



Clinical trial results:

Comparison of the Effects of Teriparatide with those of Risedronate on Lumbar Spine BMD (Bone Mineral Density) in Men and Postmenopausal Women with Low Bone Mass and a Recent Pertrochanteric Hip Fracture Summary

| | |
|--------------------------|--|
| EudraCT number | 2008-002693-35 |
| Trial protocol | DK DE GB ES IT GR SE AT FR CZ IE FI NO |
| Global end of trial date | 20 August 2015 |

Results information

| | |
|--------------------------------|---|
| Result version number | v2 (current) |
| This version publication date | 27 November 2016 |
| First version publication date | 31 July 2016 |
| Version creation reason | <ul style="list-style-type: none">• Correction of full data set Correction needed to full data set. |

Trial information

Trial identification

| | |
|-----------------------|-------|
| Sponsor protocol code | 12400 |
|-----------------------|-------|

Additional study identifiers

| | |
|------------------------------------|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT00887354 |
| WHO universal trial number (UTN) | - |
| Other trial identifiers | Trial Alias: B3D-EW-GHDK, Trial ID: 12400 |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Eli Lilly and Company |
| Sponsor organisation address | Lilly Corporate Center, Indianapolis, IN, United States, 46285 |
| Public contact | Available Mon-Fri 9AM-5PM EST, Eli Lilly and Company, +1 877-CTLilly, |
| Scientific contact | Available Mon-Fri 9AM-5PM EST, Eli Lilly and Company, +1 877-285-4559, |

Notes:

Paediatric regulatory details

| | |
|--|----|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

Results analysis stage

| | |
|--|----------------|
| Analysis stage | Final |
| Date of interim/final analysis | 20 August 2015 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 20 August 2015 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

This study will evaluate whether teriparatide is superior to the active comparator in the change from baseline of lumbar spine BMD (bone mineral density) in men and postmenopausal women with low bone mass and a recent pertrochanteric hip fracture.

Protection of trial subjects:

This study was conducted in accordance with International Code of Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

| | |
|---|---------------|
| Actual start date of recruitment | 28 April 2009 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects**Subjects enrolled per country**

| | |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | France: 13 |
| Country: Number of subjects enrolled | Germany: 3 |
| Country: Number of subjects enrolled | Spain: 40 |
| Country: Number of subjects enrolled | United Kingdom: 1 |
| Country: Number of subjects enrolled | Austria: 1 |
| Country: Number of subjects enrolled | Ireland: 1 |
| Country: Number of subjects enrolled | Sweden: 5 |
| Country: Number of subjects enrolled | Canada: 2 |
| Country: Number of subjects enrolled | Greece: 7 |
| Country: Number of subjects enrolled | Czech Republic: 20 |
| Country: Number of subjects enrolled | United States: 5 |
| Country: Number of subjects enrolled | Norway: 7 |
| Country: Number of subjects enrolled | Denmark: 22 |
| Country: Number of subjects enrolled | Italy: 26 |
| Country: Number of subjects enrolled | Mexico: 18 |
| Worldwide total number of subjects | 171 |
| EEA total number of subjects | 146 |

Notes:

| Subjects enrolled per age group | |
|---|-----|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 12 |
| From 65 to 84 years | 131 |
| 85 years and over | 28 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Full Analysis Set (FAS) is defined as all randomized participants receiving at least one dose of study drug with at least one post-baseline efficacy measure.

Period 1

| | |
|------------------------------|--|
| Period 1 title | Treatment Phase (Week 0 to Week 26) |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Carer, Assessor |

Arms

| | |
|------------------------------|--------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Teriparatide |

Arm description:

20 microgram (mcg) a day by subcutaneous (SC) injection treatment phase throughout study (Week 0 to Week 26).

Calcium: Approximately 500 to 1000 milligram per day (mg/day) administered orally throughout study.

Vitamin D: Approximately 800 International Units per day (IU/day) administered orally throughout study.

| | |
|--|---------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Teriparatide |
| Investigational medicinal product code | |
| Other name | LY333334, Forteo, Forsteo |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

20 micrograms (mcg) a day by subcutaneous injection throughout study.

| | |
|--|----------|
| Investigational medicinal product name | Calcium |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Approximately 500 to 1000 mg/day administered orally throughout study.

| | |
|--|-----------|
| Investigational medicinal product name | Vitamin D |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Approximately 800 International Units per day (IU/day) administered orally throughout study.

| | |
|--|--------------|
| Investigational medicinal product name | Oral Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |

| | |
|---|-------------------------|
| Routes of administration | Oral use |
| Dosage and administration details: Weekly 35mg oral placebo | |
| Arm title | Risedronate |
| Arm description: 35 mg risedronate sodium orally once weekly throughout study. Calcium: Approximately 500 to 1000 mg/day administered orally throughout study. Vitamin D: Approximately 800 International Units per day (IU/day) administered orally throughout study. | |
| Arm type | Active comparator |
| Investigational medicinal product name | Risedronate |
| Investigational medicinal product code | |
| Other name | Actonel |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: 35 milligrams (mg) risedronate sodium orally once weekly throughout study. | |
| Investigational medicinal product name | Calcium |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: Approximately 500 to 1000 mg/day administered orally throughout study. | |
| Investigational medicinal product name | Vitamin D |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: Approximately 800 International Units per day (IU/day) administered orally throughout study. | |
| Investigational medicinal product name | Daily Placebo Injection |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |
| Dosage and administration details: Placebo 20 micrograms (mcg) daily | |

| Number of subjects in period 1 | Teriparatide | Risedronate |
|---------------------------------------|--------------|-------------|
| Started | 111 | 113 |
| Included in Full Analysis Set | 86 | 85 |
| Completed | 86 | 85 |
| Not completed | 25 | 28 |

| | | |
|------------------|----|----|
| Lack of efficacy | 20 | 25 |
| Not treated | 5 | 3 |

Period 2

| | |
|------------------------------|---|
| Period 2 title | Treatment Phase FAS (Week 0 to Week 26) |
| Is this the baseline period? | Yes ^[1] |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Investigator, Carer, Assessor, Subject |

Arms

| | |
|------------------------------|--------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Teriparatide |

Arm description:

20 microgram (mcg) a day by subcutaneous (SC) injection throughout study (FAS Week 0 to Week 26).

Calcium: Approximately 500 to 1000 milligram per day (mg/day) administered orally throughout study.

Vitamin D: Approximately 800 International Units per day (IU/day) administered orally throughout study.

| | |
|--|---------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Teriparatide |
| Investigational medicinal product code | |
| Other name | LY333334, Forteo, Forsteo |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

20 micrograms (mcg) a day by subcutaneous injection throughout study.

| | |
|--|----------|
| Investigational medicinal product name | Calcium |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Approximately 500 to 1000 milligram per day (mg/day) administered orally throughout study.

| | |
|--|-----------|
| Investigational medicinal product name | Vitamin D |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Approximately 800 International Units per day (IU/day) administered orally throughout study.

| | |
|--|--------------|
| Investigational medicinal product name | Oral Placebo |
| Investigational medicinal product code | |
| Other name | |

| | |
|---|-------------------------|
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| Weekly 35mg oral placebo | |
| Arm title | Risedronate |
| Arm description: | |
| 35 mg risedronate sodium orally once weekly throughout study. | |
| Calcium: Approximately 500 to 1000 mg/day administered orally throughout study. | |
| Vitamin D: Approximately 800 International Units per day (IU/day) administered orally throughout study. | |
| Arm type | Active comparator |
| Investigational medicinal product name | Risedronate |
| Investigational medicinal product code | |
| Other name | Actonel |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| 35 mg risedronate sodium orally once weekly throughout study. | |
| Investigational medicinal product name | Calcium |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| Approximately 500 to 1000 mg/day administered orally throughout study. | |
| Investigational medicinal product name | Vitamin D |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| Approximately 800 International Units per day (IU/day) administered orally throughout study. | |
| Investigational medicinal product name | Daily Placebo Injection |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |
| Dosage and administration details: | |
| Placebo 20 micrograms (mcg) daily | |
| Notes: | |
| [1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period. | |
| Justification: Period 1 accounts for the number of participants who were randomized and received at least one dose of study drug. Period 2 is the baseline period as it reports the efficacy results based on the FAS population, which is defined as those participants who received at least one dose of study drug with at least one post-baseline efficacy measure. | |

| Number of subjects in period 2 | Teriparatide | Risedronate |
|--------------------------------|--------------|-------------|
| Started | 86 | 85 |
| Completed | 60 | 65 |
| Not completed | 26 | 20 |
| Consent withdrawn by subject | 14 | 8 |
| Physician decision | 2 | 1 |
| Adverse event, non-fatal | 3 | 3 |
| Death | - | 1 |
| Caregiver decision | 1 | 2 |
| Lost to follow-up | 2 | 1 |
| Sponsor decision | 1 | 1 |
| Entry criteria not met | 3 | 3 |

Period 3

| | |
|------------------------------|---------------------------------------|
| Period 3 title | Open Label Phase (Week 26 to Week 78) |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|--------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Teriparatide |

Arm description:

20 microgram (mcg) a day by subcutaneous (SC) injection throughout study (Open Label Phase Week 26 to Week 78).

Calcium: Approximately 500 to 1000 milligram per day (mg/day) administered orally throughout study.

Vitamin D: Approximately 800 International Units per day (IU/day) administered orally throughout study.

| | |
|--|---------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Teriparatide |
| Investigational medicinal product code | |
| Other name | LY333334, Forteo, Forsteo |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

20 micrograms (mcg) a day by subcutaneous injection throughout study.

| | |
|--|----------|
| Investigational medicinal product name | Calcium |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Approximately 500 to 1000 mg/day administered orally throughout study.

| | |
|--|-------------|
| Investigational medicinal product name | Vitamin D |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| Approximately 800 International Units per day (IU/day) administered orally throughout study. | |
| Arm title | Risedronate |

Arm description:

35 mg risedronate sodium orally once weekly throughout study.

Calcium: Approximately 500 to 1000 mg/day administered orally throughout study.

Vitamin D: Approximately 800 International Units per day (IU/day) administered orally throughout study.

| | |
|--|-------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Risedronate |
| Investigational medicinal product code | |
| Other name | Actonel |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

35 milligrams (mg) risedronate sodium orally once weekly throughout study.

| | |
|--|----------|
| Investigational medicinal product name | Calcium |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Approximately 500 to 1000 mg/day administered orally throughout study.

| | |
|--|-----------|
| Investigational medicinal product name | Vitamin D |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Approximately 800 International Units per day (IU/day) administered orally throughout study.

| Number of subjects in period 3 | Teriparatide | Risedronate |
|---------------------------------------|--------------|-------------|
| Started | 60 | 65 |
| Completed | 57 | 59 |
| Not completed | 3 | 6 |
| Consent withdrawn by subject | 1 | 2 |
| Physician decision | - | 1 |
| Adverse event, non-fatal | 1 | - |
| Death | - | 2 |
| Lost to follow-up | 1 | 1 |

Baseline characteristics

Reporting groups

| | |
|---|--------------|
| Reporting group title | Teriparatide |
| Reporting group description: | |
| 20 microgram (mcg) a day by subcutaneous (SC) injection throughout study (FAS Week 0 to Week 26). | |
| Calcium: Approximately 500 to 1000 milligram per day (mg/day) administered orally throughout study. | |
| Vitamin D: Approximately 800 International Units per day (IU/day) administered orally throughout study. | |
| Reporting group title | Risedronate |
| Reporting group description: | |
| 35 mg risedronate sodium orally once weekly throughout study. | |
| Calcium: Approximately 500 to 1000 mg/day administered orally throughout study. | |
| Vitamin D: Approximately 800 International Units per day (IU/day) administered orally throughout study. | |

| Reporting group values | Teriparatide | Risedronate | Total |
|---|--------------|-------------|-------|
| Number of subjects | 86 | 85 | 171 |
| Age categorical Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 8 | 4 | 12 |
| From 65-84 years | 62 | 69 | 131 |
| 85 years and over | 16 | 12 | 28 |
| Age Continuous Units: years | | | |
| arithmetic mean | 77.2 | 76.4 | |
| standard deviation | ± 7.96 | ± 7.47 | - |
| Gender, Male/Female Units: participants | | | |
| Female | 66 | 66 | 132 |
| Male | 20 | 19 | 39 |
| Race (NIH/OMB) Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 0 | 0 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 |
| White | 86 | 85 | 171 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 0 | 0 | 0 |

| | | | |
|--|----|----|----|
| Region of Enrollment | | | |
| Number of participants for Country/Region of Enrollment reflects FAS population. | | | |
| Units: Subjects | | | |
| Greece | 3 | 4 | 7 |
| Canada | 0 | 2 | 2 |
| Czech Republic | 8 | 12 | 20 |
| United States | 1 | 4 | 5 |
| Norway | 5 | 2 | 7 |
| Denmark | 13 | 9 | 22 |
| Italy | 16 | 10 | 26 |
| Mexico | 6 | 12 | 18 |
| France | 5 | 8 | 13 |
| Germany | 2 | 1 | 3 |
| Spain | 21 | 19 | 40 |
| United Kingdom | 1 | 0 | 1 |
| Austria | 1 | 0 | 1 |
| Ireland | 1 | 0 | 1 |
| Sweden | 3 | 2 | 5 |

End points

End points reporting groups

| | |
|-----------------------|--------------|
| Reporting group title | Teriparatide |
|-----------------------|--------------|

Reporting group description:

20 microgram (mcg) a day by subcutaneous (SC) injection treatment phase throughout study (Week 0 to Week 26).

Calcium: Approximately 500 to 1000 milligram per day (mg/day) administered orally throughout study.

Vitamin D: Approximately 800 International Units per day (IU/day) administered orally throughout study.

| | |
|-----------------------|-------------|
| Reporting group title | Risedronate |
|-----------------------|-------------|

Reporting group description:

35 mg risedronate sodium orally once weekly throughout study.

Calcium: Approximately 500 to 1000 mg/day administered orally throughout study.

Vitamin D: Approximately 800 International Units per day (IU/day) administered orally throughout study.

| | |
|-----------------------|--------------|
| Reporting group title | Teriparatide |
|-----------------------|--------------|

Reporting group description:

20 microgram (mcg) a day by subcutaneous (SC) injection throughout study (FAS Week 0 to Week 26).

Calcium: Approximately 500 to 1000 milligram per day (mg/day) administered orally throughout study.

Vitamin D: Approximately 800 International Units per day (IU/day) administered orally throughout study.

| | |
|-----------------------|-------------|
| Reporting group title | Risedronate |
|-----------------------|-------------|

Reporting group description:

35 mg risedronate sodium orally once weekly throughout study.

Calcium: Approximately 500 to 1000 mg/day administered orally throughout study.

Vitamin D: Approximately 800 International Units per day (IU/day) administered orally throughout study.

| | |
|-----------------------|--------------|
| Reporting group title | Teriparatide |
|-----------------------|--------------|

Reporting group description:

20 microgram (mcg) a day by subcutaneous (SC) injection throughout study (Open Label Phase Week 26 to Week 78).

Calcium: Approximately 500 to 1000 milligram per day (mg/day) administered orally throughout study.

Vitamin D: Approximately 800 International Units per day (IU/day) administered orally throughout study.

| | |
|-----------------------|-------------|
| Reporting group title | Risedronate |
|-----------------------|-------------|

Reporting group description:

35 mg risedronate sodium orally once weekly throughout study.

Calcium: Approximately 500 to 1000 mg/day administered orally throughout study.

Vitamin D: Approximately 800 International Units per day (IU/day) administered orally throughout study.

Primary: Change in Lumbar Spine Areal Bone Mineral Density

| | |
|-----------------|---|
| End point title | Change in Lumbar Spine Areal Bone Mineral Density |
|-----------------|---|

End point description:

Least squares (LS) means obtained from mixed model repeated measures analysis including as fixed effects treatment and time with interaction, further adjusted for baseline lumbar spine BMD, type of hip fracture (31-A1/31-A2) and glucocorticoids used at baseline (Yes/No).

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Baseline, Week 78

| End point values | Teriparatide | Risedronate | | |
|--|-------------------|-------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 61 ^[1] | 66 ^[2] | | |
| Units: gram per square centimeter (g/cm ²) | | | | |
| least squares mean (standard error) | 0.094 (± 0.0075) | 0.055 (± 0.0081) | | |

Notes:

[1] - Post-Baseline Efficacy data was collected for 61 Participants of the 86 participants in the FAS.

[2] - Post-Baseline Efficacy data was collected for 66 Participants of the 85 participants in the FAS.

Statistical analyses

| | |
|---|---------------------------------------|
| Statistical analysis title | Primary Endpoint Statistical Analysis |
| Comparison groups | Teriparatide v Risedronate |
| Number of subjects included in analysis | 127 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Mixed models analysis |
| Parameter estimate | LS Mean |
| Point estimate | 0.04 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.025 |
| upper limit | 0.055 |

Secondary: Change in Lumbar Spine Areal Bone Mineral Density

| | |
|-----------------|---|
| End point title | Change in Lumbar Spine Areal Bone Mineral Density |
|-----------------|---|

End point description:

Least squares (LS) means obtained from mixed model repeated measures analysis including as fixed effects treatment and time with interaction, further adjusted for baseline lumbar spine BMD, type of hip fracture (31-A1/31-A2) and glucocorticoids used at baseline (Yes/No).

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Week 26 and Baseline, Week 52

| End point values | Teriparatide | Risedronate | | |
|-------------------------------------|-------------------|-------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 61 ^[3] | 66 ^[4] | | |
| Units: g/cm ² | | | | |
| least squares mean (standard error) | | | | |
| Week 26 | 0.053 (± 0.0074) | 0.032 (± 0.0081) | | |
| Week 52 | 0.078 (± 0.0074) | 0.044 (± 0.0081) | | |

Notes:

[3] - Post-baseline efficacy data was collected for 61 participants of the 86 participants of the FAS.

[4] - Post-baseline efficacy data was collected for 66 participants or the 85 participants of the FAS.

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Areal Bone Mineral Density Measured at the Femoral Neck and Total Hip of the Non-Fractured Limb

| | |
|-----------------|---|
| End point title | Change in Areal Bone Mineral Density Measured at the Femoral Neck and Total Hip of the Non-Fractured Limb |
|-----------------|---|

End point description:

Change from baseline in areal bone mineral density at the femoral Neck/Total Hip of the non-fractured limb at 26 weeks, 52 weeks and 78 weeks. Femoral neck BMD: Least squares (LS) means obtained from mixed model repeated measures analysis including as fixed effects treatment and time with interaction, further adjusted for baseline femoral neck BMD and type of hip fracture (31-A1/31-A2) .

Total hip BMD: Least squares (LS) means obtained from mixed model repeated measures analysis including as fixed effects treatment and time with interaction, further adjusted for baseline total hip BMD, type of hip fracture (31-A1/31-A2) and duration of prior bisphosphonate use.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Week 26; Baseline, Week 52; Baseline, Week 78

| End point values | Teriparatide | Risedronate | | |
|-------------------------------------|-------------------|-------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 60 ^[5] | 61 ^[6] | | |
| Units: g/cm ² | | | | |
| least squares mean (standard error) | | | | |
| Total Hip 26 Weeks | -0.001 (± 0.0042) | -0.001 (± 0.0042) | | |
| Total Hip 52 Weeks | 0.001 (± 0.0042) | -0.001 (± 0.0042) | | |
| Total Hip 78 Weeks | 0.007 (± 0.0042) | 0.005 (± 0.0043) | | |
| Femoral Neck 26 Weeks | 0.002 (± 0.0044) | -0.009 (± 0.0043) | | |
| Femoral Neck 52 Weeks | 0 (± 0.0044) | -0.006 (± 0.0044) | | |

| | | | | |
|-----------------------|-----------------------|------------------------|--|--|
| Femoral Neck 78 Weeks | 0.012 (\pm 0.0044) | -0.007 (\pm 0.0045) | | |
|-----------------------|-----------------------|------------------------|--|--|

Notes:

[5] - Post-baseline efficacy data was collected for 60 participants of 86 participants in the FAS.

[6] - Post-baseline efficacy data was collected for 61 participants of 85 participants in the FAS.

Statistical analyses

No statistical analyses for this end point

Secondary: Short form-36 (SF-36) Questionnaire

| | |
|-----------------|-------------------------------------|
| End point title | Short form-36 (SF-36) Questionnaire |
|-----------------|-------------------------------------|

End point description:

SF-36 is a self-reported questionnaire consisting of 36 questions covering 8 health domains. Each domain was scored by summing the individual items and transforming the scores into a 0 to 100 scale, with higher scores indicating better health status or functioning. The physical component summary (PCS) has been constructed based on the 8 SF-36 domains and consist of the physical functioning, bodily pain, role-physical, and general health scales (range = 0 to 100).

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, 6, 12, 18, and 26 Weeks of Treatment

| End point values | Teriparatide | Risedronate | | |
|-------------------------------------|----------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 67 ^[7] | 65 ^[8] | | |
| Units: units on a scale | | | | |
| least squares mean (standard error) | | | | |
| Baseline, Week 6 | 7.37 (\pm 1.065) | 5.1 (\pm 1.087) | | |
| Baseline, Week 12 | 11.32 (\pm 1.207) | 11.09 (\pm 1.208) | | |
| Baseline, Week 18 | 14.37 (\pm 1.256) | 12.81 (\pm 1.26) | | |
| Baseline, Week 26 | 16.34 (\pm 1.278) | 14.36 (\pm 1.258) | | |

Notes:

[7] - Post-baseline efficacy data was collected for 67 participants of 86 participants in the FAS.

[8] - Post-baseline efficacy data was collected for 65 participants of 85 participants in the FAS.

Statistical analyses

No statistical analyses for this end point

Secondary: Timed "Up and Go" Test

| | |
|-----------------|------------------------|
| End point title | Timed "Up and Go" Test |
|-----------------|------------------------|

End point description:

Timed "Up and Go" test measures, in seconds, the time taken by an individual to stand up from a standard chair, walk a distance of 3 meters, turn, walk back to the chair, and sit down. Least squares (LS) means obtained from mixed model repeated measures analysis including as fixed effects treatment and time with interaction, further adjusted for age, type of fracture (31-A1/31-A2), type of reduction (open/close), type of walking aid, baseline SF-36 PCS and baseline Charnley's pain score.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:
6, 12, 18, and 26 Weeks

| End point values | Teriparatide | Risedronate | | |
|-------------------------------------|-------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 79 ^[9] | 78 ^[10] | | |
| Units: seconds (sec) | | | | |
| least squares mean (standard error) | | | | |
| Week 6 | 26.45 (± 1.09) | 32.38 (± 1.085) | | |
| Week 12 | 20.13 (± 1.092) | 24.48 (± 1.086) | | |
| Week 18 | 17.75 (± 1.093) | 21.14 (± 1.087) | | |
| Week 26 | 16.69 (± 1.095) | 19.91 (± 1.088) | | |

Notes:

[9] - Post-baseline efficacy data was collected for 79 participants of 86 participants in the FAS.

[10] - Post-baseline efficacy data was collected for 78 participants of 85 participants in the FAS.

Statistical analyses

No statistical analyses for this end point

Secondary: Visual Analog Scale

| | |
|--|---------------------|
| End point title | Visual Analog Scale |
| End point description: | |
| Visual analog pain scale is a measurement instrument to measure the level of hip pain. Scores range from 0 to 100 millimeter (mm) with higher score indicating greater pain. Least squares (LS) means obtained from mixed model repeated measures analysis including as fixed effects treatment and time with interaction, further adjusted for type of fracture (31-A1/31-A2), type of reduction (open/close), use of opioids (Yes/No), use of non-steroidal anti-inflammatory drugs, adequate reduction (Yes/No) and interaction between treatment and adequate reduction. | |
| End point type | Secondary |
| End point timeframe: | |
| 6, 12, 18, and 26 Weeks | |

| End point values | Teriparatide | Risedronate | | |
|-------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 63 ^[11] | 62 ^[12] | | |
| Units: millimeter (mm) | | | | |
| least squares mean (standard error) | | | | |
| Week 6 | 16.44 (± 3.977) | 23.54 (± 4.443) | | |
| Week 12 | 9.28 (± 4.048) | 19.24 (± 4.452) | | |
| Week 18 | 6.9 (± 4.147) | 18.19 (± 4.508) | | |
| Week 26 | 4.48 (± 4.128) | 13.74 (± 4.505) | | |

Notes:

[11] - Post-baseline efficacy data was collected for 63 participants of 86 participants in the FAS.

[12] - Post-baseline efficacy data was collected for 62 participants of 85 participants in the FAS.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Reporting Hip Pain in Modification of the Charnley's Pain Scale

| | |
|-----------------|--|
| End point title | Percentage of Participants Reporting Hip Pain in Modification of the Charnley's Pain Scale |
|-----------------|--|

End point description:

Self-reported hip pain scale in which 0=no pain; 1=pain is slight or intermittent, pain on starting to walk but getting less with normal activity; 2=pain occurs only after some activity, disappears quickly with rest; 3=pain is tolerable, permitting limited activity; 4=pain is severe on attempting to walk, prevents all activity; 5=pain is severe and spontaneous.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline

| End point values | Teriparatide | Risedronate | | |
|---|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 85 | 85 | | |
| Units: Percentage of Participants | | | | |
| number (not applicable) | | | | |
| 0- No Pain | 9.4 | 8.2 | | |
| 1- Pain slight or intermittent | 4.7 | 12.9 | | |
| 2- Pain occurs only after some activity | 23.5 | 20 | | |
| 3- Pain is tolerable | 36.5 | 38.8 | | |
| 4- Pain severe on attempting to walk | 20 | 15.3 | | |
| 5- Pain severe and spontaneous | 5.9 | 4.7 | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment

Adverse event reporting additional description:

B3D-EW-GHDK

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 18.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|--------------|
| Reporting group title | Teriparatide |
|-----------------------|--------------|

Reporting group description: -

| | |
|-----------------------|-------------|
| Reporting group title | Risedronate |
|-----------------------|-------------|

Reporting group description: -

| Serious adverse events | Teriparatide | Risedronate | |
|---|-------------------|-------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 21 / 106 (19.81%) | 27 / 110 (24.55%) | |
| number of deaths (all causes) | 2 | 7 | |
| number of deaths resulting from adverse events | 0 | 0 | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| pancreatic carcinoma metastatic | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 0 / 106 (0.00%) | 1 / 110 (0.91%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Vascular disorders | | | |
| aortic stenosis | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 0 / 106 (0.00%) | 1 / 110 (0.91%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| orthostatic hypotension | | | |
| alternative dictionary used: MedDRA 18.0 | | | |

| | | | |
|--|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 106 (0.00%) | 1 / 110 (0.91%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| venous thrombosis | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 0 / 106 (0.00%) | 1 / 110 (0.91%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |
| chest pain | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 1 / 106 (0.94%) | 0 / 110 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| death | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 1 / 106 (0.94%) | 1 / 110 (0.91%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| device breakage | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 0 / 106 (0.00%) | 1 / 110 (0.91%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| device failure | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 1 / 106 (0.94%) | 0 / 110 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| medical device complication | | | |
| alternative dictionary used: MedDRA 18.0 | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 106 (0.00%) | 1 / 110 (0.91%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| bronchial polyp | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 1 / 106 (0.94%) | 0 / 110 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| chronic obstructive pulmonary disease | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 0 / 106 (0.00%) | 1 / 110 (0.91%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| dyspnoea | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 1 / 106 (0.94%) | 0 / 110 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| pleural effusion | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 0 / 106 (0.00%) | 1 / 110 (0.91%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| pneumothorax | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 0 / 106 (0.00%) | 1 / 110 (0.91%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| pulmonary embolism | | | |
| alternative dictionary used: MedDRA 18.0 | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 106 (0.00%) | 1 / 110 (0.91%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Psychiatric disorders | | | |
| confusional state | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 1 / 106 (0.94%) | 0 / 110 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| delirium | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 1 / 106 (0.94%) | 0 / 110 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury, poisoning and procedural complications | | | |
| fall | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 6 / 106 (5.66%) | 9 / 110 (8.18%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| femoral neck fracture | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 0 / 106 (0.00%) | 1 / 110 (0.91%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| femur fracture | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 0 / 106 (0.00%) | 1 / 110 (0.91%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| forearm fracture | | | |
| alternative dictionary used: MedDRA 18.0 | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 1 / 106 (0.94%) | 0 / 110 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| head injury | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 0 / 106 (0.00%) | 1 / 110 (0.91%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| hip fracture | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 2 / 106 (1.89%) | 4 / 110 (3.64%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| humerus fracture | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 1 / 106 (0.94%) | 1 / 110 (0.91%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| lumbar vertebral fracture | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 0 / 106 (0.00%) | 1 / 110 (0.91%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| pelvic fracture | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 0 / 106 (0.00%) | 2 / 110 (1.82%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| rib fracture | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 0 / 106 (0.00%) | 1 / 110 (0.91%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|--|---|---|--|
| subdural haematoma alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 106 (0.00%) 0 / 0 0 / 0 | 1 / 110 (0.91%) 0 / 1 0 / 0 | |
| Cardiac disorders bradycardia alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 106 (0.00%) 0 / 0 0 / 0 | 1 / 110 (0.91%) 0 / 1 0 / 0 | |
| cardiac failure alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 106 (0.94%) 0 / 1 0 / 0 | 0 / 110 (0.00%) 0 / 0 0 / 0 | |
| cardiac failure congestive alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 106 (0.00%) 0 / 0 0 / 0 | 2 / 110 (1.82%) 0 / 2 0 / 2 | |
| mitral valve incompetence alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 106 (0.00%) 0 / 0 0 / 0 | 1 / 110 (0.91%) 0 / 1 0 / 1 | |
| Nervous system disorders amnesia alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all cerebral infarction alternative dictionary used: MedDRA 18.0 | 1 / 106 (0.94%) 0 / 1 0 / 0 | 0 / 110 (0.00%) 0 / 0 0 / 0 | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 106 (0.00%) | 1 / 110 (0.91%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| cerebrovascular accident | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 0 / 106 (0.00%) | 2 / 110 (1.82%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| headache | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 1 / 106 (0.94%) | 0 / 110 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ischaemic stroke | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 1 / 106 (0.94%) | 0 / 110 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| monoplegia | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 1 / 106 (0.94%) | 0 / 110 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| speech disorder | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 1 / 106 (0.94%) | 0 / 110 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| syncope | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 1 / 106 (0.94%) | 1 / 110 (0.91%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|--|--|--|--|
| <p>Eye disorders</p> <p>retinal detachment</p> <p>alternative dictionary used: MedDRA 18.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>0 / 106 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | <p>1 / 110 (0.91%)</p> <p>0 / 2</p> <p>0 / 0</p> | |
| <p>Gastrointestinal disorders</p> <p>oedema mouth</p> <p>alternative dictionary used: MedDRA 18.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>0 / 106 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | <p>1 / 110 (0.91%)</p> <p>0 / 1</p> <p>0 / 0</p> | |
| <p>Hepatobiliary disorders</p> <p>liver disorder</p> <p>alternative dictionary used: MedDRA 18.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>1 / 106 (0.94%)</p> <p>0 / 1</p> <p>0 / 0</p> | <p>0 / 110 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | |
| <p>Musculoskeletal and connective tissue disorders</p> <p>arthralgia</p> <p>alternative dictionary used: MedDRA 18.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>3 / 106 (2.83%)</p> <p>0 / 3</p> <p>0 / 0</p> | <p>0 / 110 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | |
| <p>back pain</p> <p>alternative dictionary used: MedDRA 18.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p> | <p>1 / 106 (0.94%)</p> <p>0 / 1</p> <p>0 / 0</p> | <p>0 / 110 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p> | |
| <p>Infections and infestations</p> <p>gastroenteritis</p> <p>alternative dictionary used: MedDRA 18.0</p> | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 1 / 106 (0.94%) | 0 / 110 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| pneumonia | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 1 / 106 (0.94%) | 1 / 110 (0.91%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| postoperative wound infection | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 0 / 106 (0.00%) | 1 / 110 (0.91%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| septic shock | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 1 / 106 (0.94%) | 1 / 110 (0.91%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| subcutaneous abscess | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 0 / 106 (0.00%) | 1 / 110 (0.91%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| urinary tract infection | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 1 / 106 (0.94%) | 2 / 110 (1.82%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| wound infection staphylococcal | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 1 / 106 (0.94%) | 0 / 110 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|--|-----------------|-----------------|--|
| Metabolism and nutrition disorders | | | |
| dehydration | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 1 / 106 (0.94%) | 0 / 110 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| hyperglycaemia | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 1 / 106 (0.94%) | 0 / 110 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| type 2 diabetes mellitus | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 1 / 106 (0.94%) | 0 / 110 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 1 %

| Non-serious adverse events | Teriparatide | Risedronate | |
|--|-------------------|-------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 53 / 106 (50.00%) | 47 / 110 (42.73%) | |
| Vascular disorders | | | |
| hypertension | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 5 / 106 (4.72%) | 2 / 110 (1.82%) | |
| occurrences (all) | 5 | 2 | |
| Reproductive system and breast disorders | | | |
| benign prostatic hyperplasia | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed ^[1] | 0 / 106 (0.00%) | 1 / 23 (4.35%) | |
| occurrences (all) | 0 | 1 | |
| vulval ulceration | | | |
| alternative dictionary used: MedDRA 18.0 | | | |

| | | | |
|--|--|--|--|
| <p>subjects affected / exposed^[2]</p> <p>0 / 106 (0.00%)</p> <p>1 / 87 (1.15%)</p> <p>occurrences (all)</p> <p>0</p> <p>1</p> <p>vulvovaginal dryness</p> <p>alternative dictionary used: MedDRA 18.0</p> <p>subjects affected / exposed^[3]</p> <p>1 / 81 (1.23%)</p> <p>0 / 110 (0.00%)</p> <p>occurrences (all)</p> <p>1</p> <p>0</p> | | | |
| <p>Psychiatric disorders</p> <p>delirium</p> <p>alternative dictionary used: MedDRA 18.0</p> <p>subjects affected / exposed</p> <p>2 / 106 (1.89%)</p> <p>0 / 110 (0.00%)</p> <p>occurrences (all)</p> <p>2</p> <p>0</p> <p>depression</p> <p>alternative dictionary used: MedDRA 18.0</p> <p>subjects affected / exposed</p> <p>1 / 106 (0.94%)</p> <p>3 / 110 (2.73%)</p> <p>occurrences (all)</p> <p>1</p> <p>3</p> <p>insomnia</p> <p>alternative dictionary used: MedDRA 18.0</p> <p>subjects affected / exposed</p> <p>3 / 106 (2.83%)</p> <p>1 / 110 (0.91%)</p> <p>occurrences (all)</p> <p>3</p> <p>1</p> | | | |
| <p>Investigations</p> <p>blood creatine phosphokinase increased</p> <p>alternative dictionary used: MedDRA 18.0</p> <p>subjects affected / exposed</p> <p>2 / 106 (1.89%)</p> <p>0 / 110 (0.00%)</p> <p>occurrences (all)</p> <p>2</p> <p>0</p> <p>platelet count increased</p> <p>alternative dictionary used: MedDRA 18.0</p> <p>subjects affected / exposed</p> <p>2 / 106 (1.89%)</p> <p>0 / 110 (0.00%)</p> <p>occurrences (all)</p> <p>2</p> <p>0</p> | | | |
| <p>Injury, poisoning and procedural complications</p> <p>fall</p> <p>alternative dictionary used: MedDRA 18.0</p> <p>subjects affected / exposed</p> <p>7 / 106 (6.60%)</p> <p>5 / 110 (4.55%)</p> <p>occurrences (all)</p> <p>8</p> <p>5</p> | | | |
| Nervous system disorders | | | |

| | | | |
|---|----------------------|----------------------|--|
| dizziness alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all) | 2 / 106 (1.89%) 2 | 1 / 110 (0.91%) 1 | |
| headache alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all) | 2 / 106 (1.89%) 2 | 0 / 110 (0.00%) 0 | |
| Blood and lymphatic system disorders anaemia alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all) | 0 / 106 (0.00%) 0 | 2 / 110 (1.82%) 2 | |
| Gastrointestinal disorders abdominal pain upper alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all) | 3 / 106 (2.83%) 3 | 1 / 110 (0.91%) 1 | |
| constipation alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all) | 2 / 106 (1.89%) 2 | 3 / 110 (2.73%) 3 | |
| diarrhoea alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all) | 3 / 106 (2.83%) 3 | 0 / 110 (0.00%) 0 | |
| nausea alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all) | 2 / 106 (1.89%) 6 | 0 / 110 (0.00%) 0 | |
| Skin and subcutaneous tissue disorders eczema alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all) | 2 / 106 (1.89%) 2 | 0 / 110 (0.00%) 0 | |
| rash | | | |

| | | | |
|--|---|--|--|
| alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all) | 1 / 106 (0.94%) 1 | 2 / 110 (1.82%) 2 | |
| Renal and urinary disorders urinary incontinence alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all) | 1 / 106 (0.94%) 1 | 2 / 110 (1.82%) 2 | |
| Musculoskeletal and connective tissue disorders arthralgia alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all) back pain alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all) bone pain alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all) groin pain alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all) musculoskeletal pain alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all) pain in extremity alternative dictionary used: MedDRA 18.0 subjects affected / exposed occurrences (all) osteoarthritis alternative dictionary used: | 12 / 106 (11.32%) 16 3 / 106 (2.83%) 6 0 / 106 (0.00%) 0 1 / 106 (0.94%) 1 2 / 106 (1.89%) 2 3 / 106 (2.83%) 7 | 7 / 110 (6.36%) 8 3 / 110 (2.73%) 3 2 / 110 (1.82%) 2 2 / 110 (1.82%) 2 1 / 110 (0.91%) 1 2 / 110 (1.82%) 3 | |

| | | | |
|---|-----------------|-----------------|--|
| MedDRA 18.0 | | | |
| subjects affected / exposed | 2 / 106 (1.89%) | 2 / 110 (1.82%) | |
| occurrences (all) | 2 | 2 | |
| Infections and infestations | | | |
| bronchitis | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 4 / 106 (3.77%) | 0 / 110 (0.00%) | |
| occurrences (all) | 4 | 0 | |
| gastroenteritis | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 2 / 106 (1.89%) | 0 / 110 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| influenza | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 2 / 106 (1.89%) | 1 / 110 (0.91%) | |
| occurrences (all) | 2 | 1 | |
| nasopharyngitis | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 2 / 106 (1.89%) | 2 / 110 (1.82%) | |
| occurrences (all) | 2 | 2 | |
| urinary tract infection | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 7 / 106 (6.60%) | 4 / 110 (3.64%) | |
| occurrences (all) | 7 | 7 | |
| viral infection | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 3 / 106 (2.83%) | 0 / 110 (0.00%) | |
| occurrences (all) | 4 | 0 | |
| Metabolism and nutrition disorders | | | |
| hypercalcaemia | | | |
| alternative dictionary used: MedDRA 18.0 | | | |
| subjects affected / exposed | 1 / 106 (0.94%) | 2 / 110 (1.82%) | |
| occurrences (all) | 1 | 2 | |

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects

exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported