2 at Baseline
<= -3	73	65	89,0411	78	70	89,7436	-0,7025	-11,1610	9,4832	0,9286	0,3294	2,6180	0,9922	0,8888	1,1076	0,8885
> -3	620	561	90,4839	608	544	89,4737	1,0102	-2,3671	4,4042	1,1186	0,7705	1,6242	1,0113	0,9742	1,0498	0,5555

The risk difference was calculated as (Abaloparatide-SC - Teriparatide). 95% CI was based on the Newcombe's method.

The odds ratio and relative risk were calculated as Abaloparatide-SC/Teriparatide. 95% CI was based on the Wald's method. When no event in one or more arms, zero cell correction of 0.5 to all cells was applied. see <https://training.cochrane.org/handbook/current/chapter-10>, section 10.4.4.1 Studies with no events in one or more arms.

P-value obtained from the Chi-Square test or Fisher's exact test if event count is less than 5 in either treatment group.

Tabelle 4-12: Subgruppenanalyse Schwere UE (sUE)

Subgroup	Abalopar- atide Total Subject	Abalopar- atide Subject with Event	Abalopar- atide Percent of Patients with Event	Teri- par- atide Total Sub- ject	Teri- par- atide Sub- ject with Event	Teripara- tide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
All Safety Population	694	38	5,4755	686	36	5,2478	0,2277	-2,1941	2,6484	1,0459	0,6546	1,6711	1,0434	0,6697	1,6257	0,8511
Age (Years)
<65	101	3	2,9703	99	4	4,0404	-1,0701	-7,2776	4,8644	0,7270	0,1585	3,3352	0,7351	0,1689	3,2007	0,7196
65 to <75	454	26	5,7269	443	22	4,9661	0,7607	-2,2635	3,7906	1,1625	0,6486	2,0835	1,1532	0,6637	2,0037	0,6127
>=75	139	9	6,4748	144	10	6,9444	-0,4696	-6,6330	5,7475	0,9277	0,3652	2,3567	0,9324	0,3907	2,2252	0,8746
Years Since Menopause
<15	136	6	4,4118	154	4	2,5974	1,8144	-2,7431	6,9437	1,7308	0,4780	6,2672	1,6985	0,4896	5,8927	0,5235
15 to <25	338	19	5,6213	324	14	4,3210	1,3003	-2,1371	4,7554	1,3189	0,6498	2,6767	1,3009	0,6635	2,5508	0,4422
>=25	220	13	5,9091	208	18	8,6538	-2,7448	-7,9525	2,2723	0,6629	0,3163	1,3895	0,6828	0,3433	1,3583	0,2735
Ethnicity
White	533	33	6,1914	513	32	6,2378	-0,0464	-3,0449	2,9254	0,9921	0,6004	1,6391	0,9926	0,6198	1,5895	0,9752
Black/African- American	26	0	0,0000	24	1	4,1667	-4,1667	-20,2418	9,1547	0,2956	0,0115	7,6116	0,3086	0,0132	7,2316	0,4800
Asian	128	5	3,9063	137	1	0,7299	3,1763	-0,7951	8,1254	5,5285	0,6370	47,9783	5,3516	0,6338	45,1893	0,1098
Other	7	0	0,0000	12	2	16,6667	-16,6667	-44,8031	20,7337	0,2800	0,0117	6,7174	0,3250	0,0178	5,9411	0,5088
Region
North America	17	2	11,7647	9	0	0,0000	11,7647	-19,3276	34,3364	3,0645	0,1324	70,9387	2,7778	0,1474	52,3507	0,5292
South America	222	8	3,6036	222	14	6,3063	-2,7027	-7,0748	1,4810	0,5554	0,2282	1,3516	0,5714	0,2446	1,3349	0,1895
Europe	330	23	6,9697	323	21	6,5015	0,4681	-3,4881	4,4159	1,0774	0,5839	1,9879	1,0720	0,6054	1,8981	0,8114
Asia	125	5	4,0000	132	1	0,7576	3,2424	-0,8583	8,3036	5,4583	0,6287	47,3901	5,2800	0,6255	44,5664	0,1118
Any Prior Fracture
Yes	405	23	5,6790	397	26	6,5491	-0,8701	-4,2962	2,5130	0,8591	0,4815	1,5328	0,8671	0,5035	1,4935	0,6070
No	289	15	5,1903	289	10	3,4602	1,7301	-1,7152	5,2906	1,5274	0,6745	3,4587	1,5000	0,6853	3,2832	0,3066
Any Prior Vertebral Fracture

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- atide Total Subject	Abalopar- atide Subject with Event	Abalopar- atide Percent of Patients with Event	Teri- para- atide Total Sub- ject	Teri- para- atide Sub- ject with Event	Teripara- atide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Yes	144	9	6,2500	182	10	5,4945	0,7555	-4,4653	6,5187	1,1467	0,4532	2,9013	1,1375	0,4748	2,7249	0,7725
No	550	29	5,2727	504	26	5,1587	0,1140	-2,6685	2,8404	1,0233	0,5941	1,7626	1,0221	0,6105	1,7113	0,9337
Any Prior Nonvertebral Fracture
Yes	306	18	5,8824	271	20	7,3801	-1,4977	-5,8045	2,6137	0,7844	0,4059	1,5159	0,7971	0,4307	1,4749	0,4691
No	388	20	5,1546	415	16	3,8554	1,2992	-1,6291	4,3487	1,3553	0,6918	2,6552	1,3370	0,7031	2,5423	0,3740
Any Prior Clinical Major Osteoporotic Fracture
Yes	237	15	6,3291	208	14	6,7308	-0,4017	-5,3093	4,2886	0,9363	0,4408	1,9889	0,9403	0,4650	1,9014	0,8640
No	457	23	5,0328	478	22	4,6025	0,4303	-2,3776	3,2887	1,0984	0,6034	1,9997	1,0935	0,6182	1,9341	0,7586
Prevalence of Vertebral Fracture at Baseline
Yes	144	9	6,2500	182	10	5,4945	0,7555	-4,4653	6,5187	1,1467	0,4532	2,9013	1,1375	0,4748	2,7249	0,7725
No	550	29	5,2727	504	26	5,1587	0,1140	-2,6685	2,8404	1,0233	0,5941	1,7626	1,0221	0,6105	1,7113	0,9337
Number of Prevalence of Vertebral Fracture at Baseline
0	550	29	5,2727	504	26	5,1587	0,1140	-2,6685	2,8404	1,0233	0,5941	1,7626	1,0221	0,6105	1,7113	0,9337
1	111	6	5,4054	126	8	6,3492	-0,9438	-7,3235	5,7092	0,8429	0,2832	2,5086	0,8514	0,3048	2,3782	0,7584
>=2	33	3	9,0909	56	2	3,5714	5,5195	-4,8952	20,2303	2,7000	0,4271	17,0691	2,5455	0,4482	14,4549	0,3554
Severity of Vertebral Fracture (SQ Score) at Baseline
0	550	29	5,2727	505	26	5,1485	0,1242	-2,6547	2,8488	1,0255	0,5954	1,7662	1,0241	0,6117	1,7147	0,9278
1	89	4	4,4944	106	5	4,7170	-0,2226	-6,6821	6,8091	0,9506	0,2474	3,6524	0,9528	0,2638	3,4414	1,0000
>=2	55	5	9,0909	75	5	6,6667	2,4242	-7,0945	13,5732	1,4000	0,3848	5,0942	1,3636	0,4149	4,4813	0,6083

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatid Total Subject	Abaloparatid Subject with Event	Abaloparatid Percent of Patients with Event	Teriparatid Total Subject	Teriparatid Subject with Event	Teriparatid Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Severe Disease (least BMD T-score <= -2.5 and Prevalent Vertebral Fracture) at Baseline
Yes	113	9	7,9646	142	8	5,6338	2,3308	-3,9716	9,3727	1,4495	0,5407	3,8863	1,4137	0,5635	3,5466	0,4586
No	581	29	4,9914	544	28	5,1471	-0,1557	-2,8077	2,4498	0,9682	0,5682	1,6498	0,9698	0,5847	1,6084	0,9053
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	529	28	5,2930	511	24	4,6967	0,5963	-2,1246	3,3123	1,1341	0,6482	1,9840	1,1270	0,6624	1,9175	0,6591
> -2.5	165	10	6,0606	175	12	6,8571	-0,7965	-6,2734	4,7515	0,8763	0,3681	2,0866	0,8838	0,3925	1,9904	0,7654
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	394	19	4,8223	365	15	4,1096	0,7127	-2,3674	3,7557	1,1822	0,5915	2,3628	1,1734	0,6054	2,2745	0,6353
> -3	300	19	6,3333	321	21	6,5421	-0,2087	-4,1581	3,8086	0,9659	0,5085	1,8347	0,9681	0,5312	1,7645	0,9157
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	5	2,9412	154	8	5,1948	-2,2536	-7,2634	2,2821	0,5530	0,1770	1,7280	0,5662	0,1892	1,6939	0,3020
> -2.5	523	33	6,3098	532	28	5,2632	1,0466	-1,8144	3,9452	1,2122	0,7216	2,0364	1,1989	0,7352	1,9548	0,4665
Total Hip BMD T-score Group 2 at Baseline
<= -3	52	1	1,9231	51	1	1,9608	-0,0377	-8,5303	8,3171	0,9804	0,0597	16,1080	0,9808	0,0630	15,2617	1,0000
> -3	641	37	5,7722	635	35	5,5118	0,2604	-2,3189	2,8401	1,0501	0,6526	1,6899	1,0472	0,6685	1,6407	0,8402
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	8	3,7736	207	11	5,3140	-1,5404	-5,9014	2,6549	0,6988	0,2753	1,7738	0,7101	0,2915	1,7298	0,4486

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Subject	Teriparatide Subject with Event	Teriparatide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
> -2.5	481	30	6,2370	479	25	5,2192	1,0178	-1,9801	4,0409	1,2080	0,6994	2,0865	1,1950	0,7137	2,0009	0,4975
Femoral Neck BMD T-score Group 2 at Baseline
<= -3	73	3	4,1096	78	5	6,4103	-2,3007	-10,4925	5,8486	0,6257	0,1441	2,7171	0,6411	0,1588	2,5876	0,7203
> -3	620	35	5,6452	608	31	5,0987	0,5465	-2,0267	3,1216	1,1136	0,6775	1,8303	1,1072	0,6918	1,7720	0,6712

The risk difference was calculated as (Abaloparatide-SC - Teriparatide). 95% CI was based on the Newcombe's method.

The odds ratio and relative risk were calculated as Abaloparatide-SC/Teriparatide. 95% CI was based on the Wald's method. When no event in one or more arms, zero cell correction of 0.5 to all cells was applied. see <https://training.cochrane.org/handbook/current/chapter-10>, section 10.4.4.1 Studies with no events in one or more arms.

P-value obtained from the Chi-Square test or Fisher's exact test if event count is less than 5 in either treatment group.

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Tabelle 4-13: Subgruppenanalyse Schwerwiegende UE (SUE)

Subgroup	Abalopar- tide Total Subject	Abalopar- tide Subject with Event	Abalopar- tide Percent of Patients with Event	Teri- para- tide Total Sub- ject	Teri- para- tide Sub- ject with Event	Teripara- tide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
All Safety Population	694	62	8,9337	686	64	9,3294	-0,3957	-3,4649	2,6649	0,9534	0,6609	1,3753	0,9576	0,6864	1,3359	0,7986
Age (Years)
<65	101	4	3,9604	99	9	9,0909	-5,1305	-12,8089	2,0374	0,4124	0,1227	1,3860	0,4356	0,1387	1,3686	0,1620
65 to <75	454	41	9,0308	443	36	8,1264	0,9044	-2,8143	4,6172	1,1223	0,7028	1,7924	1,1113	0,7243	1,7051	0,6288
>=75	139	17	12,2302	144	19	13,1944	-0,9642	-8,8386	6,9753	0,9167	0,4551	1,8466	0,9269	0,5029	1,7084	0,8077
Years Since Menopause
<15	136	11	8,0882	154	10	6,4935	1,5947	-4,5533	8,1052	1,2672	0,5208	3,0835	1,2456	0,5460	2,8415	0,6010
15 to <25	338	29	8,5799	324	23	7,0988	1,4811	-2,7049	5,6570	1,2282	0,6947	2,1714	1,2086	0,7145	2,0444	0,4789
>=25	220	22	10,0000	208	31	14,9038	-4,9038	-11,2973	1,3823	0,6344	0,3542	1,1362	0,6710	0,4019	1,1201	0,1237
Ethnicity
White	533	39	7,3171	513	49	9,5517	-2,2346	-5,6722	1,1515	0,7476	0,4818	1,1599	0,7661	0,5121	1,1460	0,1931
Black/African- American	26	0	0,0000	24	0	0,0000	.	.	.	0,9245	0,0177	48,4126	0,9259	0,0191	44,9269	.
Asian	128	22	17,1875	137	13	9,4891	7,6984	-0,5289	16,1035	1,9797	0,9511	4,1204	1,8113	0,9533	3,4417	0,0644
Other	7	1	14,2857	12	2	16,6667	-2,3810	-32,8599	36,5329	0,8333	0,0616	11,2772	0,8571	0,0938	7,8297	1,0000
Region
North America	17	1	5,8824	9	0	0,0000	5,8824	-24,4206	26,9820	1,7273	0,0638	46,7676	1,6667	0,0746	37,2138	1,0000
South America	222	12	5,4054	222	17	7,6577	-2,2523	-7,0892	2,4839	0,6891	0,3211	1,4788	0,7059	0,3453	1,4432	0,3369
Europe	330	27	8,1818	323	34	10,5263	-2,3445	-6,9115	2,1675	0,7574	0,4457	1,2872	0,7773	0,4803	1,2579	0,3033
Asia	125	22	17,6000	132	13	9,8485	7,7515	-0,7113	16,3518	1,9552	0,9379	4,0760	1,7871	0,9418	3,3909	0,0702
Any Prior Fracture
Yes	405	38	9,3827	397	45	11,3350	-1,9523	-6,2331	2,2959	0,8099	0,5134	1,2777	0,8278	0,5499	1,2461	0,3641
No	289	24	8,3045	289	19	6,5744	1,7301	-2,6383	6,1464	1,2870	0,6887	2,4051	1,2632	0,7077	2,2546	0,4280
Any Prior Vertebral Fracture

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- atide Total Subject	Abalopar- atide Subject with Event	Abalopar- atide Percent of Patients with Event	Teri- para- atide Total Sub- ject	Teri- para- atide Sub- ject with Event	Teripara- atide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Yes	144	9	6,2500	182	22	12,0879	-5,8379	-12,0998	0,7040	0,4848	0,2160	1,0884	0,5170	0,2457	1,0881	0,0744
No	550	53	9,6364	504	42	8,3333	1,3030	-2,2065	4,7715	1,1730	0,7675	1,7929	1,1564	0,7857	1,7019	0,4606
Any Prior Nonvertebral Fracture
Yes	306	31	10,1307	271	30	11,0701	-0,9394	-6,1212	4,1010	0,9056	0,5325	1,5399	0,9151	0,5693	1,4710	0,7142
No	388	31	7,9897	415	34	8,1928	-0,2031	-4,0158	3,6622	0,9731	0,5857	1,6167	0,9752	0,6116	1,5551	0,9160
Any Prior Clinical Major Osteoporotic Fracture
Yes	237	27	11,3924	208	26	12,5000	-1,1076	-7,3322	4,9331	0,9000	0,5070	1,5977	0,9114	0,5499	1,5106	0,7189
No	457	35	7,6586	478	38	7,9498	-0,2911	-3,7705	3,2160	0,9603	0,5953	1,5492	0,9634	0,6199	1,4972	0,8683
Prevalence of Vertebral Fracture at Baseline
Yes	144	9	6,2500	182	22	12,0879	-5,8379	-12,0998	0,7040	0,4848	0,2160	1,0884	0,5170	0,2457	1,0881	0,0744
No	550	53	9,6364	504	42	8,3333	1,3030	-2,2065	4,7715	1,1730	0,7675	1,7929	1,1564	0,7857	1,7019	0,4606
Number of Prevalence of Vertebral Fracture at Baseline
0	550	53	9,6364	504	42	8,3333	1,3030	-2,2065	4,7715	1,1730	0,7675	1,7929	1,1564	0,7857	1,7019	0,4606
1	111	8	7,2072	126	15	11,9048	-4,6976	-12,3592	3,1366	0,5748	0,2339	1,4122	0,6054	0,2668	1,3736	0,2228
>=2	33	1	3,0303	56	7	12,5000	-9,4697	-20,8711	4,3445	0,2188	0,0257	1,8632	0,2424	0,0312	1,8844	0,2494
Severity of Vertebral Fracture (SQ Score) at Baseline
0	550	53	9,6364	505	42	8,3168	1,3195	-2,1860	4,7855	1,1756	0,7692	1,7968	1,1587	0,7873	1,7053	0,4545
1	89	4	4,4944	106	11	10,3774	-5,8830	-13,6355	2,0122	0,4064	0,1247	1,3242	0,4331	0,1429	1,3130	0,1776
>=2	55	5	9,0909	75	11	14,6667	-5,5758	-16,5718	6,6449	0,5818	0,1898	1,7832	0,6198	0,2284	1,6819	0,3391

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- atide Total Subject	Abalopar- atide Subject with Event	Abalopar- atide Percent of Patients with Event	Teri- para- atide Total Sub- ject	Teri- para- atide Sub- ject with Event	Teripara- atide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Severe Disease (least BMD T-score <= -2.5 and Prevalent Vertebral Fracture) at Baseline
Yes	113	7	6,1947	142	17	11,9718	-5,7771	-12,8839	1,6748	0,4856	0,1940	1,2153	0,5174	0,2223	1,2044	0,1165
No	581	55	9,4664	544	47	8,6397	0,8267	-2,5759	4,1987	1,1057	0,7351	1,6631	1,0957	0,7558	1,5884	0,6294
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	529	48	9,0737	511	43	8,4149	0,6589	-2,8219	4,1250	1,0861	0,7060	1,6709	1,0783	0,7278	1,5977	0,7070
> -2.5	165	14	8,4848	175	21	12,0000	-3,5152	-10,0890	3,0967	0,6799	0,3334	1,3864	0,7071	0,3721	1,3435	0,2864
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	394	33	8,3756	365	30	8,2192	0,1565	-3,8716	4,1202	1,0208	0,6091	1,7106	1,0190	0,6347	1,6361	0,9378
> -3	300	29	9,6667	321	34	10,5919	-0,9252	-5,7121	3,9196	0,9033	0,5357	1,5232	0,9126	0,5705	1,4599	0,7027
Total Hip BMD T- score Group 1 at Baseline
<= -2.5	170	14	8,2353	154	11	7,1429	1,0924	-5,0433	7,0753	1,1667	0,5130	2,6533	1,1529	0,5397	2,4628	0,7129
> -2.5	523	48	9,1778	532	53	9,9624	-0,7846	-4,3675	2,8020	0,9133	0,6057	1,3770	0,9212	0,6354	1,3356	0,6650
Total Hip BMD T- score Group 2 at Baseline
<= -3	52	4	7,6923	51	2	3,9216	3,7707	-6,6269	14,6298	2,0417	0,3571	11,6720	1,9615	0,3756	10,2428	0,6781
> -3	641	58	9,0484	635	62	9,7638	-0,7154	-3,9511	2,5100	0,9194	0,6312	1,3393	0,9267	0,6591	1,3031	0,6616
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	20	9,4340	207	18	8,6957	0,7383	-4,9146	6,3719	1,0938	0,5610	2,1325	1,0849	0,5911	1,9913	0,7925

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Subject	Teriparatide Subject with Event	Teriparatide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
> -2.5	481	42	8,7318	479	46	9,6033	-0,8715	-4,5710	2,8158	0,9006	0,5807	1,3967	0,9092	0,6103	1,3547	0,6399
Femoral Neck BMD T-score Group 2 at Baseline
<= -3	73	12	16,4384	78	6	7,6923	8,7460	-1,8082	19,6840	2,3607	0,8364	6,6631	2,1370	0,8461	5,3976	0,0974
> -3	620	50	8,0645	608	58	9,5395	-1,4750	-4,6881	1,7137	0,8318	0,5598	1,2359	0,8454	0,5890	1,2133	0,3615

The risk difference was calculated as (Abaloparatide-SC - Teriparatide). 95% CI was based on the Newcombe's method.

The odds ratio and relative risk were calculated as Abaloparatide-SC/Teriparatide. 95% CI was based on the Wald's method. When no event in one or more arms, zero cell correction of 0.5 to all cells was applied. see <https://training.cochrane.org/handbook/current/chapter-10>, section 10.4.4.1 Studies with no events in one or more arms.

P-value obtained from the Chi-Square test or Fisher's exact test if event count is less than 5 in either treatment group.

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Tabelle 4-14: Subgruppenanalyse Therapieabbrüche aufgrund von UE

Subgroup	Abalopar- paratide Total Subject	Abalopar- paratide Subject with Event	Abalopar- paratide Percent of Patients with Event	Teri- paratide Total Sub- ject	Teri- paratide Sub- ject with Event	Teripara- tide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
All Safety Population	694	68	9,7983	686	46	6,7055	3,0927	0,1791	6,0316	1,5113	1,0232	2,2323	1,4612	1,0205	2,0923	0,0369
Age (Years)
<65	101	8	7,9208	99	4	4,0404	3,8804	-3,1591	11,2394	2,0430	0,5949	7,0163	1,9604	0,6098	6,3024	0,3730
65 to <75	454	48	10,5727	443	31	6,9977	3,5749	-0,1552	7,3334	1,5713	0,9801	2,5189	1,5109	0,9807	2,3278	0,0589
>=75	139	12	8,6331	144	11	7,6389	0,9942	-5,6113	7,7213	1,1424	0,4866	2,6823	1,1302	0,5159	2,4759	0,7596
Years Since Menopause
<15	136	13	9,5588	154	5	3,2468	6,3121	0,6420	12,6958	3,1496	1,0926	9,0789	2,9441	1,0774	8,0453	0,0262
15 to <25	338	35	10,3550	324	19	5,8642	4,4908	0,2943	8,7397	1,8543	1,0375	3,3141	1,7658	1,0318	3,0220	0,0348
>=25	220	20	9,0909	208	22	10,5769	-1,4860	-7,3146	4,2335	0,8455	0,4469	1,5996	0,8595	0,4836	1,5276	0,6055
Ethnicity
White	533	56	10,5066	513	36	7,0175	3,4890	0,0410	6,9524	1,5556	1,0043	2,4093	1,4972	1,0028	2,2352	0,0464
Black/African- American	26	0	0,0000	24	2	8,3333	-8,3333	-25,8488	5,8766	0,1698	0,0077	3,7242	0,1852	0,0093	3,6724	0,2253
Asian	128	12	9,3750	137	8	5,8394	3,5356	-3,0309	10,4489	1,6681	0,6588	4,2240	1,6055	0,6783	3,7998	0,2762
Other	7	0	0,0000	12	0	0,0000	.	.	.	1,6667	0,0298	93,1236	1,6250	0,0356	74,0851	.
Region
North America	17	3	17,6471	9	0	0,0000	17,6471	-14,3860	41,0295	4,5862	0,2120	99,1963	3,8889	0,2226	67,9453	0,5292
South America	222	9	4,0541	222	13	5,8559	-1,8018	-6,1464	2,4183	0,6793	0,2843	1,6232	0,6923	0,3021	1,5866	0,3817
Europe	330	44	13,3333	323	25	7,7399	5,5934	0,8646	10,3596	1,8338	1,0935	3,0753	1,7227	1,0807	2,7461	0,0201
Asia	125	12	9,6000	132	8	6,0606	3,5394	-3,2289	10,6189	1,6460	0,6493	4,1727	1,5840	0,6699	3,7451	0,2898
Any Prior Fracture
Yes	405	36	8,8889	397	24	6,0453	2,8435	-0,8377	6,5666	1,5163	0,8870	2,5920	1,4704	0,8940	2,4184	0,1259
No	289	32	11,0727	289	22	7,6125	3,4602	-1,3365	8,3136	1,5111	0,8553	2,6700	1,4545	0,8667	2,4411	0,1529
Any Prior Vertebral Fracture

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- atide Total Subject	Abalopar- atide Subject with Event	Abalopar- atide Percent of Patients with Event	Teri- para- atide Total Sub- ject	Teri- para- atide Sub- ject with Event	Teripara- atide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Yes	144	13	9,0278	182	11	6,0440	2,9838	-2,7905	9,3594	1,5427	0,6696	3,5541	1,4937	0,6898	3,2345	0,3056
No	550	55	10,0000	504	35	6,9444	3,0556	-0,3441	6,4373	1,4889	0,9568	2,3169	1,4400	0,9593	2,1616	0,0762
Any Prior Nonvertebral Fracture
Yes	306	29	9,4771	271	19	7,0111	2,4661	-2,1555	7,0040	1,3886	0,7597	2,5380	1,3517	0,7761	2,3544	0,2844
No	388	39	10,0515	415	27	6,5060	3,5455	-0,2789	7,4836	1,6059	0,9628	2,6784	1,5450	0,9649	2,4738	0,0676
Any Prior Clinical Major Osteoporotic Fracture
Yes	237	19	8,0169	208	14	6,7308	1,2861	-3,8158	6,2377	1,2077	0,5897	2,4736	1,1911	0,6127	2,3155	0,6054
No	457	49	10,7221	478	32	6,6946	4,0275	0,4069	7,7309	1,6739	1,0511	2,6655	1,6016	1,0454	2,4538	0,0286
Prevalence of Vertebral Fracture at Baseline
Yes	144	13	9,0278	182	11	6,0440	2,9838	-2,7905	9,3594	1,5427	0,6696	3,5541	1,4937	0,6898	3,2345	0,3056
No	550	55	10,0000	504	35	6,9444	3,0556	-0,3441	6,4373	1,4889	0,9568	2,3169	1,4400	0,9593	2,1616	0,0762
Number of Prevalence of Vertebral Fracture at Baseline
0	550	55	10,0000	504	35	6,9444	3,0556	-0,3441	6,4373	1,4889	0,9568	2,3169	1,4400	0,9593	2,1616	0,0762
1	111	11	9,9099	126	10	7,9365	1,9734	-5,4471	9,8020	1,2760	0,5203	3,1296	1,2486	0,5513	2,8279	0,5937
>=2	33	2	6,0606	56	1	1,7857	4,2749	-4,5501	17,9000	3,5484	0,3091	40,7304	3,3939	0,3199	36,0028	0,5525
Severity of Vertebral Fracture (SQ Score) at Baseline
0	550	55	10,0000	505	36	7,1287	2,8713	-0,5450	6,2678	1,4475	0,9334	2,2448	1,4028	0,9380	2,0978	0,0970
1	89	11	12,3596	106	6	5,6604	6,6992	-1,4239	15,6616	2,3504	0,8326	6,6356	2,1835	0,8411	5,6684	0,0986
>=2	55	2	3,6364	75	4	5,3333	-1,6970	-9,7333	7,5747	0,6698	0,1182	3,7943	0,6818	0,1295	3,5907	1,0000

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- atide Total Subject	Abalopar- atide Subject with Event	Abalopar- atide Percent of Patients with Event	Teri- para- atide Total Sub- ject	Teri- para- atide Sub- ject with Event	Teripara- atide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Severe Disease (least BMD T-score <= -2.5 and Prevalent Vertebral Fracture) at Baseline
Yes	113	10	8,8496	142	7	4,9296	3,9200	-2,3842	11,0576	1,8724	0,6893	5,0863	1,7952	0,7057	4,5670	0,2125
No	581	58	9,9828	544	39	7,1691	2,8137	-0,4898	6,1095	1,4360	0,9399	2,1940	1,3925	0,9440	2,0539	0,0929
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	529	52	9,8299	511	34	6,6536	3,1762	-0,1906	6,5625	1,5294	0,9747	2,3998	1,4774	0,9757	2,2369	0,0630
> -2.5	165	16	9,6970	175	12	6,8571	2,8398	-3,1402	9,0303	1,4586	0,6681	3,1843	1,4141	0,6900	2,8984	0,3411
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	394	39	9,8985	365	26	7,1233	2,7752	-1,2605	6,7895	1,4324	0,8532	2,4047	1,3896	0,8639	2,2353	0,1722
> -3	300	29	9,6667	321	20	6,2305	3,4361	-0,8475	7,8701	1,6105	0,8902	2,9137	1,5515	0,8974	2,6824	0,1125
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	13	7,6471	154	6	3,8961	3,7510	-1,5985	9,1695	2,0425	0,7566	5,5136	1,9627	0,7648	5,0369	0,1513
> -2.5	523	55	10,5163	532	40	7,5188	2,9975	-0,4743	6,5107	1,4455	0,9436	2,2143	1,3987	0,9479	2,0637	0,0890
Total Hip BMD T-score Group 2 at Baseline
<= -3	52	5	9,6154	51	2	3,9216	5,6938	-5,0748	17,0488	2,6064	0,4819	14,0962	2,4519	0,4982	12,0680	0,4367
> -3	641	63	9,8284	635	44	6,9291	2,8993	-0,1551	5,9787	1,4640	0,9796	2,1880	1,4184	0,9806	2,0517	0,0617
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	20	9,4340	207	11	5,3140	4,1200	-0,9909	9,3509	1,8561	0,8661	3,9774	1,7753	0,8725	3,6123	0,1072

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Subject	Teriparatide Subject with Event	Teriparatide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
> -2.5	481	48	9,9792	479	35	7,3069	2,6723	-0,9093	6,2845	1,4063	0,8919	2,2172	1,3657	0,9002	2,0721	0,1407
Femoral Neck BMD T-score Group 2 at Baseline
<= -3	73	7	9,5890	78	5	6,4103	3,1788	-5,9582	12,8010	1,5485	0,4688	5,1152	1,4959	0,4968	4,5045	0,4705
> -3	620	61	9,8387	608	41	6,7434	3,0953	-0,0043	6,2184	1,5091	0,9988	2,2801	1,4590	0,9981	2,1328	0,0494

The risk difference was calculated as (Abaloparatide-SC - Teriparatide). 95% CI was based on the Newcombe's method.

The odds ratio and relative risk were calculated as Abaloparatide-SC/Teriparatide. 95% CI was based on the Wald's method. When no event in one or more arms, zero cell correction of 0.5 to all cells was applied. see <https://training.cochrane.org/handbook/current/chapter-10>, section 10.4.4.1 Studies with no events in one or more arms.

P-value obtained from the Chi-Square test or Fisher's exact test if event count is less than 5 in either treatment group.

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

4.1.3 Subgruppenanalysen für den Endpunkt Nebenwirkungen – Unerwünschte Ereignisse gegliedert nach SOC und PT**4.1.3.1 Ergebnisse der Interaktionsterme**

Tabelle 4-15: Ergebnisse der Interaktionsterme für den Endpunkt Nebenwirkungen – Unerwünschte Ereignisse gegliedert nach SOC und PT

Category	Age	Years Since Menopause	Ethnicity	Region	Any Prior Fracture	Any Prior Vertebral Fracture	Any Prior Non-vertebral Fracture	Any Prior Clinical MOF	Num of Prevalence of VF	Severity of VF (SQ Score)	Severe Disease at Baseline	Lumbar Spine BMD T-score Cutoff - 2.5	Lumbar Spine BMD T-score Cutoff - 3	Total Hip BMD T-score Cutoff - 2.5	Total Hip BMD T-score Cutoff - 3	Femoral Neck BMD T-score Cutoff - 2.5	Femoral Neck BMD T-score Cutoff - 3
PT=Bronchitis	0,3486	0,7250	0,4997	0,6668	0,0316	0,2112	0,0046	0,4924	0,0237	0,4382	0,0212	0,2729	0,2492	0,0064	NA	0,0002	0,1310
PT=Hypercalcaemia	0,2568	0,4649	0,7681	0,6256	0,9655	0,8832	0,3076	0,6437	0,8070	0,6439	0,8604	0,1508	0,2547	0,3742	0,7893	0,1817	0,0160
PT=Influenza	0,5550	0,7117	0,6180	0,4537	0,4277	0,1479	0,7150	0,8665	0,1890	0,2429	0,3909	0,5346	0,2878	0,2214	0,1397	0,1421	0,8621
PT=Nausea	0,4807	0,2817	0,7915	0,9253	0,0195	0,6554	0,7641	0,8315	0,5787	0,6255	0,3943	0,1853	0,1355	0,2233	0,9255	0,1829	0,9807
PT=Osteoarthritis	0,4995	0,6499	0,6710	0,5761	0,9950	0,9657	0,8896	0,1012	0,8447	0,9317	0,6294	0,3787	0,5524	0,9465	0,9679	0,6582	0,1727
PT=Palpitations	0,1652	0,3828	0,5270	0,7418	0,6022	0,1411	0,3897	0,9360	0,3515	0,3445	0,1996	0,7925	0,8681	0,2511	0,5496	0,2902	0,4689
SOC=Cardiac disorders	0,5225	0,5691	0,4153	0,8849	0,6579	0,7543	0,5027	0,5443	0,9649	0,9166	0,2861	0,1101	0,0919	0,0687	0,7418	0,6492	0,1933
SOC=Nervous system disorders	0,6067	0,5352	0,6692	0,5723	0,9130	0,6226	0,2664	0,2540	0,5044	0,8802	0,7826	0,6400	0,8359	0,7593	0,2309	0,6959	0,1499
SOC=Reproductive system and breast disorders	0,7789	0,3656	0,9924	0,9178	0,1549	0,6836	0,2321	0,8132	0,4609	0,1671	0,5339	0,3914	0,0867	0,6596	0,9950	0,4613	0,2249

Note: Treatment-subgroup interactions were assessed by the Breslow-Day test.

NA=Not available.

4.1.3.2 Nebenwirkungen – Unerwünschte Ereignisse gegliedert nach SOC und PT

Tabelle 4-16: Subgruppenanalyse Jegliche UE – PT Bronchitis

Subgroup	Abalopar- atide Total Subject	Abalopar- atide Subject with Event	Abalopar- atide Percent of Patients with Event	Teri- para- atide Total Sub- ject	Teri- para- atide Sub- ject with Event	Teripara- atide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
All Safety Population	694	12	1,7291	686	24	3,4985	-1,7694	-3,5806	-0,0662	0,4853	0,2407	0,9785	0,4942	0,2492	0,9803	0,0392
Age (Years)
<65	101	2	1,9802	99	5	5,0505	-3,0703	-9,4657	2,6574	0,3798	0,0719	2,0054	0,3921	0,0779	1,9737	0,2767
65 to <75	454	7	1,5419	443	17	3,8375	-2,2956	-4,6546	-0,1465	0,3924	0,1611	0,9557	0,4018	0,1683	0,9594	0,0332
>=75	139	3	2,1583	144	2	1,3889	0,7694	-3,0392	4,8892	1,5662	0,2577	9,5183	1,5540	0,2636	9,1592	0,6798
Years Since Menopause
<15	136	3	2,2059	154	10	6,4935	-4,2876	-9,5387	0,7335	0,3248	0,0875	1,2057	0,3397	0,0955	1,2089	0,0931
15 to <25	338	6	1,7751	324	9	2,7778	-1,0026	-3,6023	1,4241	0,6325	0,2226	1,7975	0,6391	0,2301	1,7752	0,3862
>=25	220	3	1,3636	208	5	2,4038	-1,0402	-4,2669	1,8718	0,5613	0,1324	2,3788	0,5673	0,1373	2,3439	0,4929
Ethnicity
White	533	12	2,2514	513	23	4,4834	-2,2320	-4,5900	-0,0229	0,4907	0,2415	0,9968	0,5022	0,2525	0,9985	0,0448
Black/African- American	26	0	0,0000	24	0	0,0000	.	.	.	0,9245	0,0177	48,4126	0,9259	0,0191	44,9269	.
Asian	128	0	0,0000	137	1	0,7299	-0,7299	-4,0186	2,2451	0,3541	0,0143	8,7709	0,3566	0,0147	8,6748	1,0000
Other	7	0	0,0000	12	0	0,0000	.	.	.	1,6667	0,0298	93,1236	1,6250	0,0356	74,0851	.
Region
North America	17	2	11,7647	9	1	11,1111	0,6536	-32,8261	24,9988	1,0667	0,0834	13,6501	1,0588	0,1104	10,1508	1,0000
South America	222	1	0,4505	222	5	2,2523	-1,8018	-4,7361	0,6240	0,1964	0,0228	1,6947	0,2000	0,0236	1,6981	0,2156
Europe	330	9	2,7273	323	17	5,2632	-2,5359	-5,8027	0,5371	0,5047	0,2216	1,1493	0,5182	0,2344	1,1455	0,0975
Asia	125	0	0,0000	132	1	0,7576	-0,7576	-4,1663	2,2885	0,3493	0,0141	8,6541	0,3519	0,0145	8,5572	1,0000
Any Prior Fracture
Yes	405	10	2,4691	397	11	2,7708	-0,3016	-2,7022	2,0528	0,8884	0,3730	2,1158	0,8911	0,3828	2,0748	0,7891
No	289	2	0,6920	289	13	4,4983	-3,8062	-6,8920	-1,2274	0,1479	0,0331	0,6616	0,1538	0,0350	0,6757	0,0067

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- tide Total Subject	Abalopar- tide Subject with Event	Abalopar- tide Percent of Patients with Event	Teri- para- tide Total Sub- ject	Teri- para- tide Sub- ject with Event	Teripara- tide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Any Prior Vertebral Fracture
Yes	144	4	2,7778	182	5	2,7473	0,0305	-3,8767	4,4635	1,0114	0,2666	3,8371	1,0111	0,2765	3,6970	1,0000
No	550	8	1,4545	504	19	3,7698	-2,3153	-4,4798	-0,3829	0,3768	0,1635	0,8685	0,3858	0,1704	0,8736	0,0175
Any Prior Nonvertebral Fracture
Yes	306	10	3,2680	271	7	2,5830	0,6849	-2,3535	3,6413	1,2741	0,4782	3,3950	1,2652	0,4883	3,2777	0,6273
No	388	2	0,5155	415	17	4,0964	-3,5809	-5,9756	-1,5493	0,1213	0,0278	0,5286	0,1258	0,0293	0,5411	0,0007
Any Prior Clinical Major Osteoporotic Fracture
Yes	237	7	2,9536	208	10	4,8077	-1,8541	-5,9588	1,8650	0,6026	0,2252	1,6127	0,6143	0,2381	1,5850	0,3086
No	457	5	1,0941	478	14	2,9289	-1,8348	-3,8608	0,0256	0,3666	0,1310	1,0262	0,3736	0,1356	1,0287	0,0469
Prevalence of Vertebral Fracture at Baseline
Yes	144	4	2,7778	182	5	2,7473	0,0305	-3,8767	4,4635	1,0114	0,2666	3,8371	1,0111	0,2765	3,6970	1,0000
No	550	8	1,4545	504	19	3,7698	-2,3153	-4,4798	-0,3829	0,3768	0,1635	0,8685	0,3858	0,1704	0,8736	0,0175
Number of Prevalence of Vertebral Fracture at Baseline
0	550	8	1,4545	504	19	3,7698	-2,3153	-4,4798	-0,3829	0,3768	0,1635	0,8685	0,3858	0,1704	0,8736	0,0175
1	111	4	3,6036	126	1	0,7937	2,8100	-1,3758	8,1475	4,6729	0,5144	42,4462	4,5405	0,5151	40,0228	0,1887
>=2	33	0	0,0000	56	4	7,1429	-7,1429	-16,9754	4,1476	0,1741	0,0091	3,3393	0,1863	0,0103	3,3541	0,2923
Severity of Vertebral Fracture (SQ Score) at Baseline
0	550	8	1,4545	505	19	3,7624	-2,3078	-4,4686	-0,3772	0,3775	0,1638	0,8702	0,3866	0,1708	0,8753	0,0177
1	89	2	2,2472	106	2	1,8868	0,3604	-4,6451	6,1060	1,1954	0,1650	8,6627	1,1910	0,1712	8,2847	1,0000
>=2	55	2	3,6364	75	3	4,0000	-0,3636	-7,9485	8,7130	0,9057	0,1462	5,6121	0,9091	0,1572	5,2579	1,0000

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- atide Total Subject	Abalopar- atide Subject with Event	Abalopar- atide Percent of Patients with Event	Teri- para- atide Total Sub- ject	Teri- para- atide Sub- ject with Event	Teripara- atide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Severe Disease (least BMD T-score <= -2.5 and Prevalent Vertebral Fracture) at Baseline
Yes	113	4	3,5398	142	2	1,4085	2,1314	-2,0481	7,4403	2,5688	0,4619	14,2846	2,5133	0,4687	13,4757	0,4106
No	581	8	1,3769	544	22	4,0441	-2,6672	-4,7817	-0,7755	0,3313	0,1462	0,7505	0,3405	0,1529	0,7583	0,0055
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	529	6	1,1342	511	16	3,1311	-1,9969	-3,9879	-0,2180	0,3549	0,1378	0,9143	0,3622	0,1429	0,9184	0,0253
> -2.5	165	6	3,6364	175	8	4,5714	-0,9351	-5,5593	3,7084	0,7877	0,2674	2,3209	0,7955	0,2820	2,2436	0,6645
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	394	4	1,0152	365	12	3,2877	-2,2724	-4,7223	-0,1740	0,3017	0,0964	0,9440	0,3088	0,1005	0,9489	0,0408
> -3	300	8	2,6667	321	12	3,7383	-1,0717	-4,0556	1,8949	0,7055	0,2843	1,7505	0,7133	0,2957	1,7209	0,4497
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	5	2,9412	154	1	0,6494	2,2918	-1,0908	6,0879	4,6364	0,5356	40,1332	4,5294	0,5351	38,3412	0,2178
> -2.5	523	7	1,3384	532	23	4,3233	-2,9849	-5,1762	-0,9881	0,3002	0,1277	0,7058	0,3096	0,1340	0,7152	0,0035
Total Hip BMD T-score Group 2 at Baseline
<= -3	52	0	0,0000	51	0	0,0000	.	.	.	0,9810	0,0191	50,3752	0,9811	0,0198	48,5293	.
> -3	641	12	1,8721	635	24	3,7795	-1,9075	-3,8605	-0,0674	0,4857	0,2407	0,9799	0,4953	0,2499	0,9818	0,0396
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	8	3,7736	207	2	0,9662	2,8074	-0,2922	6,3717	4,0196	0,8433	19,1585	3,9057	0,8393	18,1748	0,1054
> -2.5	481	4	0,8316	479	22	4,5929	-3,7613	-6,0806	-1,7540	0,1742	0,0596	0,5094	0,1811	0,0629	0,5215	0,0003

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Subject	Teriparatide Subject with Event	Teriparatide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Femoral Neck BMD T-score Group 2 at Baseline
<= -3	73	1	1,3699	78	0	0,0000	1,3699	-3,4575	7,3597	3,2483	0,1302	81,0134	3,2027	0,1325	77,3900	0,4834
> -3	620	11	1,7742	608	24	3,9474	-2,1732	-4,1894	-0,2945	0,4395	0,2134	0,9053	0,4495	0,2221	0,9095	0,0221

Each patient was counted once for the same system organ class and the same preferred term.

The risk difference was calculated as (Abaloparatide-SC - Teriparatide). 95% CI was based on the Newcombe's method.

The odds ratio and relative risk were calculated as Abaloparatide-SC/Teriparatide. 95% CI was based on the Wald's method. When no event in one or more arms, zero cell correction of 0.5 to all cells was applied. see <https://training.cochrane.org/handbook/current/chapter-10>, section 10.4.4.1 Studies with no events in one or more arms.

P-value obtained from the Chi-Square test or Fisher's exact test if event count is less than 5 in either treatment group.

Tabelle 4-17: Subgruppenanalyse Jegliche UE – PT Hyperkalzämie

Subgroup	Abalopar- paratide Total Subject	Abalopar- paratide Subject with Event	Abalopar- paratide Percent of Patients with Event	Teri- para- tide Total Sub- ject	Teri- para- tide Sub- ject with Event	Teripara- tide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
All Safety Population	694	11	1,5850	686	28	4,0816	-2,4966	-4,3845	-0,7475	0,3785	0,1869	0,7664	0,3883	0,1949	0,7738	0,0051
Age (Years)
<65	101	2	1,9802	99	1	1,0101	0,9701	-3,7451	5,9938	1,9798	0,1766	22,1900	1,9604	0,1806	21,2752	1,0000
65 to <75	454	7	1,5419	443	18	4,0632	-2,5214	-4,9237	-0,3388	0,3697	0,1529	0,8942	0,3795	0,1601	0,8996	0,0218
>=75	139	2	1,4388	144	9	6,2500	-4,8112	-10,1157	-0,1281	0,2190	0,0465	1,0322	0,2302	0,0506	1,0467	0,0608
Years Since Menopause
<15	136	3	2,2059	154	4	2,5974	-0,3915	-4,5441	3,9835	0,8459	0,1859	3,8483	0,8493	0,1935	3,7273	1,0000
15 to <25	338	4	1,1834	324	14	4,3210	-3,1376	-6,0296	-0,6270	0,2652	0,0864	0,8143	0,2739	0,0911	0,8234	0,0158
>=25	220	4	1,8182	208	10	4,8077	-2,9895	-6,9620	0,5269	0,3667	0,1132	1,1879	0,3782	0,1205	1,1871	0,1044
Ethnicity
White	533	7	1,3133	513	18	3,5088	-2,1955	-4,2772	-0,3201	0,3660	0,1516	0,8837	0,3743	0,1577	0,8886	0,0201
Black/African- American	26	0	0,0000	24	1	4,1667	-4,1667	-20,2418	9,1547	0,2956	0,0115	7,6116	0,3086	0,0132	7,2316	0,4800
Asian	128	4	3,1250	137	9	6,5693	-3,4443	-9,2116	2,1177	0,4588	0,1377	1,5284	0,4757	0,1502	1,5067	0,2585
Other	7	0	0,0000	12	0	0,0000	.	.	.	1,6667	0,0298	93,1236	1,6250	0,0356	74,0851	.
Region
North America	17	0	0,0000	9	0	0,0000	.	.	.	0,5429	0,0100	29,6009	0,5556	0,0119	25,9239	.
South America	222	3	1,3514	222	12	5,4054	-4,0541	-7,9606	-0,6322	0,2397	0,0667	0,8615	0,2500	0,0715	0,8738	0,0322
Europe	330	4	1,2121	323	7	2,1672	-0,9551	-3,3121	1,2150	0,5539	0,1606	1,9106	0,5593	0,1653	1,8923	0,3790
Asia	125	4	3,2000	132	9	6,8182	-3,6182	-9,5780	2,0948	0,4518	0,1355	1,5064	0,4693	0,1483	1,4854	0,2568
Any Prior Fracture
Yes	405	4	0,9877	397	10	2,5189	-1,5312	-3,6730	0,3750	0,3860	0,1201	1,2412	0,3921	0,1240	1,2399	0,1121
No	289	7	2,4221	289	18	6,2284	-3,8062	-7,4276	-0,4468	0,3737	0,1537	0,9090	0,3889	0,1649	0,9169	0,0245
Any Prior Vertebral Fracture
Yes	144	1	0,6944	182	4	2,1978	-1,5034	-4,8684	1,9051	0,3112	0,0344	2,8150	0,3160	0,0357	2,7962	0,3882

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- atid Total Subject	Abalopar- atid Subject with Event	Abalopar- atid Percent of Patients with Event	Teri- para- atid Total Sub- ject	Teri- para- atid Sub- ject with Event	Teripara- atid Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
No	550	10	1,8182	504	24	4,7619	-2,9437	-5,3183	-0,7958	0,3704	0,1753	0,7824	0,3818	0,1844	0,7905	0,0069
Any Prior Nonvertebral Fracture
Yes	306	4	1,3072	271	5	1,8450	-0,5378	-3,0674	1,7276	0,7046	0,1873	2,6512	0,7085	0,1922	2,6116	0,7408
No	388	7	1,8041	415	23	5,5422	-3,7380	-6,5330	-1,1260	0,3131	0,1328	0,7383	0,3255	0,1413	0,7500	0,0053
Any Prior Clinical Major Osteoporotic Fracture
Yes	237	3	1,2658	208	5	2,4038	-1,1380	-4,3474	1,6174	0,5205	0,1229	2,2050	0,5266	0,1274	2,1768	0,4822
No	457	8	1,7505	478	23	4,8117	-3,0612	-5,5215	-0,7626	0,3525	0,1560	0,7963	0,3638	0,1644	0,8050	0,0090
Prevalence of Vertebral Fracture at Baseline
Yes	144	1	0,6944	182	4	2,1978	-1,5034	-4,8684	1,9051	0,3112	0,0344	2,8150	0,3160	0,0357	2,7962	0,3882
No	550	10	1,8182	504	24	4,7619	-2,9437	-5,3183	-0,7958	0,3704	0,1753	0,7824	0,3818	0,1844	0,7905	0,0069
Number of Prevalence of Vertebral Fracture at Baseline
0	550	10	1,8182	504	24	4,7619	-2,9437	-5,3183	-0,7958	0,3704	0,1753	0,7824	0,3818	0,1844	0,7905	0,0069
1	111	1	0,9009	126	4	3,1746	-2,2737	-7,0358	2,1928	0,2773	0,0305	2,5185	0,2838	0,0322	2,5014	0,3748
>=2	33	0	0,0000	56	0	0,0000	.	.	.	1,6866	0,0327	86,9952	1,6765	0,0340	82,5615	.
Severity of Vertebral Fracture (SQ Score) at Baseline
0	550	10	1,8182	505	24	4,7525	-2,9343	-5,3049	-0,7885	0,3711	0,1757	0,7840	0,3826	0,1848	0,7921	0,0070
1	89	0	0,0000	106	2	1,8868	-1,8868	-6,6199	2,4711	0,2335	0,0111	4,9282	0,2378	0,0116	4,8889	0,5012
>=2	55	1	1,8182	75	2	2,6667	-0,8485	-7,5622	7,1753	0,6759	0,0597	7,6479	0,6818	0,0634	7,3310	1,0000
Severe Disease (least BMD T-score <= -2.5 and Prevalent

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- atide Total Subject	Abalopar- atide Subject with Event	Abalopar- atide Percent of Patients with Event	Teri- para- atide Total Sub- ject	Teri- para- atide Sub- ject with Event	Teripara- atide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Vertebral Fracture) at Baseline																
Yes	113	1	0,8850	142	4	2,8169	-1,9319	-6,1964	2,3822	0,3080	0,0339	2,7952	0,3142	0,0356	2,7717	0,3864
No	581	10	1,7212	544	24	4,4118	-2,6906	-4,9028	-0,6773	0,3795	0,1797	0,8011	0,3901	0,1883	0,8082	0,0084
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	529	11	2,0794	511	23	4,5010	-2,4216	-4,7692	-0,2359	0,4506	0,2173	0,9341	0,4620	0,2276	0,9379	0,0281
> -2.5	165	0	0,0000	175	5	2,8571	-2,8571	-6,5131	-0,0579	0,0937	0,0051	1,7071	0,0964	0,0054	1,7296	0,0287
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	394	10	2,5381	365	20	5,4795	-2,9414	-5,9994	-0,1282	0,4492	0,2074	0,9730	0,4632	0,2198	0,9763	0,0377
> -3	300	1	0,3333	321	8	2,4922	-2,1589	-4,5226	-0,1992	0,1309	0,0163	1,0525	0,1338	0,0168	1,0630	0,0387
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	6	3,5294	154	10	6,4935	-2,9641	-8,3568	1,9577	0,5268	0,1868	1,4854	0,5435	0,2023	1,4604	0,2188
> -2.5	523	5	0,9560	532	18	3,3835	-2,4274	-4,4057	-0,6631	0,2756	0,1016	0,7480	0,2826	0,1057	0,7555	0,0069
Total Hip BMD T-score Group 2 at Baseline
<= -3	52	2	3,8462	51	4	7,8431	-3,9970	-15,0117	6,2996	0,4700	0,0822	2,6870	0,4904	0,0939	2,5607	0,4367
> -3	641	9	1,4041	635	24	3,7795	-2,3755	-4,2776	-0,6293	0,3625	0,1672	0,7862	0,3715	0,1740	0,7929	0,0075
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	7	3,3019	207	11	5,3140	-2,0121	-6,3094	2,0681	0,6084	0,2312	1,6012	0,6214	0,2456	1,5718	0,3098
> -2.5	481	4	0,8316	479	17	3,5491	-2,7175	-4,8398	-0,8728	0,2279	0,0761	0,6824	0,2343	0,0794	0,6912	0,0039
Femoral Neck BMD T-score Group 2 at Baseline

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Sub- ject	Teriparatide Sub- ject with Event	Teriparatide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
<= -3	73	6	8,2192	78	5	6,4103	1,8089	-7,0874	11,1252	1,3075	0,3813	4,4833	1,2822	0,4088	4,0215	0,6691
> -3	620	5	0,8065	608	23	3,7829	-2,9764	-4,8632	-1,3334	0,2068	0,0781	0,5475	0,2132	0,0816	0,5571	0,0005

Each patient was counted once for the same system organ class and the same preferred term.

The risk difference was calculated as (Abaloparatide-SC - Teriparatide). 95% CI was based on the Newcombe's method.

The odds ratio and relative risk were calculated as Abaloparatide-SC/Teriparatide. 95% CI was based on the Wald's method. When no event in one or more arms, zero cell correction of 0.5 to all cells was applied. see <https://training.cochrane.org/handbook/current/chapter-10>, section 10.4.4.1 Studies with no events in one or more arms.

P-value obtained from the Chi-Square test or Fisher's exact test if event count is less than 5 in either treatment group.

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Tabelle 4-18: Subgruppenanalyse Jegliche UE – PT Influenza

Subgroup	Abalopar- paratide Total Subject	Abalopar- paratide Subject with Event	Abalopar- paratide Percent of Patients with Event	Teri- para- tide Total Sub- ject	Teri- para- tide Sub- ject with Event	Teripara- tide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
All Safety Population	694	43	6,1960	686	23	3,3528	2,8432	0,5859	5,1701	1,9040	1,1345	3,1954	1,8480	1,1263	3,0323	0,0133
Age (Years)
<65	101	3	2,9703	99	2	2,0202	0,9501	-4,4640	6,5465	1,4847	0,2427	9,0820	1,4703	0,2510	8,6111	1,0000
65 to <75	454	26	5,7269	443	16	3,6117	2,1151	-0,7005	4,9971	1,6212	0,8574	3,0655	1,5856	0,8625	2,9149	0,1338
>=75	139	14	10,0719	144	5	3,4722	6,5997	0,6701	13,0365	3,1136	1,0903	8,8914	2,9007	1,0734	7,8391	0,0266
Years Since Menopause
<15	136	8	5,8824	154	6	3,8961	1,9862	-3,2200	7,6825	1,5417	0,5211	4,5607	1,5098	0,5374	4,2421	0,4310
15 to <25	338	20	5,9172	324	8	2,4691	3,4480	0,3442	6,7258	2,4843	1,0783	5,7233	2,3964	1,0708	5,3635	0,0276
>=25	220	15	6,8182	208	9	4,3269	2,4913	-2,0481	7,0907	1,6179	0,6921	3,7819	1,5758	0,7050	3,5222	0,2629
Ethnicity
White	533	36	6,7542	513	21	4,0936	2,6607	-0,1160	5,4870	1,6970	0,9767	2,9485	1,6500	0,9767	2,7874	0,0581
Black/African- American	26	4	15,3846	24	1	4,1667	11,2179	-7,3209	29,6854	4,1818	0,4329	40,3933	3,6923	0,4432	30,7583	0,3508
Asian	128	2	1,5625	137	0	0,0000	1,5625	-1,3910	5,5181	5,4348	0,2584	114,293 4	5,3488	0,2592	110,359 1	0,2324
Other	7	1	14,2857	12	1	8,3333	5,9524	-23,5308	43,6072	1,8333	0,0964	34,8491	1,7143	0,1260	23,3212	1,0000
Region
North America	17	1	5,8824	9	0	0,0000	5,8824	-24,4206	26,9820	1,7273	0,0638	46,7676	1,6667	0,0746	37,2138	1,0000
South America	222	19	8,5586	222	8	3,6036	4,9550	0,4544	9,7157	2,5037	1,0722	5,8465	2,3750	1,0620	5,3113	0,0289
Europe	330	21	6,3636	323	15	4,6440	1,7197	-1,8795	5,3684	1,3955	0,7062	2,7576	1,3703	0,7192	2,6107	0,3357
Asia	125	2	1,6000	132	0	0,0000	1,6000	-1,4566	5,6463	5,3644	0,2550	112,845 8	5,2778	0,2559	108,861 4	0,2356
Any Prior Fracture
Yes	405	24	5,9259	397	15	3,7783	2,1476	-0,8906	5,2596	1,6042	0,8287	3,1054	1,5684	0,8353	2,9451	0,1574
No	289	19	6,5744	289	8	2,7682	3,8062	0,3194	7,5280	2,4718	1,0641	5,7414	2,3750	1,0567	5,3377	0,0301
Any Prior Vertebral Fracture

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Subject	Teriparatide Subject with Event	Teriparatide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Yes	144	10	6,9444	182	11	6,0440	0,9005	-4,5420	6,8793	1,1601	0,4784	2,8130	1,1490	0,5020	2,6297	0,7422
No	550	33	6,0000	504	12	2,3810	3,6190	1,1933	6,1385	2,6170	1,3363	5,1252	2,5200	1,3161	4,8250	0,0037
Any Prior Nonvertebral Fracture
Yes	306	15	4,9020	271	8	2,9520	1,9499	-1,4092	5,3061	1,6946	0,7070	4,0615	1,6605	0,7152	3,8555	0,2321
No	388	28	7,2165	415	15	3,6145	3,6020	0,4622	6,9319	2,0741	1,0903	3,9456	1,9966	1,0830	3,6807	0,0235
Any Prior Clinical Major Osteoporotic Fracture
Yes	237	10	4,2194	208	5	2,4038	1,8156	-1,8256	5,4563	1,7885	0,6013	5,3201	1,7553	0,6098	5,0524	0,2897
No	457	33	7,2210	478	18	3,7657	3,4553	0,5266	6,5249	1,9890	1,1034	3,5855	1,9176	1,0956	3,3564	0,0200
Prevalence of Vertebral Fracture at Baseline
Yes	144	10	6,9444	182	11	6,0440	0,9005	-4,5420	6,8793	1,1601	0,4784	2,8130	1,1490	0,5020	2,6297	0,7422
No	550	33	6,0000	504	12	2,3810	3,6190	1,1933	6,1385	2,6170	1,3363	5,1252	2,5200	1,3161	4,8250	0,0037
Number of Prevalence of Vertebral Fracture at Baseline
0	550	33	6,0000	504	12	2,3810	3,6190	1,1933	6,1385	2,6170	1,3363	5,1252	2,5200	1,3161	4,8250	0,0037
1	111	7	6,3063	126	9	7,1429	-0,8366	-7,5358	6,1542	0,8750	0,3148	2,4325	0,8829	0,3400	2,2925	0,7979
>=2	33	3	9,0909	56	2	3,5714	5,5195	-4,8952	20,2303	2,7000	0,4271	17,0691	2,5455	0,4482	14,4549	0,3554
Severity of Vertebral Fracture (SQ Score) at Baseline
0	550	33	6,0000	505	12	2,3762	3,6238	1,2004	6,1424	2,6223	1,3390	5,1356	2,5250	1,3187	4,8346	0,0036
1	89	6	6,7416	106	8	7,5472	-0,8056	-8,3686	7,2731	0,8855	0,2953	2,6554	0,8933	0,3220	2,4779	0,8282
>=2	55	4	7,2727	75	3	4,0000	3,2727	-5,0955	13,6005	1,8824	0,4038	8,7745	1,8182	0,4240	7,7974	0,4555
Severe Disease (least BMD T-score <= -2.5 and Prevalent

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Subject	Teriparatide Subject with Event	Teriparatide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Vertebral Fracture) at Baseline																
Yes	113	7	6,1947	142	7	4,9296	1,2651	-4,5629	7,8124	1,2736	0,4333	3,7431	1,2566	0,4540	3,4783	0,6595
No	581	36	6,1962	544	16	2,9412	3,2550	0,8004	5,7810	2,1798	1,1952	3,9756	2,1067	1,1829	3,7520	0,0094
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	529	32	6,0491	511	15	2,9354	3,1137	0,5788	5,7435	2,1290	1,1387	3,9807	2,0607	1,1297	3,7592	0,0157
> -2.5	165	11	6,6667	175	8	4,5714	2,0952	-3,0014	7,4595	1,4911	0,5844	3,8044	1,4583	0,6016	3,5354	0,4006
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	394	26	6,5990	365	10	2,7397	3,8593	0,8265	7,0100	2,5082	1,1922	5,2766	2,4086	1,1780	4,9250	0,0124
> -3	300	17	5,6667	321	13	4,0498	1,6168	-1,8465	5,2432	1,4232	0,6791	2,9828	1,3992	0,6915	2,8312	0,3477
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	12	7,0588	154	3	1,9481	5,1108	0,4233	10,1498	3,8228	1,0579	13,8135	3,6235	1,0421	12,5997	0,0343
> -2.5	523	31	5,9273	532	20	3,7594	2,1679	-0,4519	4,8713	1,6130	0,9071	2,8682	1,5767	0,9106	2,7301	0,1007
Total Hip BMD T-score Group 2 at Baseline
<= -3	52	7	13,4615	51	1	1,9608	11,5008	0,7467	23,4223	7,7778	0,9209	65,6878	6,8654	0,8756	53,8322	0,0599
> -3	641	36	5,6162	635	22	3,4646	2,1517	-0,1558	4,5194	1,6580	0,9641	2,8513	1,6210	0,9648	2,7237	0,0650
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	17	8,0189	207	5	2,4155	5,6034	1,3129	10,2590	3,5221	1,2747	9,7318	3,3198	1,2478	8,8328	0,0101
> -2.5	481	26	5,4054	479	18	3,7578	1,6476	-1,0510	4,4073	1,4635	0,7914	2,7063	1,4384	0,7994	2,5884	0,2223
Femoral Neck BMD T-score Group 2 at Baseline

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Subject	Teriparatide Subject with Event	Teriparatide Percent of Subject with Event	Risk Difference (Abaloparatide vs Teriparatide)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Abaloparatide vs Teriparatide)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Abaloparatide vs Teriparatide)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Abaloparatide vs Teriparatide)
<= -3	73	4	5,4795	78	2	2,5641	2,9153	-4,2196	10,9137	2,2029	0,3912	12,4057	2,1370	0,4034	11,3192	0,4304
> -3	620	39	6,2903	608	21	3,4539	2,8364	0,4144	5,3288	1,8763	1,0904	3,2287	1,8212	1,0843	3,0589	0,0212

Each patient was counted once for the same system organ class and the same preferred term.

The risk difference was calculated as (Abaloparatide-SC - Teriparatide). 95% CI was based on the Newcombe's method.

The odds ratio and relative risk were calculated as Abaloparatide-SC/Teriparatide. 95% CI was based on the Wald's method. When no event in one or more arms, zero cell correction of 0.5 to all cells was applied. see <https://training.cochrane.org/handbook/current/chapter-10>, section 10.4.4.1 Studies with no events in one or more arms.

P-value obtained from the Chi-Square test or Fisher's exact test if event count is less than 5 in either treatment group.

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Tabelle 4-19: Subgruppenanalyse Jegliche UE – PT Übelkeit

Subgroup	Abaloparotide Total Subject	Abaloparotide Subject with Event	Abaloparotide Percent of Patients with Event	Teriparotide Total Subject	Teriparotide Subject with Event	Teriparotide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
All Safety Population	694	59	8,5014	686	37	5,3936	3,1079	0,4159	5,8384	1,6298	1,0651	2,4937	1,5762	1,0595	2,3449	0,0233
Age (Years)
<65	101	9	8,9109	99	9	9,0909	-0,1800	-8,5699	8,1410	0,9783	0,3714	2,5769	0,9802	0,4060	2,3664	0,9645
65 to <75	454	43	9,4714	443	23	5,1919	4,2795	0,8549	7,7695	1,9105	1,1310	3,2272	1,8243	1,1186	2,9751	0,0141
>=75	139	7	5,0360	144	5	3,4722	1,5637	-3,5329	6,9359	1,4742	0,4566	4,7600	1,4504	0,4715	4,4617	0,5140
Years Since Menopause
<15	136	15	11,0294	154	10	6,4935	4,5359	-2,0490	11,5483	1,7851	0,7739	4,1179	1,6985	0,7894	3,6545	0,1696
15 to <25	338	32	9,4675	324	15	4,6296	4,8378	0,9121	8,8577	2,1542	1,1435	4,0584	2,0450	1,1290	3,7042	0,0154
>=25	220	12	5,4545	208	12	5,7692	-0,3147	-4,9694	4,2308	0,9423	0,4135	2,1472	0,9455	0,4345	2,0571	0,8875
Ethnicity
White	533	47	8,8180	513	27	5,2632	3,5549	0,4357	6,7139	1,7407	1,0667	2,8406	1,6754	1,0603	2,6474	0,0250
Black/African-American	26	1	3,8462	24	0	0,0000	3,8462	-10,3096	18,8928	2,8824	0,1120	74,2092	2,7778	0,1186	65,0847	1,0000
Asian	128	10	7,8125	137	8	5,8394	1,9731	-4,3526	8,5909	1,3665	0,5219	3,5784	1,3379	0,5451	3,2839	0,5235
Other	7	1	14,2857	12	2	16,6667	-2,3810	-32,8599	36,5329	0,8333	0,0616	11,2772	0,8571	0,0938	7,8297	1,0000
Region
North America	17	2	11,7647	9	1	11,1111	0,6536	-32,8261	24,9988	1,0667	0,0834	13,6501	1,0588	0,1104	10,1508	1,0000
South America	222	13	5,8559	222	9	4,0541	1,8018	-2,4183	6,1464	1,4721	0,6161	3,5175	1,4444	0,6303	3,3102	0,3817
Europe	330	34	10,3030	323	19	5,8824	4,4207	0,2032	8,7108	1,8378	1,0251	3,2948	1,7515	1,0207	3,0057	0,0386
Asia	125	10	8,0000	132	8	6,0606	1,9394	-4,5846	8,7198	1,3478	0,5142	3,5332	1,3200	0,5383	3,2367	0,5426
Any Prior Fracture
Yes	405	33	8,1481	397	29	7,3048	0,8434	-2,9207	4,6067	1,1257	0,6697	1,8921	1,1155	0,6907	1,8014	0,6548
No	289	26	8,9965	289	8	2,7682	6,2284	2,4210	10,3196	3,4724	1,5446	7,8062	3,2500	1,4966	7,0577	0,0015
Any Prior Vertebral Fracture
Yes	144	13	9,0278	182	12	6,5934	2,4344	-3,4355	8,8717	1,4059	0,6210	3,1825	1,3692	0,6445	2,9089	0,4121

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatid Total Subject	Abaloparatid Subject with Event	Abaloparatid Percent of Patients with Event	Teriparatid Total Subject	Teriparatid Subject with Event	Teriparatid Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
No	550	46	8,3636	504	25	4,9603	3,4033	0,3626	6,4554	1,7487	1,0577	2,8913	1,6861	1,0520	2,7025	0,0277
Any Prior Nonvertebral Fracture
Yes	306	28	9,1503	271	17	6,2731	2,8773	-1,6033	7,2924	1,5049	0,8045	2,8148	1,4587	0,8167	2,6053	0,1983
No	388	31	7,9897	415	20	4,8193	3,1704	-0,2345	6,7200	1,7150	0,9602	3,0632	1,6579	0,9615	2,8587	0,0656
Any Prior Clinical Major Osteoporotic Fracture
Yes	237	21	8,8608	208	11	5,2885	3,5723	-1,3686	8,4577	1,7412	0,8187	3,7031	1,6755	0,8276	3,3920	0,1456
No	457	38	8,3151	478	26	5,4393	2,8758	-0,3864	6,2309	1,5766	0,9409	2,6420	1,5287	0,9440	2,4756	0,0817
Prevalence of Vertebral Fracture at Baseline
Yes	144	13	9,0278	182	12	6,5934	2,4344	-3,4355	8,8717	1,4059	0,6210	3,1825	1,3692	0,6445	2,9089	0,4121
No	550	46	8,3636	504	25	4,9603	3,4033	0,3626	6,4554	1,7487	1,0577	2,8913	1,6861	1,0520	2,7025	0,0277
Number of Prevalence of Vertebral Fracture at Baseline
0	550	46	8,3636	504	25	4,9603	3,4033	0,3626	6,4554	1,7487	1,0577	2,8913	1,6861	1,0520	2,7025	0,0277
1	111	11	9,9099	126	11	8,7302	1,1798	-6,3800	9,1096	1,1500	0,4781	2,7660	1,1351	0,5122	2,5158	0,7548
>=2	33	2	6,0606	56	1	1,7857	4,2749	-4,5501	17,9000	3,5484	0,3091	40,7304	3,3939	0,3199	36,0028	0,5525
Severity of Vertebral Fracture (SQ Score) at Baseline
0	550	46	8,3636	505	25	4,9505	3,4131	0,3756	6,4637	1,7524	1,0599	2,8972	1,6895	1,0540	2,7079	0,0271
1	89	9	10,1124	106	6	5,6604	4,4520	-3,2823	13,0116	1,8750	0,6406	5,4883	1,7865	0,6613	4,8263	0,2452
>=2	55	4	7,2727	75	6	8,0000	-0,7273	-10,1914	10,1392	0,9020	0,2419	3,3626	0,9091	0,2694	3,0681	1,0000
Severe Disease (least BMD T-score <= -2.5 and Prevalent

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatid Total Subject	Abaloparatid Subject with Event	Abaloparatid Percent of Patients with Event	Teriparatid Total Subject	Teriparatid Subject with Event	Teriparatid Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Vertebral Fracture) at Baseline																
Yes	113	9	7,9646	142	10	7,0423	0,9223	-5,6630	8,1390	1,1423	0,4478	2,9140	1,1310	0,4757	2,6887	0,7805
No	581	50	8,6059	544	27	4,9632	3,6426	0,6859	6,6259	1,8030	1,1118	2,9240	1,7339	1,1020	2,7282	0,0156
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	529	42	7,9395	511	30	5,8708	2,0687	-1,0529	5,2060	1,3828	0,8512	2,2462	1,3524	0,8602	2,1262	0,1889
> -2.5	165	17	10,3030	175	7	4,0000	6,3030	0,7878	12,2443	2,7568	1,1124	6,8316	2,5758	1,0964	6,0512	0,0233
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	394	38	9,6447	365	17	4,6575	4,9871	1,3010	8,7275	2,1851	1,2104	3,9445	2,0708	1,1901	3,6031	0,0081
> -3	300	21	7,0000	321	20	6,2305	0,7695	-3,2136	4,8521	1,1328	0,6011	2,1348	1,1235	0,6217	2,0304	0,6996
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	13	7,6471	154	4	2,5974	5,0497	0,0605	10,2901	3,1051	0,9903	9,7359	2,9441	0,9808	8,8379	0,0478
> -2.5	523	46	8,7954	532	33	6,2030	2,5924	-0,6062	5,8427	1,4582	0,9165	2,3201	1,4179	0,9219	2,1809	0,1097
Total Hip BMD T-score Group 2 at Baseline
<= -3	52	3	5,7692	51	2	3,9216	1,8477	-8,1893	12,1211	1,5000	0,2400	9,3741	1,4712	0,2564	8,4406	1,0000
> -3	641	56	8,7363	635	35	5,5118	3,2245	0,3917	6,0996	1,6410	1,0596	2,5414	1,5850	1,0542	2,3831	0,0252
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	22	10,3774	207	9	4,3478	6,0295	0,9829	11,2782	2,5474	1,1438	5,6730	2,3868	1,1257	5,0605	0,0184
> -2.5	481	37	7,6923	479	28	5,8455	1,8468	-1,3721	5,1012	1,3423	0,8075	2,2311	1,3159	0,8189	2,1147	0,2548
Femoral Neck BMD T-score Group 2 at Baseline

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Subject	Teriparatide Subject with Event	Teriparatide Percent of Subject with Event	Risk Difference (Abaloparatide vs Teriparatide)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Abaloparatide vs Teriparatide)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Abaloparatide vs Teriparatide)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Abaloparatide vs Teriparatide)
<= -3	73	6	8,2192	78	4	5,1282	3,0910	-5,4558	12,2148	1,6567	0,4481	6,1254	1,6027	0,4712	5,4518	0,5236
> -3	620	53	8,5484	608	33	5,4276	3,1208	0,2549	6,0249	1,6287	1,0387	2,5539	1,5750	1,0349	2,3970	0,0322

Each patient was counted once for the same system organ class and the same preferred term.

The risk difference was calculated as (Abaloparatide-SC - Teriparatide). 95% CI was based on the Newcombe's method.

The odds ratio and relative risk were calculated as Abaloparatide-SC/Teriparatide. 95% CI was based on the Wald's method. When no event in one or more arms, zero cell correction of 0.5 to all cells was applied. see <https://training.cochrane.org/handbook/current/chapter-10>, section 10.4.4.1 Studies with no events in one or more arms.

P-value obtained from the Chi-Square test or Fisher's exact test if event count is less than 5 in either treatment group.

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Tabelle 4-20: Subgruppenanalyse Jegliche UE – PT Osteoarthritis

Subgroup	Abalopar- paratide Total Subject	Abalopar- paratide Subject with Event	Abalopar- paratide Percent of Patients with Event	Teri- para- tide Total Sub- ject	Teri- para- tide Sub- ject with Event	Teripara- tide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
All Safety Population	694	32	4,6110	686	17	2,4781	2,1328	0,1645	4,1797	1,9023	1,0461	3,4591	1,8607	1,0431	3,3188	0,0323
Age (Years)
<65	101	2	1,9802	99	0	0,0000	1,9802	-2,0214	6,9346	5,0000	0,2370	105,4767	4,9020	0,2383	100,8309	0,4975
65 to <75	454	23	5,0661	443	14	3,1603	1,9058	-0,7550	4,6389	1,6352	0,8303	3,2203	1,6031	0,8357	3,0749	0,1513
>=75	139	7	5,0360	144	3	2,0833	2,9526	-1,6897	8,1316	2,4924	0,6313	9,8398	2,4173	0,6379	9,1606	0,2112
Years Since Menopause
<15	136	3	2,2059	154	1	0,6494	1,5565	-1,7200	5,6701	3,4511	0,3547	33,5746	3,3971	0,3576	32,2752	0,3441
15 to <25	338	21	6,2130	324	10	3,0864	3,1266	-0,1479	6,5267	2,0801	0,9640	4,4883	2,0130	0,9629	4,2085	0,0570
>=25	220	8	3,6364	208	6	2,8846	0,7517	-2,9679	4,4671	1,2704	0,4332	3,7257	1,2606	0,4449	3,5715	0,6621
Ethnicity
White	533	26	4,8780	513	15	2,9240	1,9541	-0,4405	4,4103	1,7026	0,8911	3,2529	1,6683	0,8940	3,1131	0,1035
Black/African- American	26	1	3,8462	24	0	0,0000	3,8462	-10,3096	18,8928	2,8824	0,1120	74,2092	2,7778	0,1186	65,0847	1,0000
Asian	128	5	3,9063	137	2	1,4599	2,4464	-1,8773	7,4716	2,7439	0,5228	14,4011	2,6758	0,5285	13,5484	0,2682
Other	7	0	0,0000	12	0	0,0000	.	.	.	1,6667	0,0298	93,1236	1,6250	0,0356	74,0851	.
Region
North America	17	0	0,0000	9	0	0,0000	.	.	.	0,5429	0,0100	29,6009	0,5556	0,0119	25,9239	.
South America	222	9	4,0541	222	3	1,3514	2,7027	-0,4779	6,2850	3,0845	0,8238	11,5488	3,0000	0,8231	10,9347	0,1405
Europe	330	18	5,4545	323	12	3,7152	1,7394	-1,5790	5,1305	1,4952	0,7083	3,1562	1,4682	0,7188	2,9987	0,2885
Asia	125	5	4,0000	132	2	1,5152	2,4848	-1,9815	7,6262	2,7083	0,5157	14,2224	2,6400	0,5217	13,3599	0,2707
Any Prior Fracture
Yes	405	19	4,6914	397	10	2,5189	2,1725	-0,4742	4,9396	1,9049	0,8745	4,1497	1,8625	0,8770	3,9551	0,0994
No	289	13	4,4983	289	7	2,4221	2,0761	-1,0282	5,3651	1,8975	0,7459	4,8272	1,8571	0,7518	4,5874	0,1721
Any Prior Vertebral Fracture

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Subject	Teriparatide Subject with Event	Teriparatide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Yes	144	6	4,1667	182	4	2,1978	1,9689	-2,0347	6,7841	1,9348	0,5355	6,9903	1,8958	0,5453	6,5915	0,3464
No	550	26	4,7273	504	13	2,5794	2,1479	-0,1702	4,5111	1,8740	0,9522	3,6882	1,8327	0,9523	3,5272	0,0650
Any Prior Nonvertebral Fracture
Yes	306	14	4,5752	271	7	2,5830	1,9921	-1,2301	5,2329	1,8082	0,7189	4,5484	1,7712	0,7256	4,3237	0,2022
No	388	18	4,6392	415	10	2,4096	2,2295	-0,3616	5,0272	1,9703	0,8980	4,3229	1,9253	0,8999	4,1189	0,0852
Any Prior Clinical Major Osteoporotic Fracture
Yes	237	9	3,7975	208	8	3,8462	-0,0487	-4,0306	3,7176	0,9868	0,3737	2,6061	0,9873	0,3880	2,5124	0,9787
No	457	23	5,0328	478	9	1,8828	3,1500	0,8077	5,7148	2,7616	1,2639	6,0341	2,6730	1,2502	5,7149	0,0081
Prevalence of Vertebral Fracture at Baseline
Yes	144	6	4,1667	182	4	2,1978	1,9689	-2,0347	6,7841	1,9348	0,5355	6,9903	1,8958	0,5453	6,5915	0,3464
No	550	26	4,7273	504	13	2,5794	2,1479	-0,1702	4,5111	1,8740	0,9522	3,6882	1,8327	0,9523	3,5272	0,0650
Number of Prevalence of Vertebral Fracture at Baseline
0	550	26	4,7273	504	13	2,5794	2,1479	-0,1702	4,5111	1,8740	0,9522	3,6882	1,8327	0,9523	3,5272	0,0650
1	111	4	3,6036	126	3	2,3810	1,2227	-3,6809	6,7472	1,5327	0,3355	7,0023	1,5135	0,3462	6,6159	0,7086
>=2	33	2	6,0606	56	1	1,7857	4,2749	-4,5501	17,9000	3,5484	0,3091	40,7304	3,3939	0,3199	36,0028	0,5525
Severity of Vertebral Fracture (SQ Score) at Baseline
0	550	26	4,7273	505	13	2,5743	2,1530	-0,1625	4,5152	1,8779	0,9542	3,6957	1,8364	0,9542	3,5343	0,0641
1	89	4	4,4944	106	3	2,8302	1,6642	-4,1770	8,4246	1,6157	0,3519	7,4187	1,5880	0,3651	6,9079	0,7043
>=2	55	2	3,6364	75	1	1,3333	2,3030	-4,1033	11,0592	2,7925	0,2468	31,5997	2,7273	0,2536	29,3240	0,5734
Severe Disease (least BMD T-score <= -2.5 and Prevalent

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparotide Total Subject	Abaloparotide Subject with Event	Abaloparotide Percent of Patients with Event	Teriparotide Total Subject	Teriparotide Subject with Event	Teriparotide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Vertebral Fracture) at Baseline																
Yes	113	6	5,3097	142	3	2,1127	3,1971	-1,6471	9,1543	2,5981	0,6352	10,6274	2,5133	0,6427	9,8285	0,1905
No	581	26	4,4750	544	14	2,5735	1,9015	-0,3024	4,1542	1,7735	0,9161	3,4332	1,7389	0,9177	3,2948	0,0852
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	529	25	4,7259	511	11	2,1526	2,5733	0,3325	4,9291	2,2547	1,0976	4,6314	2,1954	1,0917	4,4150	0,0232
> -2.5	165	7	4,2424	175	6	3,4286	0,8139	-3,6056	5,4524	1,2479	0,4105	3,7933	1,2374	0,4246	3,6055	0,6957
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	394	19	4,8223	365	8	2,1918	2,6306	-0,0590	5,4320	2,2610	0,9774	5,2303	2,2002	0,9752	4,9641	0,0506
> -3	300	13	4,3333	321	9	2,8037	1,5296	-1,4913	4,7516	1,5703	0,6612	3,7290	1,5456	0,6704	3,5629	0,3028
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	4	2,3529	154	2	1,2987	1,0542	-2,5553	4,7174	1,8313	0,3307	10,1413	1,8118	0,3365	9,7534	0,6869
> -2.5	523	28	5,3537	532	15	2,8195	2,5342	0,1247	5,0628	1,9496	1,0289	3,6942	1,8988	1,0261	3,5135	0,0374
Total Hip BMD T-score Group 2 at Baseline
<= -3	52	2	3,8462	51	1	1,9608	1,8854	-6,9109	11,1619	2,0000	0,1757	22,7690	1,9615	0,1835	20,9660	1,0000
> -3	641	30	4,6802	635	16	2,5197	2,1605	0,0956	4,3106	1,8995	1,0250	3,5204	1,8574	1,0227	3,3735	0,0385
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	6	2,8302	207	4	1,9324	0,8978	-2,4061	4,3133	1,4782	0,4110	5,3159	1,4646	0,4194	5,1150	0,7511
> -2.5	481	26	5,4054	479	13	2,7140	2,6914	0,1681	5,3376	2,0484	1,0396	4,0359	1,9917	1,0360	3,8290	0,0347
Femoral Neck BMD T-score Group 2 at Baseline

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Sub- ject	Teriparatide Sub- ject with Event	Teriparatide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
<= -3	73	3	4,1096	78	0	0,0000	4,1096	-1,3064	11,4001	7,7943	0,3957	153,543 4	7,4730	0,3926	142,233 0	0,1106
> -3	620	29	4,6774	608	17	2,7961	1,8814	-0,2726	4,1011	1,7059	0,9274	3,1378	1,6729	0,9290	3,0122	0,0826

Each patient was counted once for the same system organ class and the same preferred term.

The risk difference was calculated as (Abaloparatide-SC - Teriparatide). 95% CI was based on the Newcombe's method.

The odds ratio and relative risk were calculated as Abaloparatide-SC/Teriparatide. 95% CI was based on the Wald's method. When no event in one or more arms, zero cell correction of 0.5 to all cells was applied. see <https://training.cochrane.org/handbook/current/chapter-10>, section 10.4.4.1 Studies with no events in one or more arms.

P-value obtained from the Chi-Square test or Fisher's exact test if event count is less than 5 in either treatment group.

Tabelle 4-21: Subgruppenanalyse Jegliche UE – PT Palpitationen

Subgroup	Abaloparotide Total Subject	Abaloparotide Subject with Event	Abaloparotide Percent of Patients with Event	Teriparotide Total Subject	Teriparotide Subject with Event	Teriparotide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
All Safety Population	694	39	5,6196	686	12	1,7493	3,8703	1,9102	5,9771	3,3443	1,7356	6,4439	3,2125	1,6968	6,0824	0,0001
Age (Years)
<65	101	6	5,9406	99	1	1,0101	4,9305	-0,5784	11,4026	6,1895	0,7313	52,3828	5,8812	0,7211	47,9681	0,1185
65 to <75	454	29	6,3877	443	7	1,5801	4,8075	2,2915	7,5655	4,2501	1,8419	9,8066	4,0425	1,7895	9,1320	0,0002
>=75	139	4	2,8777	144	4	2,7778	0,0999	-4,4018	4,7094	1,0370	0,2542	4,2304	1,0360	0,2643	4,0613	1,0000
Years Since Menopause
<15	136	12	8,8235	154	2	1,2987	7,5248	2,5557	13,5650	7,3548	1,6157	33,4810	6,7941	1,5480	29,8186	0,0043
15 to <25	338	19	5,6213	324	6	1,8519	3,7694	0,8531	6,9231	3,1567	1,2444	8,0079	3,0355	1,2279	7,5043	0,0110
>=25	220	8	3,6364	208	4	1,9231	1,7133	-1,7047	5,2851	1,9245	0,5707	6,4896	1,8909	0,5780	6,1856	0,3832
Ethnicity
White	533	22	4,1276	513	5	0,9747	3,1529	1,2618	5,2704	4,3742	1,6437	11,6404	4,2349	1,6160	11,0983	0,0013
Black/African-American	26	0	0,0000	24	0	0,0000	.	.	.	0,9245	0,0177	48,4126	0,9259	0,0191	44,9269	.
Asian	128	17	13,2813	137	7	5,1095	8,1718	1,1817	15,6067	2,8443	1,1381	7,1080	2,5993	1,1148	6,0607	0,0205
Other	7	0	0,0000	12	0	0,0000	.	.	.	1,6667	0,0298	93,1236	1,6250	0,0356	74,0851	.
Region
North America	17	0	0,0000	9	0	0,0000	.	.	.	0,5429	0,0100	29,6009	0,5556	0,0119	25,9239	.
South America	222	3	1,3514	222	1	0,4505	0,9009	-1,3402	3,4735	3,0274	0,3125	29,3290	3,0000	0,3145	28,6205	0,6233
Europe	330	19	5,7576	323	4	1,2384	4,5192	1,7293	7,6703	4,8722	1,6390	14,4835	4,6492	1,5991	13,5170	0,0022
Asia	125	17	13,6000	132	7	5,3030	8,2970	1,1016	15,8996	2,8108	1,1234	7,0327	2,5646	1,1011	5,9734	0,0223
Any Prior Fracture
Yes	405	26	6,4198	397	7	1,7632	4,6565	1,9439	7,6190	3,8221	1,6394	8,9108	3,6409	1,5987	8,2917	0,0009
No	289	13	4,4983	289	5	1,7301	2,7682	-0,1494	5,9694	2,6754	0,9413	7,6042	2,6000	0,9390	7,1990	0,0554
Any Prior Vertebral Fracture
Yes	144	9	6,2500	182	1	0,5495	5,7005	1,8531	10,9211	12,0667	1,5106	96,3915	11,3750	1,4580	88,7483	0,0060

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- tide Total Subject	Abalopar- tide Subject with Event	Abalopar- tide Percent of Patients with Event	Teri- para- tide Total Sub- ject	Teri- para- tide Sub- ject with Event	Teripara- tide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
No	550	30	5,4545	504	11	2,1825	3,2720	0,9448	5,6954	2,5857	1,2818	5,2160	2,4992	1,2659	4,9340	0,0061
Any Prior Nonvertebral Fracture
Yes	306	19	6,2092	271	7	2,5830	3,6261	0,1816	7,1681	2,4968	1,0330	6,0348	2,4038	1,0264	5,6298	0,0361
No	388	20	5,1546	415	5	1,2048	3,9498	1,5570	6,7099	4,4565	1,6559	11,9940	4,2784	1,6216	11,2878	0,0013
Any Prior Clinical Major Osteoporotic Fracture
Yes	237	15	6,3291	208	4	1,9231	4,4060	0,5930	8,4303	3,4459	1,1252	10,5528	3,2911	1,1097	9,7604	0,0320
No	457	24	5,2516	478	8	1,6736	3,5780	1,2496	6,1564	3,2564	1,4476	7,3253	3,1379	1,4244	6,9126	0,0026
Prevalence of Vertebral Fracture at Baseline
Yes	144	9	6,2500	182	1	0,5495	5,7005	1,8531	10,9211	12,0667	1,5106	96,3915	11,3750	1,4580	88,7483	0,0060
No	550	30	5,4545	504	11	2,1825	3,2720	0,9448	5,6954	2,5857	1,2818	5,2160	2,4992	1,2659	4,9340	0,0061
Number of Prevalence of Vertebral Fracture at Baseline
0	550	30	5,4545	504	11	2,1825	3,2720	0,9448	5,6954	2,5857	1,2818	5,2160	2,4992	1,2659	4,9340	0,0061
1	111	8	7,2072	126	1	0,7937	6,4136	1,4105	12,8200	9,7087	1,1947	78,8999	9,0811	1,1538	71,4739	0,0138
>=2	33	1	3,0303	56	0	0,0000	3,0303	-3,8563	15,3187	5,2154	0,2064	131,785 6	5,0294	0,2108	120,013 8	0,3708
Severity of Vertebral Fracture (SQ Score) at Baseline
0	550	30	5,4545	505	11	2,1782	3,2763	0,9514	5,6990	2,5909	1,2844	5,2265	2,5041	1,2684	4,9439	0,0059
1	89	8	8,9888	106	1	0,9434	8,0454	1,9834	15,8415	10,3704	1,2712	84,5986	9,5281	1,2148	74,7324	0,0122
>=2	55	1	1,8182	75	0	0,0000	1,8182	-3,2788	9,6058	4,1560	0,1661	103,965 2	4,0714	0,1690	98,0948	0,4231
Severe Disease (least BMD T-score <= -2.5 and Prevalent

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatid Total Subject	Abaloparatid Subject with Event	Abaloparatid Percent of Patients with Event	Teriparatid Total Subject	Teriparatid Subject with Event	Teriparatid Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Vertebral Fracture) at Baseline																
Yes	113	8	7,0796	142	1	0,7042	6,3754	1,6865	12,6733	10,7429	1,3232	87,2164	10,0531	1,2760	79,2020	0,0118
No	581	31	5,3356	544	11	2,0221	3,3136	1,1119	5,6294	2,7311	1,3588	5,4892	2,6387	1,3397	5,1973	0,0034
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	529	34	6,4272	511	10	1,9569	4,4703	2,0632	7,0489	3,4412	1,6818	7,0410	3,2843	1,6399	6,5776	0,0003
> -2.5	165	5	3,0303	175	2	1,1429	1,8874	-1,5128	5,8417	2,7031	0,5171	14,1295	2,6515	0,5216	13,4786	0,2713
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	394	25	6,3452	365	7	1,9178	4,4274	1,6003	7,4466	3,4650	1,4800	8,1119	3,3086	1,4486	7,5568	0,0024
> -3	300	14	4,6667	321	5	1,5576	3,1090	0,3466	6,2509	3,0937	1,1005	8,6967	2,9960	1,0924	8,2169	0,0246
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	14	8,2353	154	2	1,2987	6,9366	2,2845	12,1349	6,8205	1,5244	30,5167	6,3412	1,4646	27,4544	0,0040
> -2.5	523	25	4,7801	532	10	1,8797	2,9004	0,7316	5,2433	2,6205	1,2458	5,5119	2,5430	1,2337	5,2420	0,0085
Total Hip BMD T-score Group 2 at Baseline
<= -3	52	4	7,6923	51	2	3,9216	3,7707	-6,6269	14,6298	2,0417	0,3571	11,6720	1,9615	0,3756	10,2428	0,6781
> -3	641	35	5,4602	635	10	1,5748	3,8854	1,8945	6,0468	3,6097	1,7719	7,3540	3,4672	1,7319	6,9415	0,0002
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	16	7,5472	207	7	3,3816	4,1655	-0,2952	8,8574	2,3324	0,9390	5,7930	2,2318	0,9376	5,3127	0,0613
> -2.5	481	23	4,7817	479	5	1,0438	3,7379	1,6467	6,1055	4,7607	1,7946	12,6290	4,5809	1,7561	11,9496	0,0006
Femoral Neck BMD T-score Group 2 at Baseline

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Subject	Teriparatide Subject with Event	Teriparatide Percent of Subject with Event	Risk Difference (Abaloparatide vs Teriparatide)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Abaloparatide vs Teriparatide)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Abaloparatide vs Teriparatide)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Abaloparatide vs Teriparatide)
<= -3	73	6	8,2192	78	1	1,2821	6,9371	-0,2060	15,5770	6,8955	0,8095	58,7358	6,4110	0,7907	51,9776	0,0569
> -3	620	33	5,3226	608	11	1,8092	3,5134	1,4550	5,7200	3,0511	1,5276	6,0941	2,9419	1,5007	5,7673	0,0009

Each patient was counted once for the same system organ class and the same preferred term.

The risk difference was calculated as (Abaloparatide-SC - Teriparatide). 95% CI was based on the Newcombe's method.

The odds ratio and relative risk were calculated as Abaloparatide-SC/Teriparatide. 95% CI was based on the Wald's method. When no event in one or more arms, zero cell correction of 0.5 to all cells was applied. see <https://training.cochrane.org/handbook/current/chapter-10>, section 10.4.4.1 Studies with no events in one or more arms.

P-value obtained from the Chi-Square test or Fisher's exact test if event count is less than 5 in either treatment group.

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Tabelle 4-22: Subgruppenanalyse Jegliche UE – SOC Herzerkrankungen

Subgroup	Abaloparotide Total Subject	Abaloparotide Subject with Event	Abaloparotide Percent of Patients with Event	Teriparotide Total Subject	Teriparotide Subject with Event	Teriparotide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
All Safety Population	694	81	11,6715	686	43	6,2682	5,4032	2,3976	8,4487	1,9759	1,3432	2,9068	1,8620	1,3063	2,6541	0,0004
Age (Years)
<65	101	10	9,9010	99	7	7,0707	2,8303	-5,2965	11,0361	1,4443	0,5269	3,9591	1,4003	0,5551	3,5322	0,4730
65 to <75	454	59	12,9956	443	27	6,0948	6,9008	3,0718	10,7878	2,3014	1,4301	3,7034	2,1322	1,3785	3,2981	0,0004
>=75	139	12	8,6331	144	9	6,2500	2,3831	-3,9569	8,9252	1,4173	0,5776	3,4776	1,3813	0,6010	3,1749	0,4445
Years Since Menopause
<15	136	19	13,9706	154	8	5,1948	8,7758	2,0146	16,0534	2,9637	1,2527	7,0114	2,6893	1,2166	5,9447	0,0103
15 to <25	338	36	10,6509	324	21	6,4815	4,1694	-0,1383	8,5121	1,7200	0,9812	3,0149	1,6433	0,9807	2,7534	0,0559
>=25	220	26	11,8182	208	14	6,7308	5,0874	-0,4971	10,7027	1,8571	0,9413	3,6640	1,7558	0,9432	3,2687	0,0707
Ethnicity
White	533	57	10,6942	513	32	6,2378	4,4564	1,0734	7,8706	1,8000	1,1464	2,8260	1,7144	1,1314	2,5979	0,0098
Black/African-American	26	2	7,6923	24	0	0,0000	7,6923	-7,1822	24,1416	5,0000	0,2281	109,6187	4,6296	0,2335	91,8090	0,4906
Asian	128	22	17,1875	137	10	7,2993	9,8882	1,9896	18,0460	2,6358	1,1954	5,8120	2,3547	1,1604	4,7780	0,0136
Other	7	0	0,0000	12	1	8,3333	-8,3333	-35,3880	27,7552	0,5111	0,0183	14,2822	0,5417	0,0250	11,7510	1,0000
Region
North America	17	1	5,8824	9	0	0,0000	5,8824	-24,4206	26,9820	1,7273	0,0638	46,7676	1,6667	0,0746	37,2138	1,0000
South America	222	14	6,3063	222	8	3,6036	2,7027	-1,4810	7,0748	1,8005	0,7398	4,3817	1,7500	0,7491	4,0883	0,1895
Europe	330	45	13,6364	323	25	7,7399	5,8964	1,1417	10,6890	1,8821	1,1244	3,1505	1,7618	1,1075	2,8026	0,0149
Asia	125	21	16,8000	132	10	7,5758	9,2242	1,1967	17,4817	2,4635	1,1100	5,4671	2,2176	1,0879	4,5205	0,0232
Any Prior Fracture
Yes	405	54	13,3333	397	27	6,8010	6,5323	2,3732	10,7425	2,1083	1,2987	3,4225	1,9605	1,2617	3,0463	0,0021
No	289	27	9,3426	289	16	5,5363	3,8062	-0,5239	8,2436	1,7583	0,9261	3,3386	1,6875	0,9294	3,0640	0,0812
Any Prior Vertebral Fracture
Yes	144	21	14,5833	182	13	7,1429	7,4405	0,6967	14,7344	2,2195	1,0700	4,6040	2,0417	1,0592	3,9353	0,0291

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- atide Total Subject	Abalopar- atide Subject with Event	Abalopar- atide Percent of Patients with Event	Teri- para- atide Total Sub- ject	Teri- para- atide Sub- ject with Event	Teripara- atide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
No	550	60	10,9091	504	30	5,9524	4,9567	1,5924	8,3288	1,9347	1,2261	3,0527	1,8327	1,2027	2,7929	0,0040
Any Prior Nonvertebral Fracture
Yes	306	40	13,0719	271	22	8,1181	4,9538	-0,1450	9,9776	1,7020	0,9837	2,9446	1,6102	0,9826	2,6386	0,0552
No	388	41	10,5670	415	21	5,0602	5,5068	1,8053	9,3692	2,2168	1,2849	3,8246	2,0882	1,2572	3,4685	0,0035
Any Prior Clinical Major Osteoporotic Fracture
Yes	237	29	12,2363	208	16	7,6923	4,5440	-1,1569	10,1400	1,6731	0,8812	3,1765	1,5907	0,8895	2,8447	0,1127
No	457	52	11,3786	478	27	5,6485	5,7300	2,1645	9,4058	2,1447	1,3219	3,4795	2,0144	1,2885	3,1494	0,0016
Prevalence of Vertebral Fracture at Baseline
Yes	144	21	14,5833	182	13	7,1429	7,4405	0,6967	14,7344	2,2195	1,0700	4,6040	2,0417	1,0592	3,9353	0,0291
No	550	60	10,9091	504	30	5,9524	4,9567	1,5924	8,3288	1,9347	1,2261	3,0527	1,8327	1,2027	2,7929	0,0040
Number of Prevalence of Vertebral Fracture at Baseline
0	550	60	10,9091	504	30	5,9524	4,9567	1,5924	8,3288	1,9347	1,2261	3,0527	1,8327	1,2027	2,7929	0,0040
1	111	19	17,1171	126	11	8,7302	8,3870	-0,1752	17,3062	2,1591	0,9784	4,7648	1,9607	0,9762	3,9379	0,0527
>=2	33	2	6,0606	56	2	3,5714	2,4892	-7,1162	16,2795	1,7419	0,2336	12,9890	1,6970	0,2507	11,4849	0,6253
Severity of Vertebral Fracture (SQ Score) at Baseline
0	550	60	10,9091	505	30	5,9406	4,9685	1,6075	8,3388	1,9388	1,2287	3,0591	1,8364	1,2050	2,7985	0,0039
1	89	14	15,7303	106	9	8,4906	7,2398	-1,9572	17,0342	2,0119	0,8262	4,8990	1,8527	0,8420	4,0763	0,1185
>=2	55	7	12,7273	75	4	5,3333	7,3939	-2,5511	19,1394	2,5885	0,7183	9,3278	2,3864	0,7346	7,7519	0,2016
Severe Disease (least BMD T-score <= -2.5 and Prevalent

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatid Total Subject	Abaloparatid Subject with Event	Abaloparatid Percent of Patients with Event	Teriparatid Total Subject	Teriparatid Subject with Event	Teriparatid Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Vertebral Fracture) at Baseline																
Yes	113	19	16,8142	142	9	6,3380	10,4761	2,6574	18,9711	2,9870	1,2948	6,8908	2,6529	1,2486	5,6366	0,0079
No	581	62	10,6713	544	34	6,2500	4,4213	1,1579	7,6974	1,7919	1,1590	2,7705	1,7074	1,1427	2,5512	0,0080
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	529	63	11,9093	511	27	5,2838	6,6255	3,2400	10,0723	2,4235	1,5170	3,8715	2,2539	1,4602	3,4792	0,0001
> -2.5	165	18	10,9091	175	16	9,1429	1,7662	-4,7251	8,4009	1,2168	0,5984	2,4745	1,1932	0,6298	2,2605	0,5874
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	394	42	10,6599	365	14	3,8356	6,8243	3,1627	10,5885	2,9915	1,6050	5,5758	2,7792	1,5439	5,0029	0,0003
> -3	300	39	13,0000	321	29	9,0343	3,9657	-0,9756	9,0088	1,5046	0,9046	2,5024	1,4390	0,9138	2,2660	0,1138
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	22	12,9412	154	5	3,2468	9,6944	3,7788	15,8547	4,4297	1,6340	12,0090	3,9859	1,5473	10,2676	0,0016
> -2.5	523	59	11,2811	532	38	7,1429	4,1382	0,6424	7,6852	1,6530	1,0786	2,5333	1,5793	1,0699	2,3313	0,0200
Total Hip BMD T-score Group 2 at Baseline
<= -3	52	5	9,6154	51	2	3,9216	5,6938	-5,0748	17,0488	2,6064	0,4819	14,0962	2,4519	0,4982	12,0680	0,4367
> -3	641	76	11,8565	635	41	6,4567	5,3998	2,2428	8,5981	1,9488	1,3104	2,8982	1,8363	1,2766	2,6415	0,0008
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	26	12,2642	207	12	5,7971	6,4670	0,9357	12,1241	2,2715	1,1135	4,6336	2,1156	1,0971	4,0795	0,0212
> -2.5	481	55	11,4345	479	31	6,4718	4,9627	1,3483	8,6326	1,8658	1,1782	2,9548	1,7668	1,1590	2,6934	0,0071
Femoral Neck BMD T-score Group 2 at Baseline

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Subject	Teriparatide Subject with Event	Teriparatide Percent of Subject with Event	Risk Difference (Abaloparatide vs Teriparatide)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Abaloparatide vs Teriparatide)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Abaloparatide vs Teriparatide)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Abaloparatide vs Teriparatide)
<= -3	73	11	15,0685	78	3	3,8462	11,2223	1,8109	21,4728	4,4355	1,1847	16,6070	3,9178	1,1382	13,4852	0,0235
> -3	620	70	11,2903	608	40	6,5789	4,7114	1,5207	7,9357	1,8073	1,2045	2,7118	1,7161	1,1830	2,4895	0,0038

Each patient was counted once for the same system organ class and the same preferred term.

The risk difference was calculated as (Abaloparatide-SC - Teriparatide). 95% CI was based on the Newcombe's method.

The odds ratio and relative risk were calculated as Abaloparatide-SC/Teriparatide. 95% CI was based on the Wald's method. When no event in one or more arms, zero cell correction of 0.5 to all cells was applied. see <https://training.cochrane.org/handbook/current/chapter-10>, section 10.4.4.1 Studies with no events in one or more arms.

P-value obtained from the Chi-Square test or Fisher's exact test if event count is less than 5 in either treatment group.

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Tabelle 4-23: Subgruppenanalyse Jegliche UE – SOC Erkrankungen des Nervensystems

Subgroup	Abalo- para- tide Total Subject	Abalo- para- tide Subject with Event	Abalo- para- tide Percent of Patients with Event	Teri- para- tide Total Sub- ject	Teri- para- tide Sub- ject with Event	Teripara- tide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
All Safety Population	694	175	25,2161	686	136	19,8251	5,3911	0,9812	9,7733	1,3636	1,0576	1,7582	1,2719	1,0438	1,5499	0,0166
Age (Years)
<65	101	24	23,7624	99	17	17,1717	6,5907	-4,6661	17,6364	1,5034	0,7505	3,0119	1,3838	0,7936	2,4130	0,2484
65 to <75	454	113	24,8899	443	93	20,9932	3,8966	-1,6146	9,3685	1,2471	0,9126	1,7043	1,1856	0,9315	1,5090	0,1654
>=75	139	38	27,3381	144	26	18,0556	9,2826	-0,4863	18,9024	1,7075	0,9703	3,0049	1,5141	0,9741	2,3534	0,0620
Years Since Menopause
<15	136	32	23,5294	154	28	18,1818	5,3476	-3,9801	14,7695	1,3846	0,7832	2,4479	1,2941	0,8237	2,0331	0,2619
15 to <25	338	94	27,8107	324	65	20,0617	7,7489	1,2373	14,1554	1,5351	1,0696	2,2031	1,3863	1,0508	1,8288	0,0196
>=25	220	49	22,2727	208	43	20,6731	1,5997	-6,2162	9,3357	1,0996	0,6927	1,7453	1,0774	0,7494	1,5490	0,6872
Ethnicity
White	533	119	22,3265	513	90	17,5439	4,7826	-0,0697	9,5958	1,3510	0,9953	1,8337	1,2726	0,9956	1,6267	0,0531
Black/African-American	26	2	7,6923	24	0	0,0000	7,6923	-7,1822	24,1416	5,0000	0,2281	109,6187	4,6296	0,2335	91,8090	0,4906
Asian	128	52	40,6250	137	44	32,1168	8,5082	-3,0385	19,7961	1,4462	0,8745	2,3916	1,2649	0,9175	1,7439	0,1499
Other	7	2	28,5714	12	2	16,6667	11,9048	-22,8193	49,4018	2,0000	0,2140	18,6874	1,7143	0,3057	9,6129	0,6027
Region
North America	17	4	23,5294	9	0	0,0000	23,5294	-9,4882	47,2618	6,3333	0,3038	132,0494	5,0000	0,2987	83,6853	0,2631
South America	222	31	13,9640	222	22	9,9099	4,0541	-2,0374	10,1778	1,4755	0,8251	2,6386	1,4091	0,8430	2,3553	0,1877
Europe	330	88	26,6667	323	70	21,6718	4,9948	-1,5817	11,5055	1,3143	0,9170	1,8838	1,2305	0,9357	1,6181	0,1362
Asia	125	52	41,6000	132	44	33,3333	8,2667	-3,5260	19,7830	1,4247	0,8577	2,3663	1,2480	0,9077	1,7158	0,1709
Any Prior Fracture
Yes	405	101	24,9383	397	77	19,3955	5,5428	-0,2150	11,2485	1,3807	0,9872	1,9311	1,2858	0,9892	1,6713	0,0589
No	289	74	25,6055	289	59	20,4152	5,1903	-1,6797	12,0033	1,3417	0,9090	1,9804	1,2542	0,9285	1,6943	0,1382

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalo- para- tide Total Subject	Abalo- para- tide Subject with Event	Abalo- paratide Percent of Patients with Event	Teri- para- tide Total Sub- ject	Teri- para- tide Sub- ject with Event	Teripara- tide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Any Prior Vertebral Fracture
Yes	144	36	25,0000	182	39	21,4286	3,5714	-5,5368	12,9078	1,2222	0,7286	2,0503	1,1667	0,7846	1,7348	0,4467
No	550	139	25,2727	504	97	19,2460	6,0267	0,9890	10,9932	1,4190	1,0583	1,9027	1,3131	1,0439	1,6518	0,0190
Any Prior Nonvertebral Fracture
Yes	306	82	26,7974	271	50	18,4502	8,3472	1,4824	15,0318	1,6180	1,0870	2,4084	1,4524	1,0638	1,9830	0,0172
No	388	93	23,9691	415	86	20,7229	3,2462	-2,5102	9,0150	1,2060	0,8647	1,6820	1,1566	0,8932	1,4978	0,2694
Any Prior Clinical Major Osteoporotic Fracture
Yes	237	65	27,4262	208	38	18,2692	9,1569	1,3017	16,7587	1,6906	1,0749	2,6592	1,5012	1,0534	2,1395	0,0223
No	457	110	24,0700	478	98	20,5021	3,5679	-1,7652	8,8993	1,2292	0,9027	1,6738	1,1740	0,9234	1,4927	0,1898
Prevalence of Vertebral Fracture at Baseline
Yes	144	36	25,0000	182	39	21,4286	3,5714	-5,5368	12,9078	1,2222	0,7286	2,0503	1,1667	0,7846	1,7348	0,4467
No	550	139	25,2727	504	97	19,2460	6,0267	0,9890	10,9932	1,4190	1,0583	1,9027	1,3131	1,0439	1,6518	0,0190
Number of Prevalence of Vertebral Fracture at Baseline
0	550	139	25,2727	504	97	19,2460	6,0267	0,9890	10,9932	1,4190	1,0583	1,9027	1,3131	1,0439	1,6518	0,0190
1	111	30	27,0270	126	26	20,6349	6,3921	-4,4137	17,2302	1,4245	0,7807	2,5992	1,3098	0,8276	2,0727	0,2477
>=2	33	6	18,1818	56	13	23,2143	-5,0325	-20,8187	13,5613	0,7350	0,2495	2,1654	0,7832	0,3293	1,8628	0,5757
Severity of Vertebral Fracture (SQ Score) at Baseline
0	550	139	25,2727	505	98	19,4059	5,8668	0,8250	10,8391	1,4046	1,0482	1,8820	1,3023	1,0362	1,6368	0,0226

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalo- para- tide Total Subject	Abalo- para- tide Subject with Event	Abalo- para- tide Percent of Patients with Event	Teri- para- tide Total Sub- ject	Teri- para- tide Sub- ject with Event	Teripara- tide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
1	89	24	26,9663	106	23	21,6981	5,2682	-6,6803	17,3761	1,3324	0,6903	2,5719	1,2428	0,7555	2,0443	0,3916
>=2	55	12	21,8182	75	15	20,0000	1,8182	-11,8606	16,4338	1,1163	0,4751	2,6226	1,0909	0,5556	2,1418	0,8007
Severe Disease (least BMD T- score <= -2.5 and Prevalent Vertebral Fracture) at Baseline
Yes	113	30	26,5487	142	28	19,7183	6,8304	-3,4772	17,3325	1,4716	0,8177	2,6483	1,3464	0,8569	2,1155	0,1962
No	581	145	24,9570	544	108	19,8529	5,1040	0,2191	9,9354	1,3426	1,0124	1,7805	1,2571	1,0089	1,5664	0,0405
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	529	132	24,9527	511	103	20,1566	4,7962	-0,2921	9,8415	1,3171	0,9832	1,7644	1,2379	0,9864	1,5537	0,0645
> -2.5	165	43	26,0606	175	33	18,8571	7,2035	-1,6667	16,0188	1,5166	0,9070	2,5360	1,3820	0,9258	2,0630	0,1111
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	394	96	24,3655	365	71	19,4521	4,9134	-0,9962	10,7402	1,3340	0,9433	1,8864	1,2526	0,9545	1,6437	0,1026
> -3	300	79	26,3333	321	65	20,2492	6,0841	-0,5616	12,7124	1,4079	0,9683	2,0470	1,3005	0,9750	1,7345	0,0726
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	40	23,5294	154	30	19,4805	4,0489	-4,9821	12,8742	1,2718	0,7460	2,1683	1,2078	0,7935	1,8386	0,3765
> -2.5	523	135	25,8126	532	106	19,9248	5,8878	0,8185	10,9291	1,3983	1,0472	1,8672	1,2955	1,0356	1,6206	0,0228
Total Hip BMD T-score Group 2 at Baseline
<= -3	52	16	30,7692	51	8	15,6863	15,0830	-1,3398	30,5350	2,3889	0,9172	6,2219	1,9615	0,9213	4,1763	0,0702
> -3	641	159	24,8050	635	128	20,1575	4,6475	0,0633	9,2062	1,3066	1,0034	1,7015	1,2306	1,0022	1,5109	0,0468

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Subject	Teriparatide Subject with Event	Teriparatide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	59	27,8302	207	43	20,7729	7,0572	-1,1733	15,1492	1,4707	0,9373	2,3078	1,3397	0,9506	1,8882	0,0924
> -2.5	481	116	24,1164	479	93	19,4154	4,7010	-0,5246	9,8964	1,3191	0,9694	1,7950	1,2421	0,9754	1,5817	0,0776
Femoral Neck BMD T-score Group 2 at Baseline
<= -3	73	19	26,0274	78	23	29,4872	-3,4598	-17,3880	10,7932	0,8414	0,4119	1,7187	0,8827	0,5263	1,4803	0,6354
> -3	620	156	25,1613	608	113	18,5855	6,5758	1,9502	11,1632	1,4728	1,1206	1,9355	1,3538	1,0922	1,6781	0,0053

Each patient was counted once for the same system organ class and the same preferred term.

The risk difference was calculated as (Abaloparatide-SC - Teriparatide). 95% CI was based on the Newcombe's method.

The odds ratio and relative risk were calculated as Abaloparatide-SC/Teriparatide. 95% CI was based on the Wald's method. When no event in one or more arms, zero cell correction of 0.5 to all cells was applied. see <https://training.cochrane.org/handbook/current/chapter-10>, section 10.4.4.1 Studies with no events in one or more arms.

P-value obtained from the Chi-Square test or Fisher's exact test if event count is less than 5 in either treatment group.

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Tabelle 4-24: Subgruppenanalyse Jegliche UE – SOC Erkrankungen der Geschlechtsorgane und der Brustdrüse

Subgroup	Abaloparotide Total Subject	Abaloparotide Subject with Event	Abaloparotide Percent of Patients with Event	Teriparotide Total Subject	Teriparotide Subject with Event	Teriparotide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
All Safety Population	694	24	3,4582	686	12	1,7493	1,7089	0,0034	3,5068	2,0119	0,9979	4,0562	1,9769	0,9967	3,9213	0,0464
Age (Years)
<65	101	4	3,9604	99	1	1,0101	2,9503	-2,1467	8,7933	4,0412	0,4437	36,8098	3,9208	0,4460	34,4668	0,3688
65 to <75	454	17	3,7445	443	9	2,0316	1,7129	-0,5509	4,0853	1,8759	0,8272	4,2542	1,8431	0,8304	4,0908	0,1263
>=75	139	3	2,1583	144	2	1,3889	0,7694	-3,0392	4,8892	1,5662	0,2577	9,5183	1,5540	0,2636	9,1592	0,6798
Years Since Menopause
<15	136	6	4,4118	154	1	0,6494	3,7624	-0,0141	8,6706	7,0615	0,8393	59,4144	6,7941	0,8283	55,7267	0,0538
15 to <25	338	14	4,1420	324	8	2,4691	1,6729	-1,1846	4,6233	1,7068	0,7063	4,1247	1,6775	0,7133	3,9452	0,2300
>=25	220	4	1,8182	208	3	1,4423	0,3759	-2,5538	3,2975	1,2654	0,2798	5,7231	1,2606	0,2856	5,5650	1,0000
Ethnicity
White	533	15	2,8143	513	7	1,3645	1,4497	-0,3513	3,3602	2,0932	0,8464	5,1767	2,0624	0,8479	5,0169	0,1024
Black/African-American	26	0	0,0000	24	0	0,0000	.	.	.	0,9245	0,0177	48,4126	0,9259	0,0191	44,9269	.
Asian	128	8	6,2500	137	4	2,9197	3,3303	-1,9794	9,2048	2,2167	0,6509	7,5484	2,1406	0,6605	6,9372	0,2429
Other	7	1	14,2857	12	1	8,3333	5,9524	-23,5308	43,6072	1,8333	0,0964	34,8491	1,7143	0,1260	23,3212	1,0000
Region
North America	17	0	0,0000	9	0	0,0000	.	.	.	0,5429	0,0100	29,6009	0,5556	0,0119	25,9239	.
South America	222	3	1,3514	222	1	0,4505	0,9009	-1,3402	3,4735	3,0274	0,3125	29,3290	3,0000	0,3145	28,6205	0,6233
Europe	330	13	3,9394	323	7	2,1672	1,7722	-0,9923	4,6771	1,8513	0,7290	4,7013	1,8177	0,7347	4,4976	0,1888
Asia	125	8	6,4000	132	4	3,0303	3,3697	-2,1089	9,3816	2,1880	0,6420	7,4568	2,1120	0,6522	6,8392	0,2447
Any Prior Fracture
Yes	405	16	3,9506	397	5	1,2594	2,6912	0,4549	5,1681	3,2247	1,1699	8,8886	3,1368	1,1602	8,4807	0,0170
No	289	8	2,7682	289	7	2,4221	0,3460	-2,4927	3,2266	1,1469	0,4104	3,2054	1,1429	0,4199	3,1103	0,7936
Any Prior Vertebral Fracture
Yes	144	5	3,4722	182	4	2,1978	1,2744	-2,5879	5,8721	1,6007	0,4219	6,0728	1,5799	0,4321	5,7766	0,5154

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- atide Total Subject	Abalopar- atide Subject with Event	Abalopar- atide Percent of Patients with Event	Teri- para- atide Total Sub- ject	Teri- para- atide Sub- ject with Event	Teripara- atide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
No	550	19	3,4545	504	8	1,5873	1,8672	-0,0841	3,9008	2,2185	0,9625	5,1135	2,1764	0,9613	4,9274	0,0553
Any Prior Nonvertebral Fracture
Yes	306	12	3,9216	271	3	1,1070	2,8146	0,1377	5,7147	3,6463	1,0179	13,0611	3,5425	1,0103	12,4208	0,0377
No	388	12	3,0928	415	9	2,1687	0,9241	-1,3873	3,3820	1,4397	0,5998	3,4557	1,4261	0,6077	3,3470	0,4122
Any Prior Clinical Major Osteoporotic Fracture
Yes	237	8	3,3755	208	4	1,9231	1,4525	-1,9010	4,8068	1,7817	0,5287	6,0045	1,7553	0,5363	5,7449	0,3936
No	457	16	3,5011	478	8	1,6736	1,8275	-0,2514	4,0923	2,1315	0,9033	5,0300	2,0919	0,9040	4,8405	0,0773
Prevalence of Vertebral Fracture at Baseline
Yes	144	5	3,4722	182	4	2,1978	1,2744	-2,5879	5,8721	1,6007	0,4219	6,0728	1,5799	0,4321	5,7766	0,5154
No	550	19	3,4545	504	8	1,5873	1,8672	-0,0841	3,9008	2,2185	0,9625	5,1135	2,1764	0,9613	4,9274	0,0553
Number of Prevalence of Vertebral Fracture at Baseline
0	550	19	3,4545	504	8	1,5873	1,8672	-0,0841	3,9008	2,2185	0,9625	5,1135	2,1764	0,9613	4,9274	0,0553
1	111	4	3,6036	126	4	3,1746	0,4290	-4,7613	6,0682	1,1402	0,2784	4,6702	1,1351	0,2907	4,4325	1,0000
>=2	33	1	3,0303	56	0	0,0000	3,0303	-3,8563	15,3187	5,2154	0,2064	131,785 6	5,0294	0,2108	120,013 8	0,3708
Severity of Vertebral Fracture (SQ Score) at Baseline
0	550	19	3,4545	505	8	1,5842	1,8704	-0,0787	3,9034	2,2229	0,9644	5,1238	2,1807	0,9632	4,9373	0,0546
1	89	3	3,3708	106	0	0,0000	3,3708	-0,7705	9,4474	8,6185	0,4392	169,126 5	8,3222	0,4356	158,987 6	0,0933
>=2	55	2	3,6364	75	4	5,3333	-1,6970	-9,7333	7,5747	0,6698	0,1182	3,7943	0,6818	0,1295	3,5907	1,0000
Severe Disease (least BMD T-score <= -2.5 and Prevalent

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- atide Total Subject	Abalopar- atide Subject with Event	Abalopar- atide Percent of Patients with Event	Teri- para- atide Total Sub- ject	Teri- para- atide Sub- ject with Event	Teripara- atide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Vertebral Fracture) at Baseline																
Yes	113	3	2,6549	142	3	2,1127	0,5422	-3,7447	5,5986	1,2636	0,2501	6,3836	1,2566	0,2585	6,1077	1,0000
No	581	21	3,6145	544	9	1,6544	1,9600	0,0458	3,9663	2,2292	1,0119	4,9108	2,1847	1,0095	4,7283	0,0414
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	529	21	3,9698	511	9	1,7613	2,2085	0,1458	4,3955	2,3058	1,0459	5,0833	2,2539	1,0422	4,8745	0,0334
> -2.5	165	3	1,8182	175	3	1,7143	0,1039	-3,3166	3,6775	1,0617	0,2112	5,3363	1,0606	0,2171	5,1807	1,0000
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	394	16	4,0609	365	4	1,0959	2,9650	0,6763	5,4885	3,8201	1,2651	11,5350	3,7056	1,2504	10,9814	0,0119
> -3	300	8	2,6667	321	8	2,4922	0,1745	-2,5137	2,9636	1,0719	0,3972	2,8931	1,0700	0,4067	2,8149	0,8909
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	6	3,5294	154	2	1,2987	2,2307	-1,5889	6,2970	2,7805	0,5528	13,9862	2,7176	0,5568	13,2652	0,2878
> -2.5	523	18	3,4417	532	10	1,8797	1,5620	-0,4281	3,6756	1,8606	0,8507	4,0696	1,8310	0,8533	3,9290	0,1145
Total Hip BMD T-score Group 2 at Baseline
<= -3	52	2	3,8462	51	1	1,9608	1,8854	-6,9109	11,1619	2,0000	0,1757	22,7690	1,9615	0,1835	20,9660	1,0000
> -3	641	22	3,4321	635	11	1,7323	1,6999	-0,0712	3,5718	2,0162	0,9694	4,1931	1,9813	0,9688	4,0517	0,0558
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	9	4,2453	207	3	1,4493	2,7960	-0,5813	6,5444	3,0148	0,8045	11,2970	2,9292	0,8043	10,6683	0,1405
> -2.5	481	15	3,1185	479	9	1,8789	1,2396	-0,8147	3,3935	1,6810	0,7284	3,8792	1,6597	0,7335	3,7558	0,2187
Femoral Neck BMD T-score Group 2 at Baseline

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Subject	Teriparatide Subject with Event	Teriparatide Percent of Subject with Event	Risk Difference (Abaloparatide vs Teriparatide)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Abaloparatide vs Teriparatide)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Abaloparatide vs Teriparatide)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Abaloparatide vs Teriparatide)
<= -3	73	1	1,3699	78	2	2,5641	-1,1942	-7,6054	5,0772	0,5278	0,0468	5,9472	0,5342	0,0495	5,7675	1,0000
> -3	620	23	3,7097	608	10	1,6447	2,0649	0,2373	4,0102	2,3039	1,0872	4,8822	2,2555	1,0827	4,6987	0,0253

Each patient was counted once for the same system organ class and the same preferred term.

The risk difference was calculated as (Abaloparatide-SC - Teriparatide). 95% CI was based on the Newcombe's method.

The odds ratio and relative risk were calculated as Abaloparatide-SC/Teriparatide. 95% CI was based on the Wald's method. When no event in one or more arms, zero cell correction of 0.5 to all cells was applied. see <https://training.cochrane.org/handbook/current/chapter-10>, section 10.4.4.1 Studies with no events in one or more arms.

P-value obtained from the Chi-Square test or Fisher's exact test if event count is less than 5 in either treatment group.

4.1.4 Subgruppenanalysen für den Endpunkt Nebenwirkungen – UE von speziellem Interesse (UESI)

4.1.4.1 Ergebnisse der Interaktionsterme

Tabelle 4-25: Ergebnisse der Interaktionsterme für den Endpunkt Nebenwirkungen – UE von speziellem Interesse (UESI)

Category	Age	Years Since Menopause	Ethnicity	Region	Any Prior Fracture	Any Prior Vertebral Fracture	Any Prior Non-vertebral Fracture	Any Prior Clinical MOF	Num of Prevalence of VF	Severity of VF (SQ Score)	Severe Disease at Baseline	Lumbar Spine BMD T-score Cutoff - 2.5	Lumbar Spine BMD T-score Cutoff - 3	Total Hip BMD T-score Cutoff - 2.5	Total Hip BMD T-score Cutoff - 3	Femoral Neck BMD T-score Cutoff - 2.5	Femoral Neck BMD T-score Cutoff - 3
Hypercalcemia	0,7504	0,6630	0,7637	0,6777	0,8025	0,6232	0,2682	0,5074	0,7130	0,8807	0,7623	0,4683	0,7499	0,3671	0,9305	0,3940	0,0418
Hypercalciuria	0,2782	0,2022	0,7256	0,8045	0,3950	0,5547	0,2710	0,1239	0,6794	0,7345	0,4235	0,2176	0,9917	0,6763	0,8067	0,3434	0,5332
Hypersensitivity	0,2138	0,4314	0,2023	0,8393	0,0315	0,0848	0,3066	0,3692	0,2090	0,2893	0,0463	0,0249	0,0301	0,2098	0,6114	0,0754	0,2016
Orthostatic hypotension	0,5006	0,6063	0,2851	0,6206	0,9560	0,2333	0,9303	0,6738	0,4172	0,4030	0,2059	0,4671	0,3362	0,0615	0,6621	0,2007	0,7703
Renal impairment	0,8299	0,0183	0,4304	0,6482	0,4015	0,5494	0,1950	0,9464	0,5970	0,7643	0,2783	0,4211	0,6464	0,3857	0,6390	0,9930	0,3586
Palpitations	0,2490	0,6366	0,8275	0,9718	0,9982	0,9258	0,1024	0,2022	0,9243	0,9682	0,3747	0,5949	0,3750	0,0638	0,7889	0,8536	0,1687
Nausea	0,3658	0,1161	0,6131	0,7642	0,0253	0,5780	0,4488	0,8397	0,7213	0,5767	0,4296	0,3282	0,0340	0,3400	0,6390	0,4205	0,8775
Dizziness	0,5429	0,6655	0,6284	0,8029	0,1826	0,7931	0,1923	0,3764	0,5356	0,7800	0,9564	0,7132	0,9826	0,7380	0,6750	0,8140	0,1775

Note: Treatment-subgroup interactions were assessed by the Breslow-Day test.

4.1.4.2 Nebenwirkungen – UE von speziellem Interesse (UESI)

Tabelle 4-26: Subgruppenanalyse UESI Hyperkalzämie

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Subject	Teriparatide Subject with Event	Teriparatide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
All Safety Population	694	15	2,1614	686	33	4,8105	-2,6491	-4,7005	-0,7124	0,4371	0,2352	0,8124	0,4493	0,2463	0,8196	0,0072
Age (Years)
<65	101	2	1,9802	99	3	3,0303	-1,0501	-6,7376	4,2907	0,6465	0,1057	3,9545	0,6535	0,1116	3,8272	0,6812
65 to <75	454	10	2,2026	443	20	4,5147	-2,3120	-4,8717	0,0817	0,4764	0,2204	1,0295	0,4879	0,2310	1,0305	0,0542
>=75	139	3	2,1583	144	10	6,9444	-4,7862	-10,3377	0,2882	0,2956	0,0796	1,0978	0,3108	0,0874	1,1056	0,0855
Years Since Menopause
<15	136	3	2,2059	154	7	4,5455	-2,3396	-7,1054	2,3560	0,4737	0,1200	1,8691	0,4853	0,1280	1,8399	0,3448
15 to <25	338	5	1,4793	324	15	4,6296	-3,1503	-6,1400	-0,5037	0,3093	0,1111	0,8611	0,3195	0,1175	0,8691	0,0179
>=25	220	7	3,1818	208	11	5,2885	-2,1066	-6,3637	1,8719	0,5886	0,2237	1,5483	0,6017	0,2377	1,5226	0,2778
Ethnicity
White	533	11	2,0638	513	22	4,2885	-2,2247	-4,5300	-0,0771	0,4703	0,2257	0,9800	0,4812	0,2358	0,9823	0,0396
Black/African-American	26	0	0,0000	24	1	4,1667	-4,1667	-20,2418	9,1547	0,2956	0,0115	7,6116	0,3086	0,0132	7,2316	0,4800
Asian	128	4	3,1250	137	10	7,2993	-4,1743	-10,1037	1,5074	0,4097	0,1252	1,3408	0,4281	0,1377	1,3309	0,1715
Other	7	0	0,0000	12	0	0,0000	.	.	.	1,6667	0,0298	93,1236	1,6250	0,0356	74,0851	.
Region
North America	17	0	0,0000	9	0	0,0000	.	.	.	0,5429	0,0100	29,6009	0,5556	0,0119	25,9239	.
South America	222	4	1,8018	222	12	5,4054	-3,6036	-7,5628	-0,0359	0,3211	0,1019	1,0114	0,3333	0,1092	1,0177	0,0716
Europe	330	7	2,1212	323	11	3,4056	-1,2844	-4,0932	1,3679	0,6147	0,2353	1,6059	0,6229	0,2445	1,5868	0,3162
Asia	125	4	3,2000	132	10	7,5758	-4,3758	-10,5023	1,4623	0,4033	0,1231	1,3210	0,4224	0,1360	1,3121	0,1698
Any Prior Fracture
Yes	405	6	1,4815	397	12	3,0227	-1,5412	-3,8690	0,6000	0,4825	0,1793	1,2983	0,4901	0,1858	1,2931	0,1407
No	289	9	3,1142	289	21	7,2664	-4,1522	-8,0269	-0,4982	0,4102	0,1846	0,9117	0,4286	0,1997	0,9198	0,0244

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- atide Total Subject	Abalopar- atide Subject with Event	Abalopar- atide Percent of Patients with Event	Teri- para- tide Total Sub- ject	Teri- para- tide Sub- ject with Event	Teripara- tide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Any Prior Vertebral Fracture
Yes	144	2	1,3889	182	4	2,1978	-0,8089	-4,2746	2,9700	0,6268	0,1132	3,4710	0,6319	0,1174	3,4018	0,6974
No	550	13	2,3636	504	29	5,7540	-3,3903	-5,9701	-1,0165	0,3965	0,2038	0,7716	0,4108	0,2160	0,7813	0,0049
Any Prior Nonvertebral Fracture
Yes	306	6	1,9608	271	7	2,5830	-0,6222	-3,4777	1,9898	0,7543	0,2504	2,2726	0,7591	0,2583	2,2311	0,6152
No	388	9	2,3196	415	26	6,2651	-3,9455	-6,9112	-1,1282	0,3553	0,1643	0,7682	0,3702	0,1757	0,7801	0,0062
Any Prior Clinical Major Osteoporotic Fracture
Yes	237	5	2,1097	208	7	3,3654	-1,2557	-4,8791	1,9766	0,6188	0,1934	1,9801	0,6269	0,2020	1,9453	0,4146
No	457	10	2,1882	478	26	5,4393	-3,2511	-5,8597	-0,7803	0,3889	0,1854	0,8159	0,4023	0,1962	0,8248	0,0098
Prevalence of Vertebral Fracture at Baseline
Yes	144	2	1,3889	182	4	2,1978	-0,8089	-4,2746	2,9700	0,6268	0,1132	3,4710	0,6319	0,1174	3,4018	0,6974
No	550	13	2,3636	504	29	5,7540	-3,3903	-5,9701	-1,0165	0,3965	0,2038	0,7716	0,4108	0,2160	0,7813	0,0049
Number of Prevalence of Vertebral Fracture at Baseline
0	550	13	2,3636	504	29	5,7540	-3,3903	-5,9701	-1,0165	0,3965	0,2038	0,7716	0,4108	0,2160	0,7813	0,0049
1	111	2	1,8018	126	4	3,1746	-1,3728	-6,2548	3,5532	0,5596	0,1005	3,1157	0,5676	0,1060	3,0395	0,6873
>=2	33	0	0,0000	56	0	0,0000	.	.	.	1,6866	0,0327	86,9952	1,6765	0,0340	82,5615	.
Severity of Vertebral Fracture (SQ Score) at Baseline
0	550	13	2,3636	505	29	5,7426	-3,3789	-5,9545	-1,0075	0,3974	0,2042	0,7732	0,4116	0,2164	0,7829	0,0050
1	89	1	1,1236	106	2	1,8868	-0,7632	-5,5859	4,3913	0,5909	0,0527	6,6266	0,5955	0,0549	6,4593	1,0000
>=2	55	1	1,8182	75	2	2,6667	-0,8485	-7,5622	7,1753	0,6759	0,0597	7,6479	0,6818	0,0634	7,3310	1,0000

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- tide Total Subject	Abalopar- tide Subject with Event	Abalopar- tide Percent of Patients with Event	Teri- para- tide Total Sub- ject	Teri- para- tide Sub- ject with Event	Teripara- tide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Severe Disease (least BMD T-score <= -2.5 and Prevalent Vertebral Fracture) at Baseline
Yes	113	1	0,8850	142	4	2,8169	-1,9319	-6,1964	2,3822	0,3080	0,0339	2,7952	0,3142	0,0356	2,7717	0,3864
No	581	14	2,4096	544	29	5,3309	-2,9212	-5,3437	-0,6670	0,4385	0,2292	0,8390	0,4520	0,2415	0,8462	0,0107
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	529	14	2,6465	511	28	5,4795	-2,8329	-5,3905	-0,4225	0,4689	0,2440	0,9014	0,4830	0,2573	0,9068	0,0203
> -2.5	165	1	0,6061	175	5	2,8571	-2,2511	-5,9409	0,9431	0,2073	0,0240	1,7936	0,2121	0,0250	1,7966	0,2158
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	394	12	3,0457	365	24	6,5753	-3,5297	-6,8172	-0,4751	0,4463	0,2198	0,9062	0,4632	0,2351	0,9126	0,0223
> -3	300	3	1,0000	321	9	2,8037	-1,8037	-4,3294	0,5095	0,3502	0,0939	1,3059	0,3567	0,0975	1,3050	0,1449
Total Hip BMD T- score Group 1 at Baseline
<= -2.5	170	7	4,1176	154	10	6,4935	-2,3759	-7,8450	2,6925	0,6184	0,2294	1,6669	0,6341	0,2475	1,6249	0,3382
> -2.5	523	8	1,5296	532	23	4,3233	-2,7937	-5,0060	-0,7536	0,3438	0,1524	0,7757	0,3538	0,1597	0,7838	0,0072
Total Hip BMD T- score Group 2 at Baseline
<= -3	52	2	3,8462	51	4	7,8431	-3,9970	-15,0117	6,2996	0,4700	0,0822	2,6870	0,4904	0,0939	2,5607	0,4367
> -3	641	13	2,0281	635	29	4,5669	-2,5388	-4,6296	-0,5734	0,4326	0,2228	0,8400	0,4441	0,2330	0,8463	0,0110
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	7	3,3019	207	11	5,3140	-2,0121	-6,3094	2,0681	0,6084	0,2312	1,6012	0,6214	0,2456	1,5718	0,3098

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Subject	Teriparatide Subject with Event	Teriparatide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
> -2.5	481	8	1,6632	479	22	4,5929	-2,9297	-5,3361	-0,7201	0,3513	0,1548	0,7972	0,3621	0,1628	0,8053	0,0091
Femoral Neck BMD T-score Group 2 at Baseline
<= -3	73	6	8,2192	78	5	6,4103	1,8089	-7,0874	11,1252	1,3075	0,3813	4,4833	1,2822	0,4088	4,0215	0,6691
> -3	620	9	1,4516	608	28	4,6053	-3,1537	-5,2398	-1,2540	0,3051	0,1428	0,6521	0,3152	0,1500	0,6624	0,0012

The risk difference was calculated as (Abaloparatide-SC - Teriparatide). 95% CI was based on the Newcombe's method. The odds ratio and relative risk were calculated as Abaloparatide-SC/Teriparatide. 95% CI was based on the Wald's method. When no event in one or more arms, zero cell correction of 0.5 to all cells was applied. see <https://training.cochrane.org/handbook/current/chapter-10>, section 10.4.4.1 Studies with no events in one or more arms. P-value obtained from the Chi-Square test or Fisher's exact test if event count is less than 5 in either treatment group.

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Tabelle 4-27: Subgruppenanalyse UESI Hyperkalziurie

Subgroup	Abalopar- tide Total Subject	Abalopar- tide Subject with Event	Abalopar- tide Percent of Patients with Event	Teri- para- tide Total Sub- ject	Teri- para- tide Sub- ject with Event	Teripara- tide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
All Safety Population	694	99	14,2651	686	121	17,6385	-3,3734	-7,2422	0,4946	0,7769	0,5816	1,0378	0,8088	0,6338	1,0320	0,0870
Age (Years)
<65	101	16	15,8416	99	13	13,1313	2,7103	-7,2389	12,5988	1,2452	0,5647	2,7461	1,2064	0,6128	2,3749	0,5863
65 to <75	454	67	14,7577	443	80	18,0587	-3,3010	-8,1628	1,5536	0,7856	0,5509	1,1201	0,8172	0,6072	1,0998	0,1818
>=75	139	16	11,5108	144	28	19,4444	-7,9337	-16,3396	0,5712	0,5389	0,2773	1,0474	0,5920	0,3353	1,0450	0,0656
Years Since Menopause
<15	136	23	16,9118	154	21	13,6364	3,2754	-5,0114	11,7778	1,2891	0,6780	2,4509	1,2402	0,7193	2,1383	0,4378
15 to <25	338	49	14,4970	324	62	19,1358	-4,6388	-10,3604	1,0661	0,7165	0,4754	1,0799	0,7576	0,5380	1,0668	0,1102
>=25	220	27	12,2727	208	38	18,2692	-5,9965	-12,8849	0,8342	0,6259	0,3667	1,0683	0,6718	0,4260	1,0593	0,0841
Ethnicity
White	533	58	10,8818	513	66	12,8655	-1,9837	-5,9458	1,9486	0,8270	0,5680	1,2040	0,8458	0,6073	1,1780	0,3211
Black/African- American	26	2	7,6923	24	1	4,1667	3,5256	-13,4828	20,3281	1,9167	0,1625	22,6064	1,8462	0,1786	19,0786	1,0000
Asian	128	39	30,4688	137	53	38,6861	-8,2174	-19,3198	3,2395	0,6945	0,4171	1,1563	0,7876	0,5628	1,1022	0,1603
Other	7	0	0,0000	12	1	8,3333	-8,3333	-35,3880	27,7552	0,5111	0,0183	14,2822	0,5417	0,0250	11,7510	1,0000
Region
North America	17	0	0,0000	9	0	0,0000	.	.	.	0,5429	0,0100	29,6009	0,5556	0,0119	25,9239	.
South America	222	30	13,5135	222	33	14,8649	-1,3514	-7,9007	5,1974	0,8949	0,5248	1,5259	0,9091	0,5750	1,4373	0,6833
Europe	330	30	9,0909	323	36	11,1455	-2,0546	-6,7680	2,6147	0,7972	0,4783	1,3287	0,8157	0,5151	1,2915	0,3838
Asia	125	39	31,2000	132	52	39,3939	-8,1939	-19,5194	3,4844	0,6977	0,4169	1,1675	0,7920	0,5663	1,1077	0,1698
Any Prior Fracture
Yes	405	52	12,8395	397	57	14,3577	-1,5182	-6,2989	3,2460	0,8787	0,5865	1,3165	0,8943	0,6305	1,2683	0,5305
No	289	47	16,2630	289	64	22,1453	-5,8824	-12,2748	0,5531	0,6828	0,4495	1,0371	0,7344	0,5230	1,0311	0,0726
Any Prior Vertebral Fracture

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Subject	Teriparatide Subject with Event	Teriparatide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Yes	144	13	9,0278	182	25	13,7363	-4,7085	-11,5374	2,4897	0,6232	0,3066	1,2666	0,6572	0,3488	1,2384	0,1883
No	550	86	15,6364	504	96	19,0476	-3,4113	-8,0149	1,1582	0,7877	0,5720	1,0847	0,8209	0,6300	1,0697	0,1433
Any Prior Nonvertebral Fracture
Yes	306	39	12,7451	271	35	12,9151	-0,1700	-5,7522	5,2874	0,9849	0,6041	1,6057	0,9868	0,6445	1,5111	0,9514
No	388	60	15,4639	415	86	20,7229	-5,2590	-10,5421	0,0891	0,6998	0,4866	1,0065	0,7462	0,5532	1,0065	0,0535
Any Prior Clinical Major Osteoporotic Fracture
Yes	237	32	13,5021	208	25	12,0192	1,4829	-4,8784	7,6792	1,1426	0,6528	2,0001	1,1234	0,6890	1,8317	0,6405
No	457	67	14,6608	478	96	20,0837	-5,4229	-10,2511	-0,5533	0,6836	0,4854	0,9628	0,7300	0,5493	0,9702	0,0289
Prevalence of Vertebral Fracture at Baseline
Yes	144	13	9,0278	182	25	13,7363	-4,7085	-11,5374	2,4897	0,6232	0,3066	1,2666	0,6572	0,3488	1,2384	0,1883
No	550	86	15,6364	504	96	19,0476	-3,4113	-8,0149	1,1582	0,7877	0,5720	1,0847	0,8209	0,6300	1,0697	0,1433
Number of Prevalence of Vertebral Fracture at Baseline
0	550	86	15,6364	504	96	19,0476	-3,4113	-8,0149	1,1582	0,7877	0,5720	1,0847	0,8209	0,6300	1,0697	0,1433
1	111	11	9,9099	126	17	13,4921	-3,5822	-11,8369	4,9331	0,7053	0,3152	1,5783	0,7345	0,3596	1,5003	0,3939
>=2	33	2	6,0606	56	8	14,2857	-8,2251	-20,4854	6,9608	0,3871	0,0771	1,9443	0,4242	0,0957	1,8798	0,3116
Severity of Vertebral Fracture (SQ Score) at Baseline
0	550	86	15,6364	505	96	19,0099	-3,3735	-7,9723	1,1919	0,7896	0,5734	1,0874	0,8225	0,6312	1,0719	0,1474
1	89	6	6,7416	106	13	12,2642	-5,5226	-13,9337	3,2137	0,5171	0,1881	1,4221	0,5497	0,2179	1,3868	0,1952
>=2	55	7	12,7273	75	12	16,0000	-3,2727	-15,0878	9,8064	0,7656	0,2803	2,0915	0,7955	0,3350	1,8888	0,6018

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- tide Total Subject	Abalopar- tide Subject with Event	Abalopar- tide Percent of Patients with Event	Teri- para- tide Total Sub- ject	Teri- para- tide Sub- ject with Event	Teripara- tide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Severe Disease (least BMD T-score <= -2.5 and Prevalent Vertebral Fracture) at Baseline
Yes	113	12	10,6195	142	24	16,9014	-6,2819	-14,5848	2,5049	0,5842	0,2781	1,2270	0,6283	0,3289	1,2005	0,1524
No	581	87	14,9742	544	97	17,8309	-2,8567	-7,2109	1,4710	0,8116	0,5914	1,1137	0,8398	0,6445	1,0943	0,1955
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	529	88	16,6352	511	99	19,3738	-2,7386	-7,4196	1,9342	0,8304	0,6048	1,1402	0,8586	0,6620	1,1138	0,2503
> -2.5	165	11	6,6667	175	22	12,5714	-5,9048	-12,3275	0,4790	0,4968	0,2329	1,0596	0,5303	0,2655	1,0592	0,0660
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	394	69	17,5127	365	80	21,9178	-4,4051	-10,0853	1,2532	0,7563	0,5281	1,0832	0,7990	0,5986	1,0666	0,1269
> -3	300	30	10,0000	321	41	12,7726	-2,7726	-7,7948	2,2953	0,7588	0,4604	1,2507	0,7829	0,5023	1,2203	0,2779
Total Hip BMD T- score Group 1 at Baseline
<= -2.5	170	32	18,8235	154	33	21,4286	-2,6050	-11,4113	6,0993	0,8502	0,4935	1,4650	0,8784	0,5688	1,3567	0,5587
> -2.5	523	67	12,8107	532	88	16,5414	-3,7306	-8,0041	0,5524	0,7413	0,5258	1,0453	0,7745	0,5772	1,0391	0,0870
Total Hip BMD T- score Group 2 at Baseline
<= -3	52	10	19,2308	51	13	25,4902	-6,2594	-22,0745	9,8456	0,6960	0,2735	1,7709	0,7544	0,3642	1,5629	0,4457
> -3	641	89	13,8846	635	108	17,0079	-3,1233	-7,0968	0,8485	0,7868	0,5800	1,0672	0,8164	0,6306	1,0569	0,1226
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	37	17,4528	207	51	24,6377	-7,1849	-14,9344	0,6306	0,6467	0,4021	1,0400	0,7084	0,4857	1,0332	0,0710

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Subject	Teriparatide Subject with Event	Teriparatide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
> -2.5	481	62	12,8898	479	70	14,6138	-1,7240	-6,1028	2,6506	0,8646	0,5984	1,2491	0,8820	0,6421	1,2117	0,4380
Femoral Neck BMD T-score Group 2 at Baseline
<= -3	73	16	21,9178	78	24	30,7692	-8,8514	-22,3781	5,2644	0,6316	0,3032	1,3158	0,7123	0,4126	1,2299	0,2180
> -3	620	83	13,3871	608	97	15,9539	-2,5669	-6,5400	1,3976	0,8142	0,5930	1,1181	0,8391	0,6400	1,1002	0,2035

The risk difference was calculated as (Abaloparatide-SC - Teriparatide). 95% CI was based on the Newcombe's method. The odds ratio and relative risk were calculated as Abaloparatide-SC/Teriparatide. 95% CI was based on the Wald's method. When no event in one or more arms, zero cell correction of 0.5 to all cells was applied. see <https://training.cochrane.org/handbook/current/chapter-10>, section 10.4.4.1 Studies with no events in one or more arms. P-value obtained from the Chi-Square test or Fisher's exact test if event count is less than 5 in either treatment group.

Tabelle 4-28: Subgruppenanalyse UESI Hypersensitivität

Subgroup	Abalopar- paratide Total Subject	Abalopar- paratide Subject with Event	Abalopar- paratide Percent of Patients with Event	Teri- para- tide Total Sub- ject	Teri- para- tide Sub- ject with Event	Teripara- tide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
All Safety Population	694	88	12,6801	686	85	12,3907	0,2894	-3,2217	3,7961	1,0268	0,7465	1,4121	1,0234	0,7744	1,3524	0,8710
Age (Years)
<65	101	7	6,9307	99	8	8,0808	-1,1501	-9,0457	6,6079	0,8471	0,2951	2,4316	0,8577	0,3233	2,2756	0,7575
65 to <75	454	55	12,1145	443	60	13,5440	-1,4295	-5,8438	2,9649	0,8799	0,5947	1,3020	0,8945	0,6356	1,2588	0,5220
>=75	139	26	18,7050	144	17	11,8056	6,8995	-1,5260	15,3660	1,7189	0,8868	3,3316	1,5844	0,9004	2,7882	0,1060
Years Since Menopause
<15	136	9	6,6176	154	16	10,3896	-3,7720	-10,3655	2,9505	0,6112	0,2609	1,4321	0,6369	0,2910	1,3942	0,2534
15 to <25	338	47	13,9053	324	40	12,3457	1,5596	-3,6388	6,7248	1,1467	0,7296	1,8024	1,1263	0,7602	1,6688	0,5527
>=25	220	32	14,5455	208	29	13,9423	0,6031	-6,1181	7,2510	1,0506	0,6107	1,8076	1,0433	0,6551	1,6615	0,8584
Ethnicity
White	533	62	11,6323	513	56	10,9162	0,7161	-3,1539	4,5669	1,0742	0,7320	1,5764	1,0656	0,7582	1,4977	0,7144
Black/African- American	26	2	7,6923	24	1	4,1667	3,5256	-13,4828	20,3281	1,9167	0,1625	22,6064	1,8462	0,1786	19,0786	1,0000
Asian	128	22	17,1875	137	28	20,4380	-3,2505	-12,5950	6,2670	0,8080	0,4350	1,5006	0,8410	0,5082	1,3917	0,4992
Other	7	2	28,5714	12	0	0,0000	28,5714	-3,0851	64,1066	11,3636	0,4643	278,137 4	8,1250	0,4445	148,527 7	0,1228
Region
North America	17	2	11,7647	9	1	11,1111	0,6536	-32,8261	24,9988	1,0667	0,0834	13,6501	1,0588	0,1104	10,1508	1,0000
South America	222	21	9,4595	222	17	7,6577	1,8018	-3,5215	7,1713	1,2599	0,6457	2,4581	1,2353	0,6700	2,2775	0,4974
Europe	330	44	13,3333	323	41	12,6935	0,6398	-4,5710	5,8333	1,0582	0,6706	1,6697	1,0504	0,7064	1,5620	0,8081
Asia	125	21	16,8000	132	26	19,6970	-2,8970	-12,3022	6,6532	0,8232	0,4360	1,5542	0,8529	0,5069	1,4352	0,5482
Any Prior Fracture
Yes	405	43	10,6173	397	54	13,6020	-2,9847	-7,5480	1,5506	0,7545	0,4923	1,1563	0,7806	0,5360	1,1368	0,1949
No	289	45	15,5709	289	31	10,7266	4,8443	-0,6931	10,3967	1,5349	0,9405	2,5050	1,4516	0,9467	2,2258	0,0849
Any Prior Vertebral Fracture

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparotide Total Subject	Abaloparotide Subject with Event	Abaloparotide Percent of Patients with Event	Teriparotide Total Subject	Teriparotide Subject with Event	Teriparotide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Yes	144	13	9,0278	182	26	14,2857	-5,2579	-12,1443	1,9942	0,5954	0,2942	1,2052	0,6319	0,3370	1,1852	0,1463
No	550	75	13,6364	504	59	11,7063	1,9300	-2,1275	5,9426	1,1909	0,8269	1,7151	1,1649	0,8468	1,6025	0,3474
Any Prior Nonvertebral Fracture
Yes	306	35	11,4379	271	36	13,2841	-1,8462	-7,3577	3,5307	0,8431	0,5129	1,3858	0,8610	0,5570	1,3310	0,5005
No	388	53	13,6598	415	49	11,8072	1,8526	-2,7686	6,5290	1,1817	0,7798	1,7909	1,1569	0,8048	1,6631	0,4308
Any Prior Clinical Major Osteoporotic Fracture
Yes	237	25	10,5485	208	26	12,5000	-1,9515	-8,0982	4,0000	0,8255	0,4605	1,4797	0,8439	0,5035	1,4144	0,5191
No	457	63	13,7856	478	59	12,3431	1,4425	-2,8887	5,8050	1,1356	0,7759	1,6618	1,1169	0,8020	1,5553	0,5127
Prevalence of Vertebral Fracture at Baseline
Yes	144	13	9,0278	182	26	14,2857	-5,2579	-12,1443	1,9942	0,5954	0,2942	1,2052	0,6319	0,3370	1,1852	0,1463
No	550	75	13,6364	504	59	11,7063	1,9300	-2,1275	5,9426	1,1909	0,8269	1,7151	1,1649	0,8468	1,6025	0,3474
Number of Prevalence of Vertebral Fracture at Baseline
0	550	75	13,6364	504	59	11,7063	1,9300	-2,1275	5,9426	1,1909	0,8269	1,7151	1,1649	0,8468	1,6025	0,3474
1	111	10	9,0090	126	19	15,0794	-6,0704	-14,3922	2,4824	0,5576	0,2474	1,2566	0,5974	0,2902	1,2298	0,1547
>=2	33	3	9,0909	56	7	12,5000	-3,4091	-16,0259	12,3880	0,7000	0,1681	2,9157	0,7273	0,2017	2,6217	0,7387
Severity of Vertebral Fracture (SQ Score) at Baseline
0	550	75	13,6364	505	60	11,8812	1,7552	-2,3123	5,7784	1,1711	0,8144	1,6840	1,1477	0,8357	1,5762	0,3939
1	89	8	8,9888	106	14	13,2075	-4,2188	-13,1109	5,1059	0,6490	0,2590	1,6263	0,6806	0,2992	1,5479	0,3537
>=2	55	5	9,0909	75	11	14,6667	-5,5758	-16,5718	6,6449	0,5818	0,1898	1,7832	0,6198	0,2284	1,6819	0,3391
Severe Disease (least BMD T-score <= -2.5 and Prevalent

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Subject	Teriparatide Subject with Event	Teriparatide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Vertebral Fracture) at Baseline ##																
Yes	113	8	7,0796	142	20	14,0845	-7,0049	-14,5141	0,8793	0,4648	0,1966	1,0988	0,5027	0,2300	1,0985	0,0755
No	581	80	13,7694	544	65	11,9485	1,8208	-2,1230	5,7336	1,1767	0,8289	1,6706	1,1524	0,8489	1,5644	0,3624
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	529	71	13,4216	511	55	10,7632	2,6583	-1,3289	6,6346	1,2853	0,8832	1,8704	1,2470	0,8961	1,7352	0,1890
> -2.5	165	17	10,3030	175	30	17,1429	-6,8398	-14,1598	0,5592	0,5552	0,2935	1,0503	0,6010	0,3448	1,0476	0,0678
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	394	56	14,2132	365	38	10,4110	3,8022	-0,9175	8,4774	1,4257	0,9191	2,2117	1,3652	0,9275	2,0094	0,1121
> -3	300	32	10,6667	321	47	14,6417	-3,9751	-9,2113	1,3093	0,6961	0,4309	1,1246	0,7285	0,4783	1,1096	0,1374
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	23	13,5294	154	27	17,5325	-4,0031	-12,0497	3,8981	0,7360	0,4020	1,3473	0,7717	0,4626	1,2872	0,3192
> -2.5	523	65	12,4283	532	58	10,9023	1,5260	-2,3654	5,4337	1,1598	0,7959	1,6903	1,1400	0,8173	1,5901	0,4400
Total Hip BMD T-score Group 2 at Baseline
<= -3	52	8	15,3846	51	6	11,7647	3,6199	-10,1407	17,2782	1,3636	0,4374	4,2516	1,3077	0,4881	3,5035	0,5920
> -3	641	80	12,4805	635	79	12,4409	0,0396	-3,6039	3,6787	1,0036	0,7199	1,3992	1,0032	0,7500	1,3418	0,9829
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	28	13,2075	207	37	17,8744	-4,6668	-11,6529	2,3027	0,6992	0,4102	1,1919	0,7389	0,4702	1,1612	0,1871
> -2.5	481	60	12,4740	479	48	10,0209	2,4531	-1,5670	6,4837	1,2797	0,8556	1,9141	1,2448	0,8703	1,7804	0,2291
Femoral Neck BMD T-score Group 2 at Baseline

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Sub- ject	Teriparatide Sub- ject with Event	Teriparatide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
<= -3	73	10	13,6986	78	16	20,5128	-6,8142	-18,7263	5,4416	0,6151	0,2591	1,4599	0,6678	0,3242	1,3757	0,2677
> -3	620	78	12,5806	608	69	11,3487	1,2320	-2,4197	4,8777	1,1242	0,7960	1,5876	1,1086	0,8180	1,5024	0,5061

The risk difference was calculated as (Abaloparatide-SC - Teriparatide). 95% CI was based on the Newcombe's method.

The odds ratio and relative risk were calculated as Abaloparatide-SC/Teriparatide. 95% CI was based on the Wald's method. When no event in one or more arms, zero cell correction of 0.5 to all cells was applied. see <https://training.cochrane.org/handbook/current/chapter-10>, section 10.4.4.1 Studies with no events in one or more arms.

P-value obtained from the Chi-Square test or Fisher's exact test if event count is less than 5 in either treatment group.

Tabelle 4-29: Subgruppenanalyse Orthostatische Hypotonie

Subgroup	Abalopar- atide Total Subject	Abalopar- atide Subject with Event	Abalopar- atide Percent of Patients with Event	Teri- para- tide Total Sub- ject	Teri- para- tide Sub- ject with Event	Teripara- tide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
All Safety Population	694	197	28,3862	686	136	19,8251	8,5611	4,0521	13,0244	1,6030	1,2485	2,0581	1,4318	1,1825	1,7338	0,0002
Age (Years)
<65	101	27	26,7327	99	20	20,2020	6,5307	-5,2527	18,0623	1,4412	0,7453	2,7869	1,3233	0,7966	2,1980	0,2761
65 to <75	454	136	29,9559	443	86	19,4131	10,5429	4,9063	16,0861	1,7753	1,3028	2,4192	1,5431	1,2185	1,9542	0,0003
>=75	139	34	24,4604	144	30	20,8333	3,6271	-6,1145	13,3420	1,2305	0,7043	2,1498	1,1741	0,7622	1,8087	0,4659
Years Since Menopause
<15	136	39	28,6765	154	31	20,1299	8,5466	-1,3228	18,3807	1,5953	0,9282	2,7417	1,4246	0,9441	2,1495	0,0896
15 to <25	338	105	31,0651	324	65	20,0617	11,0034	4,3585	17,5019	1,7956	1,2573	2,5644	1,5485	1,1830	2,0268	0,0012
>=25	220	53	24,0909	208	40	19,2308	4,8601	-2,9837	12,5809	1,3329	0,8389	2,1178	1,2527	0,8704	1,8030	0,2230
Ethnicity
White	533	141	26,4540	513	93	18,1287	8,3254	3,2814	13,3057	1,6244	1,2085	2,1835	1,4592	1,1570	1,8404	0,0012
Black/African- American	26	5	19,2308	24	0	0,0000	19,2308	1,7559	37,8763	12,5349	0,6545	240,073 1	10,1852	0,5930	174,936 5	0,0235
Asian	128	49	38,2813	137	39	28,4672	9,8141	-1,5180	20,8683	1,5586	0,9317	2,6072	1,3448	0,9526	1,8983	0,0900
Other	7	2	28,5714	12	4	33,3333	-4,7619	-39,0564	35,7822	0,8000	0,1048	6,1043	0,8571	0,2075	3,5409	1,0000
Region
North America	17	5	29,4118	9	2	22,2222	7,1895	-29,1108	35,7466	1,4583	0,2211	9,6171	1,3235	0,3177	5,5139	1,0000
South America	222	31	13,9640	222	26	11,7117	2,2523	-4,0373	8,5521	1,2235	0,7003	2,1377	1,1923	0,7327	1,9402	0,4781
Europe	330	112	33,9394	323	69	21,3622	12,5772	5,7245	19,2642	1,8912	1,3323	2,6846	1,5888	1,2278	2,0559	0,0003
Asia	125	49	39,2000	132	39	29,5455	9,6545	-1,9330	20,9388	1,5374	0,9155	2,5819	1,3268	0,9423	1,8680	0,1030
Any Prior Fracture
Yes	405	121	29,8765	397	83	20,9068	8,9697	2,9444	14,9038	1,6118	1,1679	2,2245	1,4290	1,1212	1,8214	0,0035
No	289	76	26,2976	289	53	18,3391	7,9585	1,1640	14,6706	1,5888	1,0686	2,3623	1,4340	1,0512	1,9562	0,0216
Any Prior Vertebral Fracture
Yes	144	47	32,6389	182	34	18,6813	13,9576	4,4578	23,4075	2,1092	1,2663	3,5130	1,7471	1,1908	2,5633	0,0038

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatid Total Subject	Abaloparatid Subject with Event	Abaloparatid Percent of Patients with Event	Teriparatid Total Subject	Teriparatid Subject with Event	Teriparatid Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
No	550	150	27,2727	504	102	20,2381	7,0346	1,8844	12,1054	1,4779	1,1091	1,9695	1,3476	1,0808	1,6802	0,0075
Any Prior Nonvertebral Fracture
Yes	306	92	30,0654	271	57	21,0332	9,0321	1,8822	15,9852	1,6140	1,1028	2,3622	1,4294	1,0727	1,9048	0,0134
No	388	105	27,0619	415	79	19,0361	8,0257	2,2025	13,8213	1,5780	1,1322	2,1994	1,4216	1,0994	1,8382	0,0068
Any Prior Clinical Major Osteoporotic Fracture
Yes	237	72	30,3797	208	42	20,1923	10,1874	2,0652	18,0300	1,7247	1,1137	2,6707	1,5045	1,0796	2,0967	0,0140
No	457	125	27,3523	478	94	19,6653	7,6870	2,2529	13,0875	1,5381	1,1335	2,0871	1,3909	1,0998	1,7591	0,0055
Prevalence of Vertebral Fracture at Baseline
Yes	144	47	32,6389	182	34	18,6813	13,9576	4,4578	23,4075	2,1092	1,2663	3,5130	1,7471	1,1908	2,5633	0,0038
No	550	150	27,2727	504	102	20,2381	7,0346	1,8844	12,1054	1,4779	1,1091	1,9695	1,3476	1,0808	1,6802	0,0075
Number of Prevalence of Vertebral Fracture at Baseline
0	550	150	27,2727	504	102	20,2381	7,0346	1,8844	12,1054	1,4779	1,1091	1,9695	1,3476	1,0808	1,6802	0,0075
1	111	40	36,0360	126	25	19,8413	16,1948	4,7792	27,2427	2,2761	1,2684	4,0841	1,8162	1,1819	2,7910	0,0053
>=2	33	7	21,2121	56	9	16,0714	5,1407	-10,6300	23,2515	1,4060	0,4691	4,2144	1,3199	0,5425	3,2113	0,5418
Severity of Vertebral Fracture (SQ Score) at Baseline
0	550	150	27,2727	505	102	20,1980	7,0747	1,9289	12,1417	1,4816	1,1119	1,9743	1,3503	1,0829	1,6836	0,0071
1	89	32	35,9551	106	20	18,8679	17,0871	4,5729	29,2164	2,4140	1,2586	4,6302	1,9056	1,1763	3,0870	0,0072
>=2	55	15	27,2727	75	14	18,6667	8,6061	-5,7169	23,4355	1,6339	0,7122	3,7485	1,4610	0,7705	2,7704	0,2442
Severe Disease (least BMD T-score <= -2.5 and Prevalent

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- atide Total Subject	Abalopar- atide Subject with Event	Abalopar- atide Percent of Patients with Event	Teri- para- atide Total Sub- ject	Teri- para- atide Sub- ject with Event	Teripara- atide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Vertebral Fracture) at Baseline ##																
Yes	113	39	34,5133	142	27	19,0141	15,4992	4,6177	26,2245	2,2447	1,2681	3,9735	1,8151	1,1879	2,7735	0,0050
No	581	158	27,1945	544	109	20,0368	7,1577	2,1876	12,0611	1,4907	1,1285	1,9691	1,3572	1,0955	1,6814	0,0048
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	529	148	27,9773	511	104	20,3523	7,6251	2,4192	12,7670	1,5202	1,1408	2,0257	1,3747	1,1039	1,7118	0,0041
> -2.5	165	49	29,6970	175	32	18,2857	11,4113	2,3369	20,3308	1,8877	1,1354	3,1383	1,6241	1,0980	2,4021	0,0136
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	394	111	28,1726	365	65	17,8082	10,3644	4,3761	16,2239	1,8103	1,2801	2,5600	1,5820	1,2065	2,0744	0,0007
> -3	300	86	28,6667	321	71	22,1184	6,5483	-0,2946	13,3564	1,4150	0,9838	2,0352	1,2961	0,9874	1,7012	0,0606
Total Hip BMD T- score Group 1 at Baseline
<= -2.5	170	51	30,0000	154	22	14,2857	15,7143	6,6764	24,3475	2,5714	1,4718	4,4925	2,1000	1,3392	3,2931	0,0007
> -2.5	523	146	27,9159	532	114	21,4286	6,4873	1,2844	11,6533	1,4200	1,0713	1,8821	1,3027	1,0526	1,6123	0,0145
Total Hip BMD T- score Group 2 at Baseline
<= -3	52	14	26,9231	51	8	15,6863	11,2368	-4,7316	26,5395	1,9803	0,7491	5,2349	1,7163	0,7883	3,7369	0,1642
> -3	641	183	28,5491	635	128	20,1575	8,3917	3,6849	13,0500	1,5826	1,2218	2,0501	1,4163	1,1626	1,7254	0,0005
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	67	31,6038	207	38	18,3575	13,2463	4,9607	21,2876	2,0550	1,3029	3,2412	1,7216	1,2145	2,4404	0,0018
> -2.5	481	130	27,0270	479	98	20,4593	6,5677	1,1822	11,9059	1,4399	1,0671	1,9429	1,3210	1,0500	1,6621	0,0168
Femoral Neck BMD T-score Group 2 at Baseline

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Subject	Teriparatide Subject with Event	Teriparatide Percent of Subject with Event	Risk Difference (Abaloparatide vs Teriparatide)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Abaloparatide vs Teriparatide)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Abaloparatide vs Teriparatide)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Abaloparatide vs Teriparatide)
<= -3	73	21	28,7671	78	17	21,7949	6,9723	-6,8314	20,6056	1,4491	0,6923	3,0334	1,3199	0,7584	2,2971	0,3238
> -3	620	176	28,3871	608	119	19,5724	8,8147	4,0429	13,5316	1,6289	1,2488	2,1247	1,4504	1,1828	1,7785	0,0003

The risk difference was calculated as (Abaloparatide-SC - Teriparatide). 95% CI was based on the Newcombe's method.

The odds ratio and relative risk were calculated as Abaloparatide-SC/Teriparatide. 95% CI was based on the Wald's method. When no event in one or more arms, zero cell correction of 0.5 to all cells was applied. see <https://training.cochrane.org/handbook/current/chapter-10>, section 10.4.4.1 Studies with no events in one or more arms.

P-value obtained from the Chi-Square test or Fisher's exact test if event count is less than 5 in either treatment group.

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Tabelle 4-30: Subgruppenanalyse UESI Beeinträchtigung der Nierenfunktion

Subgroup	Abaloparatid Total Subject	Abaloparatid Subject with Event	Abaloparatid Percent of Patients with Event	Teriparatid Total Subject	Teriparatid Subject with Event	Teriparatid Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
All Safety Population	694	46	6,6282	686	30	4,3732	2,2551	-0,1690	4,7211	1,5523	0,9677	2,4901	1,5157	0,9687	2,3715	0,0663
Age (Years)
<65	101	14	13,8614	99	8	8,0808	5,7806	-3,1216	14,7561	1,8305	0,7316	4,5795	1,7153	0,7530	3,9074	0,1915
65 to <75	454	24	5,2863	443	15	3,3860	1,9003	-0,8263	4,6927	1,5926	0,8241	3,0777	1,5612	0,8301	2,9363	0,1629
>=75	139	8	5,7554	144	7	4,8611	0,8943	-4,6960	6,6495	1,1952	0,4215	3,3892	1,1840	0,4411	3,1776	0,7371
Years Since Menopause
<15	136	11	8,0882	154	6	3,8961	4,1921	-1,3929	10,3739	2,1707	0,7805	6,0367	2,0760	0,7888	5,4633	0,1294
15 to <25	338	14	4,1420	324	18	5,5556	-1,4135	-4,8894	1,9458	0,7346	0,3591	1,5026	0,7456	0,3771	1,4740	0,3966
>=25	220	21	9,5455	208	6	2,8846	6,6608	2,0773	11,5223	3,5528	1,4043	8,9880	3,3091	1,3626	8,0361	0,0046
Ethnicity
White	533	37	6,9418	513	26	5,0682	1,8736	-1,0514	4,8176	1,3973	0,8333	2,3430	1,3697	0,8419	2,2284	0,2029
Black/African-American	26	0	0,0000	24	0	0,0000	.	.	.	0,9245	0,0177	48,4126	0,9259	0,0191	44,9269	.
Asian	128	8	6,2500	137	4	2,9197	3,3303	-1,9794	9,2048	2,2167	0,6509	7,5484	2,1406	0,6605	6,9372	0,2429
Other	7	1	14,2857	12	0	0,0000	14,2857	-12,6464	51,3128	5,7692	0,2049	162,4763	4,8750	0,2247	105,7593	0,3684
Region
North America	17	2	11,7647	9	1	11,1111	0,6536	-32,8261	24,9988	1,0667	0,0834	13,6501	1,0588	0,1104	10,1508	1,0000
South America	222	11	4,9550	222	5	2,2523	2,7027	-0,9256	6,6184	2,2626	0,7730	6,6225	2,2000	0,7771	6,2282	0,1266
Europe	330	26	7,8788	323	21	6,5015	1,3772	-2,6763	5,4450	1,2299	0,6773	2,2337	1,2118	0,6962	2,1093	0,4960
Asia	125	7	5,6000	132	3	2,2727	3,3273	-1,7515	9,0358	2,5508	0,6447	10,0924	2,4640	0,6515	9,3184	0,2068
Any Prior Fracture
Yes	405	19	4,6914	397	15	3,7783	0,9130	-1,9779	3,8325	1,2535	0,6278	2,5032	1,2416	0,6400	2,4087	0,5211
No	289	27	9,3426	289	15	5,1903	4,1522	-0,1245	8,5523	1,8824	0,9793	3,6185	1,8000	0,9783	3,3119	0,0545

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparotide Total Subject	Abaloparotide Subject with Event	Abaloparotide Percent of Patients with Event	Teriparotide Total Subject	Teriparotide Subject with Event	Teriparotide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Any Prior Vertebral Fracture
Yes	144	8	5,5556	182	5	2,7473	2,8083	-1,6378	8,0709	2,0824	0,6663	6,5077	2,0222	0,6760	6,0494	0,1981
No	550	38	6,9091	504	25	4,9603	1,9488	-0,9616	4,8480	1,4220	0,8455	2,3916	1,3929	0,8533	2,2737	0,1825
Any Prior Nonvertebral Fracture
Yes	306	14	4,5752	271	12	4,4280	0,1471	-3,4971	3,6496	1,0348	0,4701	2,2778	1,0332	0,4863	2,1950	0,9322
No	388	32	8,2474	415	18	4,3373	3,9101	0,5446	7,4447	1,9825	1,0936	3,5941	1,9015	1,0855	3,3310	0,0219
Any Prior Clinical Major Osteoporotic Fracture
Yes	237	12	5,0633	208	7	3,3654	1,6979	-2,3358	5,6694	1,5314	0,5915	3,9652	1,5045	0,6036	3,7503	0,3767
No	457	34	7,4398	478	23	4,8117	2,6281	-0,4680	5,8251	1,5901	0,9216	2,7436	1,5462	0,9253	2,5836	0,0932
Prevalence of Vertebral Fracture at Baseline
Yes	144	8	5,5556	182	5	2,7473	2,8083	-1,6378	8,0709	2,0824	0,6663	6,5077	2,0222	0,6760	6,0494	0,1981
No	550	38	6,9091	504	25	4,9603	1,9488	-0,9616	4,8480	1,4220	0,8455	2,3916	1,3929	0,8533	2,2737	0,1825
Number of Prevalence of Vertebral Fracture at Baseline
0	550	38	6,9091	504	25	4,9603	1,9488	-0,9616	4,8480	1,4220	0,8455	2,3916	1,3929	0,8533	2,2737	0,1825
1	111	7	6,3063	126	3	2,3810	3,9254	-1,5144	10,2637	2,7596	0,6960	10,9415	2,6486	0,7018	9,9969	0,1960
>=2	33	1	3,0303	56	2	3,5714	-0,5411	-9,4447	12,0166	0,8438	0,0735	9,6799	0,8485	0,0800	9,0007	1,0000
Severity of Vertebral Fracture (SQ Score) at Baseline

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- tide Total Subject	Abalopar- tide Subject with Event	Abalopar- tide Percent of Patients with Event	Teri- para- tide Total Sub- ject	Teri- para- tide Sub- ject with Event	Teripara- tide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
0	550	38	6,9091	505	25	4,9505	1,9586	-0,9485	4,8561	1,4250	0,8473	2,3966	1,3956	0,8550	2,2783	0,1799
1	89	6	6,7416	106	3	2,8302	3,9114	-2,3911	11,3439	2,4819	0,6025	10,2243	2,3820	0,6132	9,2526	0,3050
>=2	55	2	3,6364	75	2	2,6667	0,9697	-6,0851	9,8691	1,3774	0,1880	10,0925	1,3636	0,1982	9,3838	1,0000
Severe Disease (least BMD T- score <= -2.5 and Prevalent Vertebral Fracture) at Baseline
Yes	113	7	6,1947	142	3	2,1127	4,0820	-0,9498	10,2825	3,0597	0,7729	12,1126	2,9322	0,7757	11,0838	0,1134
No	581	39	6,7126	544	27	4,9632	1,7493	-1,0405	4,5387	1,3778	0,8313	2,2836	1,3525	0,8398	2,1781	0,2121
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	529	34	6,4272	511	19	3,7182	2,7090	0,0121	5,4680	1,7786	1,0007	3,1612	1,7286	0,9992	2,9903	0,0470
> -2.5	165	12	7,2727	175	11	6,2857	0,9870	-4,5548	6,6956	1,1693	0,5012	2,7284	1,1570	0,5251	2,5494	0,7172
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	394	21	5,3299	365	11	3,0137	2,3163	-0,6164	5,3052	1,8118	0,8611	3,8121	1,7686	0,8648	3,6169	0,1126
> -3	300	25	8,3333	321	19	5,9190	2,4143	-1,6784	6,6490	1,4450	0,7785	2,6821	1,4079	0,7919	2,5030	0,2413
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	8	4,7059	154	7	4,5455	0,1604	-4,9290	5,0530	1,0370	0,3670	2,9301	1,0353	0,3844	2,7881	0,9453
> -2.5	523	38	7,2658	532	23	4,3233	2,9425	0,1070	5,8637	1,7339	1,0180	2,9533	1,6806	1,0157	2,7807	0,0406
Total Hip BMD T-score Group 2 at Baseline

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Subject	Teriparatide Subject with Event	Teriparatide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
<= -3	52	2	3,8462	51	2	3,9216	-0,0754	-9,7784	9,4907	0,9800	0,1327	7,2353	0,9808	0,1436	6,7000	1,0000
> -3	641	44	6,8643	635	28	4,4094	2,4548	-0,0946	5,0532	1,5978	0,9817	2,6005	1,5567	0,9818	2,4683	0,0574
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	11	5,1887	207	7	3,3816	1,8070	-2,3068	6,0406	1,5636	0,5941	4,1150	1,5344	0,6066	3,8814	0,3617
> -2.5	481	35	7,2765	479	23	4,8017	2,4748	-0,5721	5,5823	1,5559	0,9048	2,6753	1,5154	0,9094	2,5253	0,1076
Femoral Neck BMD T-score Group 2 at Baseline
<= -3	73	3	4,1096	78	4	5,1282	-1,0186	-8,8294	6,9099	0,7929	0,1713	3,6696	0,8014	0,1856	3,4594	1,0000
> -3	620	43	6,9355	608	26	4,2763	2,6592	0,0672	5,3014	1,6682	1,0115	2,7513	1,6218	1,0097	2,6050	0,0431

The risk difference was calculated as (Abaloparatide-SC - Teriparatide). 95% CI was based on the Newcombe's method.

The odds ratio and relative risk were calculated as Abaloparatide-SC/Teriparatide. 95% CI was based on the Wald's method. When no event in one or more arms, zero cell correction of 0.5 to all cells was applied. see <https://training.cochrane.org/handbook/current/chapter-10>, section 10.4.4.1 Studies with no events in one or more arms.

P-value obtained from the Chi-Square test or Fisher's exact test if event count is less than 5 in either treatment group.

Tabelle 4-31: Subgruppenanalyse UESI Palpitationen

Subgroup	Abalopar- paratide Total Subject	Abalopar- paratide Subject with Event	Abalopar- paratide Percent of Patients with Event	Teri- paratide Total Sub- ject	Teri- paratide Sub- ject with Event	Teripara- tide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
All Safety Population	694	59	8,5014	686	24	3,4985	5,0029	2,5185	7,5776	2,5629	1,5750	4,1702	2,4300	1,5300	3,8595	0,0001
Age (Years)
<65	101	8	7,9208	99	4	4,0404	3,8804	-3,1591	11,2394	2,0430	0,5949	7,0163	1,9604	0,6098	6,3024	0,3730
65 to <75	454	46	10,1322	443	15	3,3860	6,7462	3,5032	10,1341	3,2170	1,7685	5,8520	2,9924	1,6959	5,2800	0,0001
>=75	139	5	3,5971	144	5	3,4722	0,1249	-4,7279	5,0842	1,0373	0,2936	3,6646	1,0360	0,3066	3,5002	0,9546
Years Since Menopause
<15	136	16	11,7647	154	5	3,2468	8,5180	2,4906	15,2696	3,9733	1,4149	11,1581	3,6235	1,3636	9,6291	0,0052
15 to <25	338	29	8,5799	324	13	4,0123	4,5675	0,8385	8,4116	2,2452	1,1456	4,4002	2,1384	1,1318	4,0400	0,0160
>=25	220	14	6,3636	208	6	2,8846	3,4790	-0,6546	7,8020	2,2880	0,8623	6,0711	2,2061	0,8640	5,6328	0,0883
Ethnicity
White	533	40	7,5047	513	16	3,1189	4,3858	1,6756	7,2030	2,5203	1,3929	4,5602	2,4062	1,3649	4,2418	0,0016
Black/African- American	26	1	3,8462	24	0	0,0000	3,8462	-10,3096	18,8928	2,8824	0,1120	74,2092	2,7778	0,1186	65,0847	1,0000
Asian	128	18	14,0625	137	8	5,8394	8,2231	0,9806	15,8489	2,6386	1,1046	6,3032	2,4082	1,0851	5,3446	0,0245
Other	7	0	0,0000	12	0	0,0000	.	.	.	1,6667	0,0298	93,1236	1,6250	0,0356	74,0851	.
Region
North America	17	1	5,8824	9	0	0,0000	5,8824	-24,4206	26,9820	1,7273	0,0638	46,7676	1,6667	0,0746	37,2138	1,0000
South America	222	7	3,1532	222	3	1,3514	1,8018	-1,2143	5,1343	2,3767	0,6067	9,3116	2,3333	0,6112	8,9080	0,3381
Europe	330	33	10,0000	323	13	4,0248	5,9752	2,0654	10,0398	2,6496	1,3677	5,1327	2,4846	1,3323	4,6335	0,0029
Asia	125	18	14,4000	132	8	6,0606	8,3394	0,8851	16,1381	2,6075	1,0902	6,2366	2,3760	1,0718	5,2673	0,0267
Any Prior Fracture
Yes	405	37	9,1358	397	15	3,7783	5,3575	1,9654	8,8840	2,5605	1,3819	4,7445	2,4179	1,3487	4,3347	0,0021
No	289	22	7,6125	289	9	3,1142	4,4983	0,7988	8,4265	2,5635	1,1594	5,6678	2,4444	1,1453	5,2175	0,0164
Any Prior Vertebral Fracture

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- atide Total Subject	Abalopar- atide Subject with Event	Abalopar- atide Percent of Patients with Event	Teri- para- atide Total Sub- ject	Teri- para- atide Sub- ject with Event	Teripara- atide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Yes	144	13	9,0278	182	7	3,8462	5,1816	-0,1624	11,3122	2,4809	0,9630	6,3915	2,3472	0,9615	5,7299	0,0529
No	550	46	8,3636	504	17	3,3730	4,9906	2,1640	7,8895	2,6146	1,4785	4,6237	2,4796	1,4406	4,2678	0,0006
Any Prior Nonvertebral Fracture
Yes	306	28	9,1503	271	15	5,5351	3,6153	-0,7500	7,9448	1,7189	0,8976	3,2917	1,6532	0,9023	3,0287	0,0989
No	388	31	7,9897	415	9	2,1687	5,8210	2,8339	9,1121	3,9172	1,8400	8,3395	3,6841	1,7770	7,6380	0,0002
Any Prior Clinical Major Osteoporotic Fracture
Yes	237	23	9,7046	208	12	5,7692	3,9354	-1,1900	8,9976	1,7555	0,8508	3,6222	1,6821	0,8585	3,2960	0,1239
No	457	36	7,8775	478	12	2,5105	5,3670	2,5590	8,3973	3,3207	1,7052	6,4666	3,1379	1,6536	5,9545	0,0002
Prevalence of Vertebral Fracture at Baseline
Yes	144	13	9,0278	182	7	3,8462	5,1816	-0,1624	11,3122	2,4809	0,9630	6,3915	2,3472	0,9615	5,7299	0,0529
No	550	46	8,3636	504	17	3,3730	4,9906	2,1640	7,8895	2,6146	1,4785	4,6237	2,4796	1,4406	4,2678	0,0006
Number of Prevalence of Vertebral Fracture at Baseline
0	550	46	8,3636	504	17	3,3730	4,9906	2,1640	7,8895	2,6146	1,4785	4,6237	2,4796	1,4406	4,2678	0,0006
1	111	11	9,9099	126	6	4,7619	5,1480	-1,6202	12,5718	2,2000	0,7858	6,1593	2,0811	0,7957	5,4430	0,1254
>=2	33	2	6,0606	56	1	1,7857	4,2749	-4,5501	17,9000	3,5484	0,3091	40,7304	3,3939	0,3199	36,0028	0,5525
Severity of Vertebral Fracture (SQ Score) at Baseline
0	550	46	8,3636	505	17	3,3663	4,9973	2,1733	7,8952	2,6200	1,4816	4,6331	2,4845	1,4434	4,2764	0,0006
1	89	9	10,1124	106	5	4,7170	5,3954	-2,1114	13,8354	2,2725	0,7327	7,0482	2,1438	0,7455	6,1649	0,1460
>=2	55	4	7,2727	75	2	2,6667	4,6061	-3,2849	14,7785	2,8627	0,5052	16,2232	2,7273	0,5179	14,3627	0,2411

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatid Total Subject	Abaloparatid Subject with Event	Abaloparatid Percent of Patients with Event	Teriparatid Total Subject	Teriparatid Subject with Event	Teriparatid Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Severe Disease (least BMD T-score <= -2.5 and Prevalent Vertebral Fracture) at Baseline
Yes	113	12	10,6195	142	4	2,8169	7,8026	1,6899	15,0381	4,0990	1,2846	13,0798	3,7699	1,2495	11,3740	0,0170
No	581	47	8,0895	544	20	3,6765	4,4130	1,6656	7,2256	2,3060	1,3479	3,9451	2,2003	1,3213	3,6643	0,0018
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	529	46	8,6957	511	17	3,3268	5,3688	2,5029	8,3477	2,7675	1,5647	4,8950	2,6138	1,5188	4,4982	0,0003
> -2.5	165	13	7,8788	175	7	4,0000	3,8788	-1,2739	9,4061	2,0526	0,7981	5,2793	1,9697	0,8057	4,8152	0,1287
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	394	33	8,3756	365	10	2,7397	5,6359	2,3969	9,0263	3,2452	1,5756	6,6837	3,0571	1,5287	6,1134	0,0008
> -3	300	26	8,6667	321	14	4,3614	4,3053	0,4085	8,4227	2,0808	1,0650	4,0657	1,9871	1,0579	3,7325	0,0290
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	20	11,7647	154	3	1,9481	9,8167	4,4066	15,6674	6,7111	1,9531	23,0602	6,0392	1,8304	19,9258	0,0004
> -2.5	523	39	7,4570	532	21	3,9474	3,5096	0,7050	6,4174	1,9607	1,1371	3,3811	1,8891	1,1270	3,1667	0,0139
Total Hip BMD T-score Group 2 at Baseline
<= -3	52	4	7,6923	51	2	3,9216	3,7707	-6,6269	14,6298	2,0417	0,3571	11,6720	1,9615	0,3756	10,2428	0,6781
> -3	641	55	8,5803	635	22	3,4646	5,1158	2,5278	7,8041	2,6152	1,5748	4,3430	2,4766	1,5293	4,0108	0,0001
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	21	9,9057	207	8	3,8647	6,0409	1,1519	11,1659	2,7349	1,1829	6,3235	2,5631	1,1615	5,6558	0,0149

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Subject	Teriparatide Subject with Event	Teriparatide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
> -2.5	481	38	7,9002	479	16	3,3403	4,5599	1,6554	7,5976	2,4822	1,3644	4,5159	2,3651	1,3372	4,1832	0,0022
Femoral Neck BMD T-score Group 2 at Baseline
<= -3	73	8	10,9589	78	1	1,2821	9,6769	1,9454	18,9409	9,4769	1,1548	77,7708	8,5479	1,0958	66,6796	0,0151
> -3	620	51	8,2258	608	23	3,7829	4,4429	1,7951	7,1739	2,2797	1,3750	3,7799	2,1745	1,3463	3,5120	0,0011

The risk difference was calculated as (Abaloparatide-SC - Teriparatide). 95% CI was based on the Newcombe's method. The odds ratio and relative risk were calculated as Abaloparatide-SC/Teriparatide. 95% CI was based on the Wald's method. When no event in one or more arms, zero cell correction of 0.5 to all cells was applied. see <https://training.cochrane.org/handbook/current/chapter-10>, section 10.4.4.1 Studies with no events in one or more arms. P-value obtained from the Chi-Square test or Fisher's exact test if event count is less than 5 in either treatment group.

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Tabelle 4-32: Subgruppenanalyse UESI Übelkeit

Subgroup	Abaloparotide Total Subject	Abaloparotide Subject with Event	Abaloparotide Percent of Patients with Event	Teriparotide Total Subject	Teriparotide Subject with Event	Teriparotide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
All Safety Population	694	62	8,9337	686	44	6,4140	2,5197	-0,3041	5,3672	1,4314	0,9579	2,1389	1,3928	0,9605	2,0198	0,0788
Age (Years)
<65	101	9	8,9109	99	10	10,1010	-1,1901	-9,7645	7,2805	0,8707	0,3379	2,2434	0,8822	0,3745	2,0781	0,7741
65 to <75	454	46	10,1322	443	27	6,0948	4,0374	0,4450	7,6751	1,7371	1,0595	2,8480	1,6624	1,0528	2,6250	0,0270
>=75	139	7	5,0360	144	7	4,8611	0,1749	-5,3010	5,7536	1,0379	0,3544	3,0397	1,0360	0,3730	2,8770	0,9459
Years Since Menopause
<15	136	15	11,0294	154	12	7,7922	3,2372	-3,5703	10,4030	1,4669	0,6612	3,2546	1,4154	0,6868	2,9173	0,3438
15 to <25	338	35	10,3550	324	17	5,2469	5,1081	0,9985	9,2936	2,0860	1,1440	3,8038	1,9735	1,1284	3,4516	0,0146
>=25	220	12	5,4545	208	15	7,2115	-1,7570	-6,6762	2,9880	0,7423	0,3389	1,6257	0,7564	0,3627	1,5775	0,4549
Ethnicity
White	533	50	9,3809	513	31	6,0429	3,3380	0,0821	6,6197	1,6096	1,0105	2,5637	1,5524	1,0085	2,3896	0,0435
Black/African-American	26	1	3,8462	24	0	0,0000	3,8462	-10,3096	18,8928	2,8824	0,1120	74,2092	2,7778	0,1186	65,0847	1,0000
Asian	128	10	7,8125	137	11	8,0292	-0,2167	-6,9778	6,6989	0,9707	0,3977	2,3696	0,9730	0,4278	2,2132	0,9480
Other	7	1	14,2857	12	2	16,6667	-2,3810	-32,8599	36,5329	0,8333	0,0616	11,2772	0,8571	0,0938	7,8297	1,0000
Region
North America	17	3	17,6471	9	1	11,1111	6,5359	-27,8192	31,6347	1,7143	0,1518	19,3588	1,5882	0,1918	13,1531	1,0000
South America	222	13	5,8559	222	10	4,5045	1,3514	-2,9659	5,7559	1,3187	0,5657	3,0737	1,3000	0,5823	2,9023	0,5206
Europe	330	36	10,9091	323	22	6,8111	4,0979	-0,3007	8,5453	1,6753	0,9625	2,9160	1,6017	0,9640	2,6612	0,0657
Asia	125	10	8,0000	132	11	8,3333	-0,3333	-7,3057	6,7592	0,9565	0,3914	2,3377	0,9600	0,4225	2,1812	0,9223
Any Prior Fracture
Yes	405	34	8,3951	397	33	8,3123	0,0827	-3,8178	3,9680	1,0109	0,6129	1,6671	1,0100	0,6385	1,5975	0,9662
No	289	28	9,6886	289	11	3,8062	5,8824	1,7953	10,1772	2,7113	1,3229	5,5568	2,5455	1,2920	5,0149	0,0048

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- tide Total Subject	Abalopar- tide Subject with Event	Abalopar- tide Percent of Patients with Event	Teri- para- tide Total Sub- ject	Teri- para- tide Sub- ject with Event	Teripara- tide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Any Prior Vertebral Fracture
Yes	144	13	9,0278	182	14	7,6923	1,3355	-4,7137	7,8955	1,1908	0,5411	2,6205	1,1736	0,5698	2,4173	0,6640
No	550	49	8,9091	504	30	5,9524	2,9567	-0,2487	6,1537	1,5453	0,9645	2,4759	1,4967	0,9659	2,3193	0,0686
Any Prior Nonvertebral Fracture
Yes	306	28	9,1503	271	21	7,7491	1,4012	-3,2907	5,9841	1,1990	0,6640	2,1653	1,1808	0,6870	2,0297	0,5468
No	388	34	8,7629	415	23	5,5422	3,2207	-0,3611	6,9313	1,6369	0,9460	2,8325	1,5811	0,9488	2,6350	0,0757
Any Prior Clinical Major Osteoporotic Fracture
Yes	237	21	8,8608	208	14	6,7308	2,1300	-3,0666	7,2004	1,3472	0,6667	2,7225	1,3165	0,6872	2,5220	0,4050
No	457	41	8,9716	478	30	6,2762	2,6954	-0,7256	6,1947	1,4718	0,9022	2,4011	1,4295	0,9086	2,2488	0,1199
Prevalence of Vertebral Fracture at Baseline
Yes	144	13	9,0278	182	14	7,6923	1,3355	-4,7137	7,8955	1,1908	0,5411	2,6205	1,1736	0,5698	2,4173	0,6640
No	550	49	8,9091	504	30	5,9524	2,9567	-0,2487	6,1537	1,5453	0,9645	2,4759	1,4967	0,9659	2,3193	0,0686
Number of Prevalence of Vertebral Fracture at Baseline
0	550	49	8,9091	504	30	5,9524	2,9567	-0,2487	6,1537	1,5453	0,9645	2,4759	1,4967	0,9659	2,3193	0,0686
1	111	11	9,9099	126	12	9,5238	0,3861	-7,3054	8,4164	1,0450	0,4417	2,4722	1,0405	0,4783	2,2639	0,9202
>=2	33	2	6,0606	56	2	3,5714	2,4892	-7,1162	16,2795	1,7419	0,2336	12,9890	1,6970	0,2507	11,4849	0,6253
Severity of Vertebral Fracture (SQ Score) at Baseline

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- tide Total Subject	Abalopar- tide Subject with Event	Abalopar- tide Percent of Patients with Event	Teri- para- tide Total Sub- ject	Teri- para- tide Sub- ject with Event	Teripara- tide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
0	550	49	8,9091	505	30	5,9406	2,9685	-0,2335	6,1636	1,5486	0,9665	2,4811	1,4997	0,9678	2,3240	0,0672
1	89	9	10,1124	106	7	6,6038	3,5086	-4,4351	12,1900	1,5911	0,5676	4,4600	1,5313	0,5942	3,9464	0,3739
>=2	55	4	7,2727	75	7	9,3333	-2,0606	-11,8149	8,9937	0,7619	0,2116	2,7430	0,7792	0,2399	2,5312	0,7590
Severe Disease (least BMD T- score <= -2.5 and Prevalent Vertebral Fracture) at Baseline
Yes	113	9	7,9646	142	11	7,7465	0,2181	-6,4971	7,5221	1,0306	0,4116	2,5803	1,0282	0,4414	2,3949	0,9487
No	581	53	9,1222	544	33	6,0662	3,0560	-0,0680	6,1849	1,5544	0,9898	2,4409	1,5038	0,9895	2,2855	0,0539
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	529	44	8,3176	511	34	6,6536	1,6640	-1,5778	4,9096	1,2728	0,7994	2,0264	1,2501	0,8126	1,9231	0,3084
> -2.5	165	18	10,9091	175	10	5,7143	5,1948	-0,7453	11,4294	2,0204	0,9039	4,5161	1,9091	0,9080	4,0141	0,0816
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	394	40	10,1523	365	18	4,9315	5,2208	1,4465	9,0430	2,1783	1,2249	3,8736	2,0587	1,2024	3,5247	0,0068
> -3	300	22	7,3333	321	26	8,0997	-0,7664	-5,0363	3,5582	0,8979	0,4973	1,6213	0,9054	0,5247	1,5622	0,7208
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	14	8,2353	154	6	3,8961	4,3392	-1,0948	9,8654	2,2137	0,8288	5,9127	2,1137	0,8330	5,3636	0,1051
> -2.5	523	48	9,1778	532	38	7,1429	2,0350	-1,2927	5,4001	1,3137	0,8428	2,0476	1,2849	0,8543	1,9325	0,2271
Total Hip BMD T-score Group 2 at Baseline

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Subject	Teriparatide Subject with Event	Teriparatide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
<= -3	52	3	5,7692	51	3	5,8824	-0,1131	-10,8460	10,4885	0,9796	0,1883	5,0959	0,9808	0,2075	4,6347	1,0000
> -3	641	59	9,2044	635	41	6,4567	2,7477	-0,2158	5,7392	1,4687	0,9703	2,2232	1,4256	0,9719	2,0910	0,0678
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	23	10,8491	207	13	6,2802	4,5689	-0,8794	10,1070	1,8160	0,8938	3,6900	1,7275	0,8995	3,3176	0,0952
> -2.5	481	39	8,1081	479	31	6,4718	1,6363	-1,6939	4,9931	1,2751	0,7815	2,0805	1,2528	0,7954	1,9733	0,3296
Femoral Neck BMD T-score Group 2 at Baseline
<= -3	73	6	8,2192	78	5	6,4103	1,8089	-7,0874	11,1252	1,3075	0,3813	4,4833	1,2822	0,4088	4,0215	0,6691
> -3	620	56	9,0323	608	39	6,4145	2,6178	-0,3883	5,6467	1,4486	0,9470	2,2159	1,4081	0,9504	2,0863	0,0860

The risk difference was calculated as (Abaloparatide-SC - Teriparatide). 95% CI was based on the Newcombe's method.

The odds ratio and relative risk were calculated as Abaloparatide-SC/Teriparatide. 95% CI was based on the Wald's method. When no event in one or more arms, zero cell correction of 0.5 to all cells was applied. see <https://training.cochrane.org/handbook/current/chapter-10>, section 10.4.4.1 Studies with no events in one or more arms.

P-value obtained from the Chi-Square test or Fisher's exact test if event count is less than 5 in either treatment group.

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Tabelle 4-33: Subgruppenanalyse UESI Schwindel

Subgroup	Abalopar- atide Total Subject	Abalopar- atide Subject with Event	Abalopar- atide Percent of Patients with Event	Teri- para- atide Total Sub- ject	Teri- para- atide Sub- ject with Event	Teripara- atide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
All Safety Population	694	77	11,0951	686	57	8,3090	2,7861	-0,3496	5,9344	1,3772	0,9608	1,9740	1,3353	0,9640	1,8496	0,0805
Age (Years)
<65	101	11	10,8911	99	5	5,0505	5,8406	-1,9652	13,9340	2,2978	0,7680	6,8749	2,1564	0,7775	5,9810	0,1280
65 to <75	454	49	10,7930	443	40	9,0293	1,7636	-2,1874	5,7131	1,2190	0,7852	1,8924	1,1953	0,8040	1,7772	0,3771
>=75	139	17	12,2302	144	12	8,3333	3,8969	-3,3103	11,2661	1,5328	0,7034	3,3400	1,4676	0,7279	2,9592	0,2799
Years Since Menopause
<15	136	17	12,5000	154	11	7,1429	5,3571	-1,5461	12,6590	1,8571	0,8374	4,1185	1,7500	0,8497	3,6042	0,1232
15 to <25	338	37	10,9467	324	30	9,2593	1,6875	-2,9752	6,3287	1,2047	0,7251	2,0014	1,1822	0,7487	1,8668	0,4718
>=25	220	23	10,4545	208	16	7,6923	2,7622	-2,8192	8,3235	1,4010	0,7181	2,7333	1,3591	0,7390	2,4994	0,3210
Ethnicity
White	533	47	8,8180	513	31	6,0429	2,7751	-0,4335	6,0040	1,5037	0,9392	2,4074	1,4592	0,9426	2,2589	0,0876
Black/African-American	26	0	0,0000	24	0	0,0000	.	.	.	0,9245	0,0177	48,4126	0,9259	0,0191	44,9269	.
Asian	128	30	23,4375	137	25	18,2482	5,1893	-4,5864	14,9760	1,3714	0,7557	2,4889	1,2844	0,8004	2,0610	0,2979
Other	7	0	0,0000	12	1	8,3333	-8,3333	-35,3880	27,7552	0,5111	0,0183	14,2822	0,5417	0,0250	11,7510	1,0000
Region
North America	17	2	11,7647	9	0	0,0000	11,7647	-19,3276	34,3364	3,0645	0,1324	70,9387	2,7778	0,1474	52,3507	0,5292
South America	222	7	3,1532	222	6	2,7027	0,4505	-3,0172	3,9773	1,1721	0,3876	3,5447	1,1667	0,3984	3,4164	0,7783
Europe	330	38	11,5152	323	26	8,0495	3,4656	-1,1380	8,0928	1,4866	0,8800	2,5113	1,4305	0,8899	2,2995	0,1364
Asia	125	30	24,0000	132	25	18,9394	5,0606	-4,9755	15,0787	1,3516	0,7430	2,4587	1,2672	0,7912	2,0296	0,3228
Any Prior Fracture
Yes	405	48	11,8519	397	29	7,3048	4,5471	0,4547	8,6758	1,7062	1,0521	2,7667	1,6225	1,0453	2,5185	0,0289
No	289	29	10,0346	289	28	9,6886	0,3460	-4,5942	5,2910	1,0397	0,6017	1,7966	1,0357	0,6326	1,6957	0,8890

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- tide Total Subject	Abalopar- tide Subject with Event	Abalopar- tide Percent of Patients with Event	Teri- para- tide Total Sub- ject	Teri- para- tide Sub- ject with Event	Teripara- tide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
Any Prior Vertebral Fracture
Yes	144	16	11,1111	182	14	7,6923	3,4188	-2,9330	10,3093	1,5000	0,7063	3,1858	1,4444	0,7295	2,8602	0,2889
No	550	61	11,0909	504	43	8,5317	2,5592	-1,0744	6,1602	1,3374	0,8871	2,0162	1,3000	0,8970	1,8840	0,1640
Any Prior Nonvertebral Fracture
Yes	306	36	11,7647	271	18	6,6421	5,1226	0,3338	9,8670	1,8741	1,0376	3,3849	1,7712	1,0305	3,0445	0,0350
No	388	41	10,5670	415	39	9,3976	1,1694	-2,9992	5,4030	1,1391	0,7177	1,8082	1,1244	0,7418	1,7045	0,5803
Any Prior Clinical Major Osteoporotic Fracture
Yes	237	27	11,3924	208	14	6,7308	4,6616	-0,8074	10,0504	1,7816	0,9077	3,4969	1,6926	0,9123	3,1403	0,0898
No	457	50	10,9409	478	43	8,9958	1,9451	-1,9137	5,8513	1,2428	0,8089	1,9094	1,2162	0,8260	1,7909	0,3205
Prevalence of Vertebral Fracture at Baseline
Yes	144	16	11,1111	182	14	7,6923	3,4188	-2,9330	10,3093	1,5000	0,7063	3,1858	1,4444	0,7295	2,8602	0,2889
No	550	61	11,0909	504	43	8,5317	2,5592	-1,0744	6,1602	1,3374	0,8871	2,0162	1,3000	0,8970	1,8840	0,1640
Number of Prevalence of Vertebral Fracture at Baseline
0	550	61	11,0909	504	43	8,5317	2,5592	-1,0744	6,1602	1,3374	0,8871	2,0162	1,3000	0,8970	1,8840	0,1640
1	111	14	12,6126	126	9	7,1429	5,4698	-2,2123	13,6341	1,8763	0,7786	4,5216	1,7658	0,7953	3,9203	0,1558
>=2	33	2	6,0606	56	5	8,9286	-2,8680	-14,0868	11,5899	0,6581	0,1203	3,6004	0,6788	0,1395	3,3034	1,0000
Severity of Vertebral Fracture (SQ Score) at Baseline

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abalopar- tide Total Subject	Abalopar- tide Subject with Event	Abalopar- tide Percent of Patients with Event	Teri- para- tide Total Sub- ject	Teri- para- tide Sub- ject with Event	Teripara- tide Percent of Subject with Event	Risk Dif- ference (Aba vs Ter)	Risk Dif- ference Lower CI	Risk Dif- ference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
0	550	61	11,0909	505	43	8,5149	2,5761	-1,0536	6,1746	1,3403	0,8891	2,0205	1,3025	0,8987	1,8878	0,1609
1	89	9	10,1124	106	9	8,4906	1,6218	-6,6964	10,5492	1,2125	0,4595	3,1991	1,1910	0,4941	2,8712	0,6968
>=2	55	7	12,7273	75	5	6,6667	6,0606	-4,2054	17,9682	2,0417	0,6119	6,8124	1,9091	0,6395	5,6988	0,2382
Severe Disease (least BMD T- score <= -2.5 and Prevalent Vertebral Fracture) at Baseline
Yes	113	13	11,5044	142	12	8,4507	3,0537	-4,3372	11,0708	1,4083	0,6161	3,2194	1,3614	0,6465	2,8667	0,4153
No	581	64	11,0155	544	45	8,2721	2,7434	-0,7374	6,2085	1,3727	0,9196	2,0492	1,3317	0,9263	1,9143	0,1201
Lumbar Spine BMD T-score Group 1 at Baseline
<= -2.5	529	60	11,3422	511	45	8,8063	2,5359	-1,1511	6,2207	1,3248	0,8817	1,9907	1,2880	0,8924	1,8588	0,1748
> -2.5	165	17	10,3030	175	12	6,8571	3,4459	-2,6145	9,7276	1,5602	0,7211	3,3757	1,5025	0,7404	3,0491	0,2556
Lumbar Spine BMD T-score Group 2 at Baseline
<= -3	394	46	11,6751	365	32	8,7671	2,9080	-1,4606	7,2411	1,3755	0,8550	2,2131	1,3317	0,8679	2,0433	0,1874
> -3	300	31	10,3333	321	25	7,7882	2,5452	-2,0035	7,2063	1,3645	0,7856	2,3700	1,3268	0,8025	2,1936	0,2685
Total Hip BMD T-score Group 1 at Baseline
<= -2.5	170	16	9,4118	154	12	7,7922	1,6196	-4,7790	7,8765	1,2294	0,5622	2,6885	1,2078	0,5903	2,4716	0,6044
> -2.5	523	61	11,6635	532	45	8,4586	3,2048	-0,4382	6,8822	1,4289	0,9524	2,1437	1,3789	0,9565	1,9878	0,0834
Total Hip BMD T-score Group 2 at Baseline

Ergänzende Unterlagen zu Med. Nutzen, med. Zusatznutzen, Patientengr. mit therap. bedeutsamem Zusatznutzen

Subgroup	Abaloparatide Total Subject	Abaloparatide Subject with Event	Abaloparatide Percent of Patients with Event	Teriparatide Total Subject	Teriparatide Subject with Event	Teriparatide Percent of Subject with Event	Risk Difference (Aba vs Ter)	Risk Difference Lower CI	Risk Difference Upper CI	Odds Ratio (Aba vs Ter)	Odds Ratio Lower CI	Odds Ratio Upper CI	Relative Risk (Aba vs Ter)	Relative Risk Lower CI	Relative Risk Upper CI	P-Value (Aba vs Ter)
<= -3	52	3	5,7692	51	3	5,8824	-0,1131	-10,8460	10,4885	0,9796	0,1883	5,0959	0,9808	0,2075	4,6347	1,0000
> -3	641	74	11,5445	635	54	8,5039	3,0405	-0,2675	6,3632	1,4042	0,9705	2,0316	1,3575	0,9729	1,8943	0,0707
Femoral Neck BMD T-score Group 1 at Baseline
<= -2.5	212	26	12,2642	207	18	8,6957	3,5685	-2,3930	9,5486	1,4677	0,7785	2,7673	1,4104	0,7979	2,4930	0,2336
> -2.5	481	51	10,6029	479	39	8,1420	2,4609	-1,2532	6,1972	1,3381	0,8639	2,0727	1,3023	0,8753	1,9374	0,1909
Femoral Neck BMD T-score Group 2 at Baseline
<= -3	73	7	9,5890	78	10	12,8205	-3,2315	-13,6351	7,3457	0,7212	0,2591	2,0071	0,7479	0,3006	1,8612	0,5301
> -3	620	70	11,2903	608	47	7,7303	3,5601	0,2672	6,8703	1,5191	1,0307	2,2390	1,4605	1,0269	2,0773	0,0336

The risk difference was calculated as (Abaloparatide-SC - Teriparatide). 95% CI was based on the Newcombe's method. The odds ratio and relative risk were calculated as Abaloparatide-SC/Teriparatide. 95% CI was based on the Wald's method. When no event in one or more arms, zero cell correction of 0.5 to all cells was applied. see <https://training.cochrane.org/handbook/current/chapter-10>, section 10.4.4.1 Studies with no events in one or more arms. P-value obtained from the Chi-Square test or Fisher's exact test if event count is less than 5 in either treatment group.