Clinical trial results:
Effect of Teriparatide on Femoral Neck Fracture Healing
Summary

EudraCT number	2010-021395-28
Trial protocol	SE ES LV FI NO LT EE DK
Global end of trial date	04 December 2013

Results information

Result version number	v1 (current)
This version publication date	04 July 2016
First version publication date	02 August 2015

Trial information

Trial identification

Sponsor protocol code	B3D-MC-GHDN

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01473589
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Alias: B3D-MC-GHDN, Trial Number: 13467

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 9 AM - 5 PM EST, Eli Lilly and Company, 1 877-CTLilly,
Scientific contact	Available Mon - Fri 9 AM - 5 PM 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	04 December 2013
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	04 December 2013
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To determine the effect of 6 months of treatment with teriparatide 20 microgram(µg)/day versus placebo on the proportion of men and postmenopausal women 50 years of age with successful fracture healing 24 months after internal fixation of a low trauma femoral neck fracture

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonisation (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	01 February 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 2
Country: Number of subjects enrolled	Lithuania: 4
Country: Number of subjects enrolled	United States: 2
Country: Number of subjects enrolled	Taiwan: 19
Country: Number of subjects enrolled	Israel: 7
Country: Number of subjects enrolled	India: 3
Country: Number of subjects enrolled	Canada: 4
Country: Number of subjects enrolled	Australia: 1
Country: Number of subjects enrolled	Japan: 29
Country: Number of subjects enrolled	New Zealand: 12
Country: Number of subjects enrolled	Korea, Republic of: 18
Country: Number of subjects enrolled	Spain: 15
Country: Number of subjects enrolled	Latvia: 5
Country: Number of subjects enrolled	Sweden: 1
Worldwide total number of subjects	122
EEA total number of subjects	27

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)	44
From 65 to 84 years	58
85 years and over	20

Subject disposition

Recruitment

Recruitment details:

No text entered.

Pre-assignment

Screening details:

No text entered.

Period 1

Period 1 title	Overall (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer

Arms

Are arms mutually exclusive?	Yes
Arm title	Teriparatide

Arm description:

Teriparatide 20 micrograms (µg) administered once-daily by subcutaneous (SC) injection for 6 months. Participants received calcium and vitamin D supplements.
Baseline characteristics values based on number of subjects that received at least 1 dose of study drug.

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

Dosage and administration details:

Teriparatide 20 micrograms (µg) administered once-daily by subcutaneous (SC) injection for 6 months. Participants received calcium and vitamin D supplements.

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

Dosage and administration details:

The supplement dose for calcium should be up to approximately 1000 milligram (mg)/day elemental calcium starting as soon as possible after screening and continuing through 12 months.

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

Dosage and administration details:

During screening, approximately 1000 International Unit (IU)/day vitamin D. The dose of vitamin D may then be increased at the discretion of the investigator.

Arm title	Placebo

Arm description:

Placebo administered once-daily by SC injection for 6 months. Participants received calcium and vitamin D supplements.
Baseline characteristics values based on number of subjects that received at least 1 dose of study drug.

Arm type	Placebo
Investigational medicinal product name	placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo administered once-daily by SC injection for 6 months. Participants received calcium and vitamin D supplements.

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

Dosage and administration details:

During screening, approximately 1000 IU/day vitamin D. The dose of vitamin D may then be increased at the discretion of the investigator.

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

Dosage and administration details:

The supplement dose for calcium should be up to approximately 1000 mg/day elemental calcium starting as soon as possible after screening and continuing through 12 months.

Number of subjects in period 1	Teriparatide	Placebo
Started	60	62
Received at Least 1 Dose of Study Drug	60	61
Completed 6 Months	51	54
Completed 12 Months	49	48
Completed	49	46
Not completed	11	16
Adverse event, serious fatal	2	-
Consent withdrawn by subject	5	11
Physician decision	-	1
Adverse event, non-fatal	1	1
Lost to follow-up	2	2
Protocol deviation	1	-
'Entry criteria not met '	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Teriparatide
Reporting group description:	
Teriparatide 20 micrograms (µg) administered once-daily by subcutaneous (SC) injection for 6 months. Participants received calcium and vitamin D supplements. Baseline characteristics values based on number of subjects that received at least 1 dose of study drug.	
Reporting group title	Placebo
Reporting group description:	
Placebo administered once-daily by SC injection for 6 months. Participants received calcium and vitamin D supplements. Baseline characteristics values based on number of subjects that received at least 1 dose of study drug.	

Reporting group values	Teriparatide	Placebo	Total
Number of subjects	60	62	122
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	68.49	70.96	
standard deviation	± 11.321	± 12.023	-
Gender categorical Units: Subjects			
Female	43	44	87
Male	17	17	34
Not recorded	0	1	1
Surgical screw type			
Surgical screws used in initial surgery to repair femur neck hip fracture.			
Units: Subjects			
Cancellous Screws	54	53	107
Sliding Hip Screws	6	8	14
Not recorded	0	1	1
Ethnicity (NIH/OMB)			
Full Analysis Set (FAS): All randomized participants who received at least 1 dose of study drug.			
Units: Subjects			
Hispanic or Latino	0	1	1
Not Hispanic or Latino	26	27	53
Unknown or Not Reported	34	33	67
Not recorded	0	1	1
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	35	34	69
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	25	27	52
More than one race	0	0	0

Unknown or Not Reported	0	0	0
Not recorded	0	1	1
Region of Enrollment Units: Subjects			
United States	1	1	2
Spain	7	8	15
Taiwan	10	9	19
Lithuania	2	2	4
Israel	3	4	7
India	2	1	3
Canada	3	1	4
Denmark	1	1	2
Australia	1	0	1
Latvia	2	3	5
Japan	14	15	29
New Zealand	5	7	12
Korea, Republic of	9	9	18
Sweden	0	1	1

End points

End points reporting groups

Reporting group title	Teriparatide
Reporting group description:	
Teriparatide 20 micrograms (µg) administered once-daily by subcutaneous (SC) injection for 6 months. Participants received calcium and vitamin D supplements. Baseline characteristics values based on number of subjects that received at least 1 dose of study drug.	
Reporting group title	Placebo
Reporting group description:	
Placebo administered once-daily by SC injection for 6 months. Participants received calcium and vitamin D supplements. Baseline characteristics values based on number of subjects that received at least 1 dose of study drug.	

Primary: Percentage of Participants With No Revision Surgery at 12 Months After Internal Fixation of a Low-Trauma Femoral Neck Fracture

End point title	Percentage of Participants With No Revision Surgery at 12 Months After Internal Fixation of a Low-Trauma Femoral Neck Fracture
End point description:	
Revision surgery (re-operation) was defined as any additional surgical intervention performed or recommended at the site of the index procedure, except those that were planned at the time of the index procedure.	
End point type	Primary
End point timeframe:	
12 months	

End point values	Teriparatide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60	61		
Units: percentage of participants				
number (confidence interval 90%)	87 (77 to 93)	86 (76 to 92)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1 for End Point 1
Comparison groups	Teriparatide v Placebo
Number of subjects included in analysis	121
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.743 [1]
Method	K-M with Greenwood SE
Parameter estimate	Difference in proportion
Point estimate	-0.04

Confidence interval	
level	90 %
sides	1-sided
lower limit	-0.14

Notes:

[1] - P-value is based on Z test statistic with Greenwood estimator for standard errors (SE) to compare two Kaplan-Meier (K-M) estimates at 12 month.

Secondary: Percentage of Participants With Radiographic Evidence of Healing

End point title	Percentage of Participants With Radiographic Evidence of Healing

End point description:

The signs of femoral neck fracture healing included disappearance of the fracture line on radiographs. If a participant had radiographic evidence of healing at the 12-month visit, that participant was considered to have radiographic evidence of healing.

Percentage was calculated as: (number of participants with radiographic evidence of healing / total number of participants analyzed) * 100.

End point type	Secondary

End point timeframe:

Randomization, 12 months

End point values	Teriparatide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60	61		
Units: percentage of participants	78	79		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Pain Control During Ambulation

End point title	Percentage of Participants With Pain Control During Ambulation

End point description:

The worst pain numeric rating scale (NRS) was used to assess the impact of pain on a participant's life. NRS Item 3 assessed the worst musculoskeletal pain severity during the walking test. Pain was measured by an 11-point Likert scale. The following cut-points were used to categorize the NRS responses: 0 = no pain, 1 to 4 = mild pain, 5 to 6 = moderate pain, and 7 to 10 = severe pain. Participants with an NRS score of <7 were categorized as having no severe fracture-site pain with ambulation and no worsening of NRS scores >2 from baseline. Percentage was calculated as: (Number of participants with pain control during ambulation / total number of participants) * 100.

End point type	Secondary

End point timeframe:

12 months

End point values	Teriparatide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	49		
Units: percentage of participants	91	90		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Without Severe Fracture-Site Pain During 24 Hours Prior to Visit

End point title	Percentage of Participants Without Severe Fracture-Site Pain During 24 Hours Prior to Visit

End point description:

The worst pain NRS was used to assess the impact of pain on a participant's life. Fracture-site pain severity was assessed for pain in the 24 hours preceding a visit. Pain was measured by an 11-point Likert scale. Participants with an NRS score of <7 in the 24 hours preceding a visit and no worsening of NRS >2 from baseline were categorized as having no severe fracture-site pain. Percentage was calculated as: (number of participants with pain control during 24 hours preceding a visit / total number of participants) * 100.

End point type	Secondary

End point timeframe:

12 months

End point values	Teriparatide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	51		
Units: percentage of participants	88	82		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Without Severe Fracture-Site Pain During Weight Bearing

End point title	Percentage of Participants Without Severe Fracture-Site Pain During Weight Bearing

End point description:

The worst pain NRS was used to assess the impact of pain on a participant's life. Fracture-site pain severity was assessed for pain on weight bearing. Pain was measured by an 11-point Likert scale. Participants with an NRS score of <7 during weight bearing and no worsening of NRS >2 from baseline were categorized as having no severe fracture-site pain. Percentage was calculated as: (number of participants with pain control during weight bearing / total number of participants) * 100.

End point type	Secondary

End point timeframe:

12 months

End point values	Teriparatide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	50		
Units: percentage of participants	89	88		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Functional Evidence of Healing

End point title	Percentage of Participants With Functional Evidence of Healing

End point description:

Functional healing was defined as ability to walk with a gait speed ≥ 0.05 meters/second (m/s) with a change from baseline ≥ -0.1 m/s. The walking test involved having the participant walk a distance of 7 meters (m) at a self-selected, comfortable pace. A 4-m portion of the test was timed to determine the participant's gait speed in m/s.

Percentage was calculated as: (number of participants with functional evidence of healing / total number of participants analyzed) * 100.

End point type	Secondary

End point timeframe:

12 Months

End point values	Teriparatide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	50		
Units: percentage of participants	85	74		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Able to Ambulate

End point title	Percentage of Participants Able to Ambulate

End point description:

Ability to ambulate was defined as ambulatory with convalescent aid or without convalescent aid. Percentage was calculated as: (number of participants able to ambulate / number of total participants analyzed) * 100.

End point type	Secondary

End point timeframe:

12 months

End point values	Teriparatide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	50		
Units: percentage of participants	98	98		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Regain Their Prefracture Ambulatory Status

End point title	Percentage of Participants Who Regain Their Prefracture Ambulatory Status

End point description:

Prefracture ambulatory status was defined as either ambulatory with or without a walking aid. A participant was considered to have regained their prefracture ambulatory status if the participant's postsurgery ambulatory status was returned to or was improved from their pre-surgery ambulatory status. Percentage was calculated as = (number of participants who regained their ambulatory status / total number analyzed) * 100.

End point type	Secondary

End point timeframe:

12 months

End point values	Teriparatide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56	58		
Units: percentage of participants	73	57		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline to 6 Months in Worst Fracture-Site Pain

End point title	Mean Change From Baseline to 6 Months in Worst Fracture-Site Pain

End point description:

The worst pain NRS was used to assess the impact of pain on a participant's life. Participants with an NRS score of <7 were categorized as having no severe fracture-site pain. Least Squares (LS) means was calculated using analysis of covariance (ANCOVA) and adjusted for baseline, treatment group, region, fracture type, and fixation type.

End point type	Secondary

End point timeframe:

Baseline, 6 Months

End point values	Teriparatide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	50		
Units: units on a scale				
least squares mean (standard error)				
During ambulation	0.2 (± 0.37)	0.2 (± 0.36)		
During 24 hours preceding visit	-0.3 (± 0.45)	-0.8 (± 0.42)		
On weight bearing	0.7 (± 0.39)	0.8 (± 0.36)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline to 6 Months in Gait Speed

End point title	Mean Change From Baseline to 6 Months in Gait Speed

End point description:

The walking test involved having the participant walk a distance of 7 m at a self-selected, comfortable pace. A 4-m portion of the test was timed to determine the participant's gait speed in m/s. LS means was calculated using ANCOVA and adjusted for baseline, treatment group, region, fracture type, and fixation type.

End point type	Secondary

End point timeframe:

Baseline, 6 Months

End point values	Teriparatide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	45	47		
Units: m/s				
least squares mean (standard error)	-0.672 (± 2.128)	1.524 (± 2.018)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Revision Surgery

End point title	Time to Revision Surgery

End point description:

Time to revision surgery was defined as the time from initial hip fracture surgery to revision surgery, or recommendation for revision surgery if recommended but not performed. Time to revision surgery was censored at the date of the last contact.

End point type	Secondary

End point timeframe:

Baseline, Revision surgery

End point values	Teriparatide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60	59		
Units: days				
median (full range (min-max))	358.5 (15 to 430)	350 (12 to 412)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline to 6 Months on Short Form-12 (SF-12) Physical (PCS) and Mental Component Summary (MCS) Scores

End point title	Mean Change From Baseline to 6 Months on Short Form-12 (SF-12) Physical (PCS) and Mental Component Summary (MCS) Scores

End point description:

SF-12 is a self-reported questionnaire covering a mental component score (MCS) and a physical component score (PCS), each scoring from a 0 to 100 (worst to best) scale. LS mean was calculated using ANCOVA and adjusted for baseline, treatment group, region, fracture type, fixation type, visit, and visit-by-treatment interaction.

End point type	Secondary

End point timeframe:

Baseline, 6 Months

End point values	Teriparatide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58	59		
Units: units on a scale				
least squares mean (standard error)				
PCS Month 6 (n = 49, 49)	-3.73 (± 1.2)	-4.75 (± 1.2)		
MCS Month 6 (n = 49, 49)	-0.58 (± 2.1)	-0.49 (± 2.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline to 6 Months on Western Ontario McMaster Osteoarthritis Index (WOMAC)

End point title	Mean Change From Baseline to 6 Months on Western Ontario McMaster Osteoarthritis Index (WOMAC)

End point description:

WOMAC is: a self-reported questionnaire that consisted of 24 questions covering 3 health domains: Pain (5 items: during walking, using stairs, in bed, sitting or lying, and standing), Stiffness (2 items: after first waking and later in the day), and Physical Function. Each domain was scored by summing the individual items and transforming the scores into a 0 to 100 (best to worst) scale. LS mean was calculated using ANCOVA and adjusted for baseline, treatment group, region, fracture type, fixation type, visit, and visit-by-treatment interaction.

End point type	Secondary

End point timeframe:

Baseline, 6 Months

End point values	Teriparatide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58	59		
Units: units on a scale				
least squares mean (standard error)				
Physical Function Score - Month 6 (n=48, 51)	12.9 (± 4.36)	12.8 (± 4.25)		
Pain Score - Month 6 (n = 51, 51)	8.2 (± 3.76)	10.3 (± 3.68)		
Stiffness Score - Month 6 (n = 51, 51)	13.1 (± 3.78)	11.8 (± 3.75)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline to 6 Months on European Quality of Life Questionnaire (EQ-5D) Health State Score

End point title	Mean Change From Baseline to 6 Months on European Quality of Life Questionnaire (EQ-5D) Health State Score

End point description:

The EQ-5D is a 5-item, self-reported, generic, multidimensional, health-related, quality-of-life instrument with 5 items. Overall health state score was also self-reported using a visual analogue scale (VAS) marked on a scale scored from 0 (worse imaginable health state) to 100 (best imaginable health state). LS mean was calculated using ANCOVA and adjusted for baseline, treatment group, and region.

End point type	Secondary

End point timeframe:

Baseline, 6 Months

End point values	Teriparatide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	51	51		
Units: units on a scale				
least squares mean (standard deviation)	7.4 (± 4.02)	7.6 (± 3.87)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Entire Study	
Adverse event reporting additional description:	
B3D-MC-GHDN	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	16.1

Reporting groups	
Reporting group title	Screening
Reporting group description: -	
Reporting group title	Placebo Acute
Reporting group description: -	
Reporting group title	Teriparatide 20 mcg Acute
Reporting group description: -	
Reporting group title	Placebo Follow-up
Reporting group description: -	
Reporting group title	Teriparatide 20 mcg Follow-up
Reporting group description: -	

Serious adverse events	Screening	Placebo Acute	Teriparatide 20 mcg Acute
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 122 (0.00%)	5 / 61 (8.20%)	2 / 60 (3.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
transitional cell carcinoma			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
fall			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femoral neck fracture			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femur fracture			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subdural haematoma			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
wound			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
bradyarrhythmia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
supraventricular tachycardia			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
syncope			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischaemic attack			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
gastritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
hepatitis toxic			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
confusional state			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
haematuria			
alternative dictionary used:			

MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
bursitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fracture nonunion			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteonecrosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
liver abscess			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
urinary tract infection			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo Follow-up	Teriparatide 20 mcg Follow-up	
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 53 (7.55%)	2 / 49 (4.08%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
transitional cell carcinoma			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (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 16.1			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
femoral neck fracture			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
femur fracture			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
subdural haematoma			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
wound			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
bradyarrhythmia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
supraventricular tachycardia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
syncope			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
transient ischaemic attack			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
gastritis			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
hepatitis toxic			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
confusional state			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
haematuria			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
bursitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
fracture nonunion			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
osteonecrosis			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
liver abscess			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (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 16.1			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
urinary tract infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Screening	Placebo Acute	Teriparatide 20 mcg Acute
Total subjects affected by non-serious adverse events			
subjects affected / exposed	39 / 122 (31.97%)	34 / 61 (55.74%)	31 / 60 (51.67%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
seborrhoeic keratosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
haematoma			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	1 / 122 (0.82%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
hypertension			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
thrombosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
Surgical and medical procedures			
cataract operation			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	2	0
cholecystectomy			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
sebaceous cyst excision			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 122 (0.82%)	2 / 61 (3.28%)	2 / 60 (3.33%)
occurrences (all)	1	2	2
device breakage			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 122 (0.82%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
facial pain			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
gait disturbance			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
oedema peripheral			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 122 (0.82%)	1 / 61 (1.64%)	1 / 60 (1.67%)
occurrences (all)	1	1	1
pyrexia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
sense of oppression			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
thirst			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 122 (0.82%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	1	0	1
Reproductive system and breast disorders			
atrophic vulvovaginitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed[1]	0 / 88 (0.00%)	0 / 44 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
prostatitis			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed[2]	0 / 34 (0.00%)	0 / 17 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
vaginal haemorrhage			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed[3]	0 / 88 (0.00%)	1 / 44 (2.27%)	0 / 43 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
bronchiectasis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
bronchitis chronic			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
cough			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 122 (0.82%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	1	1	0
oropharyngeal pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
respiratory failure			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
upper respiratory tract inflammation			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
behavioural and psychiatric symptoms of dementia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
depression			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
disorientation			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
insomnia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 122 (1.64%)	2 / 61 (3.28%)	3 / 60 (5.00%)
occurrences (all)	2	2	3
mental status changes			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
Investigations			
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
blood pressure increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
liver function test abnormal			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	1 / 122 (0.82%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
weight decreased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 122 (1.64%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	2	0	0
Injury, poisoning and procedural complications			
bone contusion			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
chest injury			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
contusion			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	4
excoriation			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
fall			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
femur fracture			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
humerus fracture			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
incision site complication			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 122 (0.82%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
joint injury			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
laceration			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
spinal compression fracture			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
tooth fracture			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 122 (0.82%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
aortic valve incompetence			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 122 (0.82%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
arrhythmia			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
palpitations			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
sinus tachycardia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 122 (0.82%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
carotid arteriosclerosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
carpal tunnel syndrome			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
dizziness			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	3 / 61 (4.92%)	1 / 60 (1.67%)
occurrences (all)	0	3	1
headache			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 122 (0.82%)	1 / 61 (1.64%)	1 / 60 (1.67%)
occurrences (all)	1	1	1
hypoaesthesia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	2 / 60 (3.33%)
occurrences (all)	0	0	2
neuralgia			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
paraesthesia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
parkinson's disease			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
presyncope			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
syncope			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
tremor			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
vascular dementia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
vertebral artery stenosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
Eye disorders			
cataract			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
conjunctival haemorrhage			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
conjunctivitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
dacryostenosis acquired			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
glaucoma			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
macular degeneration			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
abdominal pain lower			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
abdominal pain upper			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	1 / 122 (0.82%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
constipation			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	8 / 122 (6.56%)	1 / 61 (1.64%)	3 / 60 (5.00%)
occurrences (all)	8	1	3
dental caries			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
diarrhoea			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	1 / 60 (1.67%)
occurrences (all)	0	1	1
diverticulum intestinal			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
faecal incontinence			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
faecaloma			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 122 (0.82%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	1	0	1
gastritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
gastritis atrophic			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1

gastritis erosive			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
gastrointestinal disorder			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
gingival swelling			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
haemorrhoids			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
hiatus hernia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
nausea			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 122 (1.64%)	0 / 61 (0.00%)	2 / 60 (3.33%)
occurrences (all)	2	0	2
periodontal inflammation			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
stomatitis			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
toothache			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
vomiting			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
actinic keratosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
alopecia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
asteatosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
dermatitis contact			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
drug eruption			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	1 / 122 (0.82%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
dyshidrotic eczema			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
erythema			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 122 (0.82%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
hypertrophic scar			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
ingrowing nail			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
rash			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	1 / 60 (1.67%)
occurrences (all)	0	1	1
skin ulcer			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
pollakiuria			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
urinary retention			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
Endocrine disorders			
hyperparathyroidism secondary			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 122 (0.82%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 122 (0.82%)	3 / 61 (4.92%)	3 / 60 (5.00%)
occurrences (all)	1	3	3
back pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	6 / 61 (9.84%)	3 / 60 (5.00%)
occurrences (all)	0	6	3
chondropathy			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
coccydynia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
flank pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
muscular weakness			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	1 / 122 (0.82%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
musculoskeletal pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 122 (1.64%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	2	0	1
myalgia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 122 (0.82%)	1 / 61 (1.64%)	2 / 60 (3.33%)
occurrences (all)	1	1	2
neck pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
osteoarthritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 122 (0.82%)	4 / 61 (6.56%)	1 / 60 (1.67%)
occurrences (all)	1	4	1
osteonecrosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
osteoporosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	3 / 60 (5.00%)
occurrences (all)	0	1	3
pain in extremity			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
spinal column stenosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1

spinal osteoarthritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
tenosynovitis stenosans			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
trigger finger			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	1 / 60 (1.67%)
occurrences (all)	0	1	1
Infections and infestations			
adenoiditis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
bronchitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
cellulitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
cervicitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed[4]	0 / 88 (0.00%)	0 / 44 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
chronic hepatitis c			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 122 (0.82%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
diverticulitis			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
ear infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
eye infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
helicobacter infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 122 (0.82%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
laryngitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 122 (0.82%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
nail infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	3 / 61 (4.92%)	4 / 60 (6.67%)
occurrences (all)	0	4	5

oral candidiasis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
oral herpes			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
parotitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
pharyngitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 122 (0.82%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
rhinitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
skin infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
tinea pedis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
tonsillitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 122 (0.82%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	1	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	1 / 122 (0.82%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	1	1	0
urinary tract infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	2 / 61 (3.28%)	0 / 60 (0.00%)
occurrences (all)	0	2	0
wound infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
wound infection staphylococcal			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 122 (0.82%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	1	0	1
folate deficiency			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
hypercalcaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	1 / 61 (1.64%)	0 / 60 (0.00%)
occurrences (all)	0	1	0
hyperlipidaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 122 (0.00%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	0	0	1
hypoglycaemia			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	1 / 122 (0.82%)	0 / 61 (0.00%)	1 / 60 (1.67%)
occurrences (all)	1	0	1
malnutrition			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	2 / 122 (1.64%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	2	0	0
vitamin d deficiency			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	3 / 122 (2.46%)	0 / 61 (0.00%)	0 / 60 (0.00%)
occurrences (all)	3	0	0

Non-serious adverse events	Placebo Follow-up	Teriparatide 20 mcg Follow-up	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 53 (33.96%)	16 / 49 (32.65%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
seborrhoeic keratosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
Vascular disorders			
haematoma			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
hypertension			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
thrombosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Surgical and medical procedures			
cataract operation			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
cholecystectomy			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
sebaceous cyst excision			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
device breakage			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
facial pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
gait disturbance			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
oedema peripheral			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
pain			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
pyrexia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
sense of oppression			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
thirst			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
atrophic vulvovaginitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed[1]	1 / 39 (2.56%)	0 / 39 (0.00%)	
occurrences (all)	1	0	
prostatitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed[2]	0 / 14 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
vaginal haemorrhage			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed[3]	0 / 39 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
bronchiectasis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences (all)	2	0	
bronchitis chronic			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
cough			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
oropharyngeal pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
respiratory failure			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
upper respiratory tract inflammation			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
behavioural and psychiatric symptoms of dementia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
depression			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
disorientation			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
insomnia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
mental status changes			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Investigations			
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
blood pressure increased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
liver function test abnormal			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
weight decreased			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			
bone contusion			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
chest injury			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
contusion			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
excoriation			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
fall			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
femur fracture			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
humerus fracture			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
incision site complication			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
joint injury			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
laceration			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	

spinal compression fracture			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
tooth fracture			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
aortic valve incompetence			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
arrhythmia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
palpitations			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
sinus tachycardia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
carotid arteriosclerosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
carpal tunnel syndrome			

alternative dictionary used: MedDRA 16.1				
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)		
occurrences (all)	0	1		
dizziness				
alternative dictionary used: MedDRA 16.1				
subjects affected / exposed	1 / 53 (1.89%)	1 / 49 (2.04%)		
occurrences (all)	1	1		
headache				
alternative dictionary used: MedDRA 16.1				
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)		
occurrences (all)	1	0		
hypoaesthesia				
alternative dictionary used: MedDRA 16.1				
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)		
occurrences (all)	0	0		
neuralgia				
alternative dictionary used: MedDRA 16.1				
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)		
occurrences (all)	0	1		
paraesthesia				
alternative dictionary used: MedDRA 16.1				
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)		
occurrences (all)	0	0		
parkinson's disease				
alternative dictionary used: MedDRA 16.1				
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)		
occurrences (all)	0	0		
presyncope				
alternative dictionary used: MedDRA 16.1				
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)		
occurrences (all)	0	0		
syncope				
alternative dictionary used: MedDRA 16.1				

subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
tremor			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
vascular dementia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
vertebral artery stenosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
vertigo			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
cataract			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
conjunctival haemorrhage			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
conjunctivitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
dacryostenosis acquired			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
glaucoma			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
macular degeneration			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
abdominal pain lower			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
abdominal pain upper			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
constipation			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
dental caries			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
diarrhoea			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
diverticulum intestinal			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
faecal incontinence			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
faecaloma			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
gastritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
gastritis atrophic			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
gastritis erosive			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
gastrointestinal disorder			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
gingival swelling			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	

haemorrhoids			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
hiatus hernia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
nausea			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
periodontal inflammation			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
stomatitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
toothache			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
vomiting			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
Hepatobiliary disorders			
cholelithiasis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			

actinic keratosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
alopecia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
asteatosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
dermatitis contact			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
drug eruption			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
dyshidrotic eczema			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
erythema			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
hypertrophic scar			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
ingrowing nail			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
pruritus			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
rash			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
skin ulcer			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
Renal and urinary disorders			
pollakiuria			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
urinary retention			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
hyperparathyroidism secondary			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	3 / 49 (6.12%)	
occurrences (all)	0	3	
back pain			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	2 / 53 (3.77%)	0 / 49 (0.00%)	
occurrences (all)	2	0	
chondropathy			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
coccydynia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
flank pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
muscular weakness			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
musculoskeletal pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
myalgia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
neck pain			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
osteoarthritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	

osteonecrosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	2 / 49 (4.08%)	
occurrences (all)	0	2	
osteoporosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
pain in extremity			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
spinal column stenosis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
spinal osteoarthritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
tenosynovitis stenosans			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
trigger finger			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
adenoiditis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
bronchitis			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 53 (0.00%)	2 / 49 (4.08%)	
occurrences (all)	0	2	
cellulitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
cervicitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed[4]	1 / 39 (2.56%)	0 / 39 (0.00%)	
occurrences (all)	1	0	
chronic hepatitis c			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
diverticulitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
ear infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
eye infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
gastroenteritis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
helicobacter infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	

influenza			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
laryngitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
nail infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
nasopharyngitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
oral candidiasis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
oral herpes			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
parotitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
pharyngitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
rhinitis			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
skin infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
tinea pedis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
tonsillitis			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
urinary tract infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	1 / 49 (2.04%)	
occurrences (all)	0	1	
wound infection			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
wound infection staphylococcal			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 16.1			

subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
folate deficiency			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
hypercalcaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
hyperlipidaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
hypoglycaemia			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	1 / 53 (1.89%)	0 / 49 (0.00%)	
occurrences (all)	1	0	
malnutrition			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	
vitamin d deficiency			
alternative dictionary used: MedDRA 16.1			
subjects affected / exposed	0 / 53 (0.00%)	0 / 49 (0.00%)	
occurrences (all)	0	0	

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.

[4] - 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? Yes

Date	Amendment
13 December 2012	The sponsor decided to end enrolment prematurely. The decision to stop enrolment was due to operational challenges and enrolment feasibility with regard to completing the study in a timely manner and not based on any safety or efficacy concerns in the trial. All active patients who were enrolled were offered to continue, and complete the study to 12 months.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported