Clinical trial results:
An Open-label, Single-dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Etelcalcetide (AMG 416) in Paediatric Subjects Aged 2 to less than 18 Years with Secondary Hyperparathyroidism (sHPT) Receiving Maintenance Haemodialysis

Summary

EudraCT number	2015-005051-28
Trial protocol	DE BE LT GB PL Outside EU/EEA
Global end of trial date	31 October 2018

Results information

Result version number	v1 (current)
This version publication date	24 April 2019
First version publication date	24 April 2019

Trial information

Trial identification

Sponsor protocol code	20140336

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02833857
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Amgen Inc.
Sponsor organisation address	One Amgen Center Drive, Thousand Oaks, CA, United States, 91320
Public contact	IHQ Medical Info-Clinical Trials, Amgen (EUROPE) GmbH, MedInfoInternational@amgen.com
Scientific contact	IHQ Medical Info-Clinical Trials, Amgen (EUROPE) GmbH, MedInfoInternational@amgen.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-001554-PIP01-13
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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	31 October 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 October 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to evaluate the safety and tolerability of etelcalcetide after single-dose administration to pediatric subjects 2 to less than 18 years of age with secondary hyperparathyroidism (sHPT) receiving maintenance hemodialysis.

Protection of trial subjects:

This study was conducted in accordance with International Council for Harmonisation (ICH) Good Clinical Practice (GCP) and applicable national or regional regulations/guidelines.
The study protocol, subject information, informed consent form (ICF), and other written subject information were reviewed and approved by the independent ethics committee (IEC) or institutional review board (IRB) for each study center.
Before a subject's participation in the clinical study, the investigator was responsible for obtaining written informed consent from the subject's legally acceptable representative and written assent from the subject (based on local regulations and/or guidelines) after adequate explanation of the aims, methods, anticipated benefits, and potential risks of the study and before any protocol specific screening procedures or investigational product was administered.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 March 2017
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	Belgium: 1
Country: Number of subjects enrolled	Germany: 4
Country: Number of subjects enrolled	United Kingdom: 1
Country: Number of subjects enrolled	United States: 5
Worldwide total number of subjects	11
EEA total number of subjects	6

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)	5
Adolescents (12-17 years)	6
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study was conducted at 6 centers in the United States, United Kingdom, and the European Union. Participants were enrolled from 14 March 2017 to 01 October 2018.

Pre-assignment

Screening details:

Sixteen subjects were screened and 11 subjects were enrolled into the study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Etelcalcetide

Arm description:

Participants received a single, intravenous (IV) bolus administration of 0.035 mg/kg etelcalcetide at the end of hemodialysis on study day 1.

Arm type	Experimental
Investigational medicinal product name	Etelcalcetide
Investigational medicinal product code	AMG 416
Other name	Parsabiv
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

All subjects received a single, IV-bolus dose of 0.035 mg/kg etelcalcetide into the venous line of the dialysis circuit at the end of a hemodialysis session.

Number of subjects in period 1	Etelcalcetide
Started	11
Completed	11

Baseline characteristics

Reporting groups	
Reporting group title	Etelcalcetide
Reporting group description:	
Participants received a single, intravenous (IV) bolus administration of 0.035 mg/kg etelcalcetide at the end of hemodialysis on study day 1.	

Reporting group values	Etelcalcetide	Total	
Number of subjects	11	11	
Age, Customized Units: Subjects			
Children (2 to 11 years)	5	5	
Adolescents (12 to 17 years)	6	6	
Age Continuous Units: years			
arithmetic mean	10.3		
standard deviation	± 4.3	-	
Sex: Female, Male Units: Subjects			
Female	6	6	
Male	5	5	
Race/Ethnicity, Customized Units: Subjects			
Black (or African American)	2	2	
White	9	9	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	2	2	
Not Hispanic or Latino	9	9	
Unknown or Not Reported	0	0	
Serum Corrected Calcium Concentration			
When albumin was less than 4.0 mg/dL, the calcium concentration was corrected according to the formula: cCa (mmol/L) = measured total serum calcium (mmol/L) + 0.02 (40 – serum albumin [g/L]).			
Units: mmol/L			
arithmetic mean	2.42		
standard deviation	± 0.08	-	
Serum Phosphorus Concentration			
Data are provided for 10 subjects with available data			
Units: mmol/L			
arithmetic mean	1.79		
standard deviation	± 0.45	-	
Serum Potassium Concentration Units: mmol/L			
arithmetic mean	4.77		
standard deviation	± 0.55	-	
Serum Intact Parathyroid Hormone Concentration Units: pmol/L			
arithmetic mean	66.10		

standard deviation	± 57.57	-	
Serum Calcium Concentration Units: mmol/L			
arithmetic mean	2.41		
standard deviation	± 0.08	-	
Serum Ionized Calcium Concentration Units: mmol/L			
arithmetic mean	1.16		
standard deviation	± 0.07	-	
Heart Rate Units: beats/minute			
arithmetic mean	87.4		
standard deviation	± 9.9	-	
Temperature Units: degrees celsius			
arithmetic mean	36.6		
standard deviation	± 0.3	-	
Blood Pressure|Systolic blood pressure Units: mmHg			
arithmetic mean	119.4		
standard deviation	± 15.9	-	
Blood Pressure|Diastolic blood pressure Units: mmHg			
arithmetic mean	66.7		
standard deviation	± 15.1	-	
PR Interval			
The PR interval is measured using electrocardiography (ECG) and is the period from the beginning of the P wave (the onset of atrial depolarization) until the beginning of the QRS complex (the onset of ventricular depolarization); it is normally between 120 and 200 milliseconds (ms) in duration.			
Units: ms			
arithmetic mean	133.8		
standard deviation	± 8.7	-	
QRS Interval			
The QRS interval measured during ECG, denotes depolarization of the ventricles, between the beginning of the Q wave and the end of the S wave.			
Units: ms			
arithmetic mean	82.0		
standard deviation	± 10.9	-	
QT Interval			
The QT interval measured during ECG is a measure of the time between the start of the Q wave and the end of the T wave in the heart's electrical cycle. The QT interval represents electrical depolarization and repolarization of the ventricles.			
Units: ms			
arithmetic mean	363.5		
standard deviation	± 26.2	-	
Corrected (Bazett) QT Interval (QTcB) Units: ms			
arithmetic mean	424.2		
standard deviation	± 29.1	-	
Corrected (Fridericia) QT Interval (QTcF) Units: ms			
arithmetic mean	402.7		
standard deviation	± 26.1	-	

End points

End points reporting groups

Reporting group title	Etelcalcetide

Reporting group description:

Participants received a single, intravenous (IV) bolus administration of 0.035 mg/kg etelcalcetide at the end of hemodialysis on study day 1.

Primary: Common Treatment-emergent Adverse Events

End point title	Common Treatment-emergent Adverse Events[1]

End point description:

A treatment-emergent adverse event is any adverse event (AE) that begins or worsens after the initial dose of study drug (etelcalcetide) and up to 30 days after the last dose. Common adverse events were defined as adverse events occurring in at least 2 participants.

End point type	Primary

End point timeframe:

30 days

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical testing was performed.

End point values	Etelcalcetide			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: participants				
Headache	2			
Calcium ionised decreased	2			
Hypotension	2			

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Serum Corrected Calcium Concentration Over Time

End point title	Change from Baseline in Serum Corrected Calcium Concentration Over Time[2]

End point description:

When albumin was less than 4.0 mg/dL, the calcium concentration was corrected according to the formula: cCa (mmol/L) = measured total serum calcium (mmol/L) + 0.02 (40 – serum albumin [g/L]).

End point type	Primary

End point timeframe:

Baseline and Day 1, 4 hours postdose, day 3, day 8, day 10, and day 30 (end of study)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical testing was performed.

End point values	Etelcalcetide			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: mmol/L				
arithmetic mean (standard deviation)				
Day 1, 4 hours (n = 10)	-0.03 (± 0.12)			
Day 3	-0.03 (± 0.08)			
Day 8	0.03 (± 0.09)			
Day 10	0.03 (± 0.07)			
Day 30	-0.01 (± 0.16)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Serum Phosphorus Concentration at End of Study

End point title	Change from Baseline in Serum Phosphorus Concentration at End of Study[3]

End point description:

End point type	Primary

End point timeframe:

Baseline and day 30 (end of study)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical testing was performed.

End point values	Etelcalcetide			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: mmol/L				
arithmetic mean (standard deviation)	0.08 (± 0.31)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Serum Potassium Concentration at End of Study

End point title	Change from Baseline in Serum Potassium Concentration at End of Study[4]

End point description:

End point type	Primary

End point timeframe:

Baseline and day 30 (end of study)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical testing was performed.

End point values	Etelcalcetide			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: mmol/L				
arithmetic mean (standard deviation)	0.45 (± 1.21)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Intact Parathyroid Hormone (iPTH) Levels Over Time

End point title	Change from Baseline in Intact Parathyroid Hormone (iPTH) Levels Over Time[5]

End point description:

End point type	Primary

End point timeframe:

Baseline and day 1, 4 hours postdose, day 3, day 8, day 10, and day 30 (end of study)

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical testing was performed.

End point values	Etelcalcetide			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: pmol/L				
arithmetic mean (standard deviation)				
Day 1, 4 hours	-29.44 (± 37.16)			
Day 3	-14.81 (± 37.81)			
Day 8	-10.20 (± 38.16)			
Day 10	-4.68 (± 37.92)			
Day 30	-19.81 (± 51.29)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Heart Rate at End of Study

End point title	Change from Baseline in Heart Rate at End of Study[6]

End point description:

End point type	Primary

End point timeframe:

Baseline and day 30 (end of study)

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical testing was performed.

End point values	Etelcalcetide			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: beats/minute				
arithmetic mean (standard deviation)	-4.5 (± 9.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Temperature at End of Study

End point title	Change from Baseline in Temperature at End of Study[7]

End point description:

End point type	Primary

End point timeframe:

Baseline and day 30 (end of study)

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical testing was performed.

End point values	Etelcalcetide			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: degrees celsius				
arithmetic mean (standard deviation)	0.1 (± 0.4)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Blood Pressure at End of Study

End point title	Change from Baseline in Blood Pressure at End of Study[8]

End point description:

End point type	Primary

End point timeframe:

Baseline and day 30 (end of study)

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical testing was performed.

End point values	Etelcalcetide			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: mmHg				
arithmetic mean (standard deviation)				
Systolic blood pressure	0.2 (± 17.5)			
Diastolic blood pressure	3.8 (± 8.5)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in PR Interval at End of Study

End point title	Change from Baseline in PR Interval at End of Study[9]

End point description:

End point type	Primary

End point timeframe:

Baseline and day 30 (end of study)

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical testing was performed.

End point values	Etelcalcetide			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: ms				
arithmetic mean (standard deviation)	-3.6 (± 13.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in QRS Interval at End of Study

End point title	Change from Baseline in QRS Interval at End of Study[10]

End point description:

End point type	Primary

End point timeframe:

Baseline and day 30 (end of study)

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical testing was performed.

End point values	Etelcalcetide			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: ms				
arithmetic mean (standard deviation)	-2.6 (± 6.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in QT Interval at End of Study

End point title	Change from Baseline in QT Interval at End of Study[11]

End point description:

End point type	Primary

End point timeframe:

Baseline and day 30 (end of study)

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical testing was performed.

End point values	Etelcalcetide			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: ms				
arithmetic mean (standard deviation)	2.8 (± 21.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Corrected (Bazett) QT Interval at End of Study

End point title	Change from Baseline in Corrected (Bazett) QT Interval at End of Study[12]

End point description:

End point type	Primary

End point timeframe:

Baseline and day 30 (end of study)

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical testing was performed.

End point values	Etelcalcetide			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: ms				
arithmetic mean (standard deviation)	-2.1 (± 32.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Corrected (Fridericia) QT Interval at End of Study

End point title	Change from Baseline in Corrected (Fridericia) QT Interval at End of Study[13]

End point description:

End point type	Primary

End point timeframe:

Baseline and day 30 (end of study)

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical testing was performed.

End point values	Etelcalcetide			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: ms				
arithmetic mean (standard deviation)	-0.5 (± 23.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Serum Total Calcium Concentration Over Time

End point title	Change from Baseline in Serum Total Calcium Concentration Over Time

End point description:

End point type	Secondary

End point timeframe:

Baseline and Day 1, 4 hours postdose, day 3, day 8, day 10, and day 30 (end of study)

End point values	Etelcalcetide			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: mmol/L				
arithmetic mean (standard deviation)				
Day 1, 4 hours (n = 10)	-0.02 (± 0.12)			
Day 3	-0.02 (± 0.08)			
Day 8	0.03 (± 0.08)			
Day 10	0.02 (± 0.08)			
Day 30	-0.01 (± 0.16)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Serum Ionized Calcium Concentration Over Time

End point title	Change from Baseline in Serum Ionized Calcium Concentration Over Time

End point description:

End point type	Secondary

End point timeframe:

Baseline and Day 1, 4 hours postdose, day 3, day 8, day 10, and day 30 (end of study)

End point values	Etelcalcetide			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: mmol/L				
arithmetic mean (standard deviation)				
Day 1, 4 hours (n = 10)	-0.05 (± 0.13)			
Day 3 (n = 10)	-0.01 (± 0.08)			
Day 8	0.02 (± 0.07)			
Day 10	0.01 (± 0.06)			
Day 30	0.03 (± 0.06)			

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Observed Plasma Concentration (Cmax) of Etelcalcetide

End point title	Maximum Observed Plasma Concentration (Cmax) of Etelcalcetide

End point description:

Plasma etelcalcetide concentrations were measured using a validated high performance liquid chromatography assay. The lower limit of quantitation was 0.200 ng/mL.

End point type	Secondary

End point timeframe:

10 minutes, 4 hours, and 3, 5, 8, 10, and 30 days postdose

End point values	Etelcalcetide			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: ng/mL				
arithmetic mean (standard deviation)	50.8 (± 29.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Maximum Concentration (Tmax) of Etelcalcetide

End point title	Time to Maximum Concentration (Tmax) of Etelcalcetide

End point description:

Plasma etelcalcetide concentrations were measured using a validated high performance liquid chromatography assay. The lower limit of quantitation was 0.200 ng/mL.

End point type	Secondary

End point timeframe:

10 minutes, 4 hours, and 3, 5, 8, 10, and 30 days postdose

End point values	Etelcalcetide			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: hours				
median (full range (min-max))	0.17 (0.17 to 0.33)			

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Plasma Etelcalcetide Concentration-Time Curve From Time Zero to Time of Last Quantifiable Concentration (AUClast)

End point title	Area Under the Plasma Etelcalcetide Concentration-Time Curve From Time Zero to Time of Last Quantifiable Concentration (AUClast)

End point description:

Plasma etelcalcetide concentrations were measured using a validated high performance liquid chromatography assay. The lower limit of quantitation was 0.200 ng/mL. Area under the curve for plasma etelcalcetide from time zero to the last quantifiable concentration (AUClast) was estimated using the linear trapezoidal method.

End point type	Secondary

End point timeframe:

10 minutes, 4 hours, and 3, 5, 8, 10, and 30 days postdose

End point values	Etelcalcetide			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: hr*ng/mL				
arithmetic mean (standard deviation)	1360 (± 1110)			

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Plasma Etelcalcetide Concentration-Time Curve From Time Zero Infinity (AUCinf)

End point title	Area Under the Plasma Etelcalcetide Concentration-Time Curve From Time Zero Infinity (AUCinf)

End point description:

Plasma etelcalcetide concentrations were measured using a validated high performance liquid chromatography assay. The lower limit of quantitation was 0.200 ng/mL. Area under the concentration-time curve from time zero to infinite time (AUCinf) was estimated using the linear trapezoidal method.

End point type	Secondary

End point timeframe:

10 minutes, 4 hours, and 3, 5, 8, 10, and 30 days postdose

End point values	Etelcalcetide			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: hr*ng/mL				
arithmetic mean (standard deviation)	1700 (± 1420)			

Statistical analyses

No statistical analyses for this end point

Secondary: Terminal Half-life (T1/2,z) of Etelcalcetide

End point title	Terminal Half-life (T1/2,z) of Etelcalcetide

End point description:

Plasma etelcalcetide concentrations were measured using a validated high performance liquid chromatography assay. The lower limit of quantitation was 0.200 ng/mL. Terminal half life of plasma etelcalcetide (t1/2,z) was calculated as t1/2,z = ln(2)/λz, where λz is the first-order terminal rate constant estimated by linear regression of the terminal log-linear phase.

End point type	Secondary

End point timeframe:

10 minutes, 4 hours, and 3, 5, 8, 10, and 30 days postdose

End point values	Etelcalcetide			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: days				
arithmetic mean (standard deviation)	5.77 (± 2.66)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Who Developed Anti-etelcalcetide Binding Antibodies

End point title	Number of Participants Who Developed Anti-etelcalcetide Binding Antibodies

End point description:

Samples were collected predose and at end of study (day 30) and tested for anti etelcalcetide binding antibodies using a validated immunoassay. Developing antibody binding was defined as participants who were binding antibody positive postbaseline with a negative result at baseline.

End point type	Secondary

End point timeframe:

Baseline and day 30

End point values	Etelcalcetide			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: participants	2			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Treatment-emergent Adverse Events

End point title	Number of Participants with Treatment-emergent Adverse Events

End point description:

A treatment-emergent adverse event is any adverse event that begins or worsens after the initial dose of study drug (etelcalcetide) and up to 30 days after the last dose. The severity of each adverse event was graded using the National Cancer Institute-Common Terminology Criteria for Adverse Events (CTCAE) version 4.0, where Grade 1 = Mild (asymptomatic or mild symptoms), Grade 2 = Moderate (minimal, local or noninvasive intervention indicated), Grade 3 = Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated, Grade 4 = Life-threatening consequences; urgent intervention indicated, and Grade 5 = Death related to AE.

End point type	Secondary

End point timeframe:

30 days

End point values	Etelcalcetide			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: participants				
Any adverse event	6			
Adverse events ≥ grade 3	2			
Adverse events ≥ grade 4	0			
Serious adverse events	0			
AEs leading to discontinuation of etelcalcetide	0			
Fatal adverse events	0			
Treatment-related adverse events	0			
Treatment-related AEs ≥ grade 3	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 30 days	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	21.0
Reporting groups	
Reporting group title	Etelcalcetide
Reporting group description: Participants received a single, intravenous (IV) bolus administration of 0.035 mg/kg etelcalcetide at the end of hemodialysis on study day 1.	

Serious adverse events	Etelcalcetide		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 11 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Etelcalcetide		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 11 (54.55%)		
Investigations			
Calcium ionised decreased			
subjects affected / exposed	2 / 11 (18.18%)		
occurrences (all)	2		
Vascular disorders			
Hypotension			
subjects affected / exposed	2 / 11 (18.18%)		
occurrences (all)	3		
Surgical and medical procedures			
Catheter placement			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		

Gastrostomy subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1		
Nervous system disorders Dizziness subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all) Paraesthesia subjects affected / exposed occurrences (all)	 1 / 11 (9.09%) 1 2 / 11 (18.18%) 2 1 / 11 (9.09%) 1		
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all)	 1 / 11 (9.09%) 1 1 / 11 (9.09%) 1		

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