



Clinical trial results:

A Multicenter Single-arm Extension Study to Describe the Long-term Efficacy and Safety of AMG 416 in the Treatment of Secondary Hyperparathyroidism in Subjects With Chronic Kidney Disease on Hemodialysis

Summary

EudraCT number	2012-002808-41
Trial protocol	HU BE CZ GB SE ES IT AT PL NL
Global end of trial date	15 July 2015

Results information

Result version number	v1 (current)
This version publication date	16 July 2016
First version publication date	16 July 2016

Trial information

Trial identification

Sponsor protocol code	20120231
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01785875
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)	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	15 July 2015
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	15 July 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study is designed to describe the long-term safety and efficacy of etelcalcetide (AMG 416) for the treatment of secondary hyperparathyroidism (SHPT) in adults with chronic kidney disease (CKD) on hemodialysis.

Protection of trial subjects:

This study was conducted in accordance with applicable country regulations and International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) regulations/guidelines.

All subjects provided written informed consent before undergoing any study-related procedures, including screening procedures.

The study protocol, amendments, and the informed consent form (ICF) were reviewed by the Institutional Review Boards (IRBs) and Independent Ethics Committees (IECs). No subjects were recruited into the study and no investigational product (IP) was shipped until the IRB/IEC gave written approval of the protocol and ICF and Amgen received copies of these approvals.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 July 2013
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	Canada: 14
Country: Number of subjects enrolled	United States: 524
Country: Number of subjects enrolled	Australia: 21
Country: Number of subjects enrolled	Austria: 7
Country: Number of subjects enrolled	Belgium: 34
Country: Number of subjects enrolled	Czech Republic: 29
Country: Number of subjects enrolled	France: 15
Country: Number of subjects enrolled	Germany: 13
Country: Number of subjects enrolled	Hungary: 43
Country: Number of subjects enrolled	Israel: 13
Country: Number of subjects enrolled	Italy: 17
Country: Number of subjects enrolled	Netherlands: 7
Country: Number of subjects enrolled	Poland: 42
Country: Number of subjects enrolled	Russian Federation: 54
Country: Number of subjects enrolled	Spain: 49
Country: Number of subjects enrolled	Sweden: 4

Country: Number of subjects enrolled	United Kingdom: 5
Worldwide total number of subjects	891
EEA total number of subjects	265

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)	595
From 65 to 84 years	282
85 years and over	14

Subject disposition

Recruitment

Recruitment details:

This single-arm study was conducted at 205 centers in the US, Canada, Europe, Israel, Russian Federation, and Australia. Participants were enrolled from 31 July 2013 to 9 June 2014.

Pre-assignment

Screening details:

This extension study enrolled participants from 1 of 3 parent studies: 20120229 (2012-002805-23), 20120230 (2012-002806-31), or 20120359. In Studies 20120229 and 20120230, patients received either placebo or etelcalcetide 3 times a week (TIW) for up to 26 weeks; In Study 20120359, patients received 5 mg etelcalcetide TIW for 4 weeks.

Period 1

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

Blinding implementation details:

This was an open-label study in which all subjects received etelcalcetide.

Participants who completed etelcalcetide and the 30-day safety follow-up period were classified as completing the study; Participants who completed etelcalcetide and rolled over into extension study 20130213 (EudraCT Number: 2013-004136-30) were classified as discontinuing the study because of protocol-specified criteria.

Arms

Are arms mutually exclusive?	Yes
Arm title	20120229 / 20120230 Placebo

Arm description:

Participants who received placebo in parent study 20120229 or 20120230 received etelcalcetide at a starting dose of 5 mg three times a week (TIW) for up to 52 weeks in the extension study. Etelcalcetide dose could be increased at weeks 5, 9, 17, 25, 33, 41, and 49 to a maximum dose of 15 mg to achieve predialysis serum parathyroid hormone levels ≤ 300 pg/mL.

Arm type	Experimental
Investigational medicinal product name	Etelcalcetide
Investigational medicinal product code	AMG 416
Other name	
Pharmaceutical forms	Solution for infusion, Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered by bolus injection into the venous line of the dialysis circuit at the end of hemodialysis treatment, and prior to or during rinse-back with each hemodialysis session (ie, 3 times per week).

Arm title	20120229 / 20120230 Etelcalcetide
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Arm description:

Participants who received etelcalcetide in parent study 20120229 or 20120230 received etelcalcetide at a starting dose of 5 mg TIW for up to 52 weeks in the extension study. Etelcalcetide dose could be increased at weeks 5, 9, 17, 25, 33, 41, and 49 to a maximum dose of 15 mg to achieve predialysis serum parathyroid hormone levels ≤ 300 pg/mL.

Arm type	Experimental
Investigational medicinal product name	Etelcalcetide
Investigational medicinal product code	AMG 416
Other name	
Pharmaceutical forms	Powder for solution for infusion, Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered by bolus injection into the venous line of the dialysis circuit at the end of hemodialysis treatment, and prior to or during rinse-back with each hemodialysis session (ie, 3 times per week).

Arm title	20120359 Etelcalcetide
Arm description:	
Participants who received etelcalcetide in parent study 20120359 received etelcalcetide at a starting dose of 5 mg TIW for up to 52 weeks in the extension study. Etelcalcetide dose could be increased at weeks 5, 9, 17, 25, 33, 41, and 49 to a maximum dose of 15 mg to achieve predialysis serum parathyroid hormone levels ≤ 300 pg/mL.	
Arm type	Experimental
Investigational medicinal product name	Etelcalcetide
Investigational medicinal product code	AMG 416
Other name	
Pharmaceutical forms	Powder for solution for infusion, Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered by bolus injection into the venous line of the dialysis circuit at the end of hemodialysis treatment, and prior to or during rinse-back with each hemodialysis session (ie, 3 times per week).

Number of subjects in period 1	20120229 / 20120230 Placebo	20120229 / 20120230 Etelcalcetide	20120359 Etelcalcetide
Started	384	384	123
Received Etelcalcetide	383	384	123
Completed	90	95	16
Not completed	294	289	107
Consent withdrawn by subject	41	34	36
Death	27	16	7
Sponsor Decision	-	2	-
Protocol Specified Criteria	207	214	55
Lost to follow-up	19	22	6
Missing	-	1	3

Baseline characteristics

Reporting groups

Reporting group title	Overall Study
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Reporting group description: -

Reporting group values	Overall Study	Total	
Number of subjects	891	891	
Age, Customized			
Units: participants			
< 65 years	577	577	
≥ 65 years	314	314	
Age Continuous			
Units: years			
arithmetic mean	58.3		
standard deviation	± 14.4	-	
Gender, Male/Female			
Units: participants			
Female	341	341	
Male	550	550	
Race/Ethnicity, Customized			
Units: Subjects			
American Indian or Alaska Native	1	1	
Asian	29	29	
Black (or African American)	270	270	
Native Hawaiian or Other Pacific Islander	12	12	
White	567	567	
Other	12	12	
Ethnicity			
Units: Subjects			
Hispanic/Latino	122	122	
Not Hispanic/Latino	769	769	
Parathyroid Hormone (PTH) Level			
Units: Subjects			
< 600 pg/mL	405	405	
600 - ≤ 1000 pg/mL	221	221	
> 1000 pg/mL	228	228	
Missing	37	37	
PTH Concentration			
Data available for 854 participants			
Units: pg/mL			
arithmetic mean	769.5		
standard deviation	± 574.4	-	
Corrected Calcium			
Data available for 889 participants			
Units: mg/dL			
arithmetic mean	9.67		
standard deviation	± 0.68	-	

Phosphorus			
Data available for 887 participants			
Units: mg/dL			
arithmetic mean	5.63		
standard deviation	± 1.75	-	
Corrected Calcium Phosphorus Product (cCa x P)			
Data available for 887 participants			
Units: mg ² /dL ²			
arithmetic mean	54.36		
standard deviation	± 17.17	-	

End points

End points reporting groups

Reporting group title	20120229 / 20120230 Placebo
Reporting group description: Participants who received placebo in parent study 20120229 or 20120230 received etelcalcetide at a starting dose of 5 mg three times a week (TIW) for up to 52 weeks in the extension study. Etelcalcetide dose could be increased at weeks 5, 9, 17, 25, 33, 41, and 49 to a maximum dose of 15 mg to achieve predialysis serum parathyroid hormone levels ≤ 300 pg/mL.	
Reporting group title	20120229 / 20120230 Etelcalcetide
Reporting group description: Participants who received etelcalcetide in parent study 20120229 or 20120230 received etelcalcetide at a starting dose of 5 mg TIW for up to 52 weeks in the extension study. Etelcalcetide dose could be increased at weeks 5, 9, 17, 25, 33, 41, and 49 to a maximum dose of 15 mg to achieve predialysis serum parathyroid hormone levels ≤ 300 pg/mL.	
Reporting group title	20120359 Etelcalcetide
Reporting group description: Participants who received etelcalcetide in parent study 20120359 received etelcalcetide at a starting dose of 5 mg TIW for up to 52 weeks in the extension study. Etelcalcetide dose could be increased at weeks 5, 9, 17, 25, 33, 41, and 49 to a maximum dose of 15 mg to achieve predialysis serum parathyroid hormone levels ≤ 300 pg/mL.	
Subject analysis set title	Total
Subject analysis set type	Full analysis
Subject analysis set description: Participants received etelcalcetide at a starting dose of 5 mg three times a week (TIW) for up to 52 weeks. Etelcalcetide dose could be increased at weeks 5, 9, 17, 25, 33, 41, and 49 to a maximum dose of 15 mg to achieve predialysis serum parathyroid hormone levels ≤ 300 pg/mL.	

Primary: Number of Participants with Adverse Events (AEs)

End point title	Number of Participants with Adverse Events (AEs) ^[1]
End point description: Treatment-related adverse events are those the investigator indicated as having a reasonable possibility of having been caused by etelcalcetide. A serious adverse event is defined as an adverse event that meets at least 1 of the following serious criteria: • fatal • life threatening • requires in-patient hospitalization or prolongation of existing hospitalization • results in persistent or significant disability/incapacity • congenital anomaly/birth defect • other medically important serious event. Results are reported for all participants who received at least 1 dose of etelcalcetide.	
End point type	Primary
End point timeframe: From first dose until 30 days after last dose; the treatment period was 52 weeks.	
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 hypotheses were tested in this study.	

End point values	20120229 / 20120230 Placebo	20120229 / 20120230 Etelcalcetide	20120359 Etelcalcetide	Total
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	383	384	123	890
Units: participants				
number (not applicable)				
Any adverse event	354	337	108	799

Serious adverse events	161	142	53	356
Treatment-related adverse events	215	141	36	392
Treatment-related serious adverse events	6	5	2	13
AEs leading to discontinuation of etelcalcetide	22	11	8	41
Fatal adverse events	27	16	8	51

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Shift in Laboratory Values from Baseline Grade 0 or 1 to Post-baseline Grade 3 or 4

End point title	Number of Participants with Shift in Laboratory Values from Baseline Grade 0 or 1 to Post-baseline Grade 3 or 4 ^[2]
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End point description:

Laboratory toxicity grading was based on Common Terminology Criteria for Adverse Events (CTCAE) version 4.0, where Grade 0 represents values in the normal range and grade 4 represents values with life-threatening consequences and urgent intervention indicated.

Results are reported for all participants who received at least 1 dose of etelcalcetide.

End point type	Primary
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End point timeframe:

52 weeks

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 hypotheses were tested in this study.

End point values	Total			
Subject group type	Subject analysis set			
Number of subjects analysed	890			
Units: participants				
number (not applicable)				
Alanine aminotransferase increase	1			
Albumin decrease	9			
Alkaline phosphatase increase	2			
Aspartate aminotransferase increase	3			
Bilirubin increase	1			
Calcium (corrected) decrease	51			
Calcium (corrected) increase	8			
Phosphorus decrease	77			
Potassium decrease	9			
Potassium increase	69			
Hemoglobin decrease	4			
Hemoglobin increase	1			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants who Developed Anti-etelcalcetide Antibodies

End point title	Number of Participants who Developed Anti-etelcalcetide Antibodies ^[3]
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End point description:

A validated dual flow-cell biosensor immunoassay was used to detect antibodies capable of binding etelcalcetide. The number of participants with a negative or no result at baseline and positive binding antibodies at any time post-baseline is reported.

Results include participants who received at least 1 dose of etelcalcetide and with a post-baseline antibody result.

End point type	Primary
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End point timeframe:

Baseline, Week 12, Week 24, Week 36, Week 53, the 30-day follow-up visit

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 hypotheses were tested in this study.

End point values	20120229 / 20120230 Placebo	20120229 / 20120230 Etelcalcetide	20120359 Etelcalcetide	Total
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	369	384	123	876
Units: participants				
number (not applicable)	10	15	2	27

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Blood Pressure

End point title	Change from Baseline in Blood Pressure ^[4]
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End point description:

Blood pressure (BP) values were taken post-hemodialysis assessments.

Results are reported for participants who received at least 1 dose of etelcalcetide and with available data at each time point (indicated by n).

End point type	Primary
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End point timeframe:

Baseline and Weeks 24 and 48

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 hypotheses were tested in this study.

End point values	20120229 / 20120230 Placebo	20120229 / 20120230 Etelcalcetide	20120359 Etelcalcetide	Total
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	383	384	123	890
Units: mmHg				
arithmetic mean (standard error)				

Systolic BP Week 24 (n = 329, 342, 104, 775)	4 (± 1.5)	4.5 (± 1.4)	-5.5 (± 2.8)	2.9 (± 1)
Systolic BP Week 48 (n = 305, 317, 74, 696)	3.5 (± 1.6)	6.5 (± 1.5)	-6.8 (± 3)	3.8 (± 1)
Diastolic BP Week 24 (n = 329, 343, 104, 776)	2.2 (± 0.8)	1.2 (± 0.9)	-5.1 (± 1.5)	0.8 (± 0.6)
Diastolic BP Week 48 (n = 305, 317, 74, 696)	1.1 (± 0.9)	0.8 (± 0.9)	-2.6 (± 1.7)	0.6 (± 0.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With > 30% Reduction From Baseline in PTH During the Efficacy Assessment Phase

End point title	Percentage of Participants With > 30% Reduction From Baseline in PTH During the Efficacy Assessment Phase
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End point description:

The efficacy assessment phase (EAP) is defined as the last 6 weeks before ending treatment, which was only for participants who completed a minimum of 8 weeks of treatment with etelcalcetide. If multiple assessments were available during the EAP, values were averaged.
Participants with pre-dialysis PTH assessment at baseline and during the EAP who completed a minimum of 8 weeks of treatment with etelcalcetide are included in the analysis.

End point type	Secondary
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End point timeframe:

Baseline and the efficacy assessment phase (defined as the last 6 weeks prior to ending treatment for participants who completed a minimum of 8 weeks of treatment)

End point values	20120229 / 20120230 Placebo	20120229 / 20120230 Etelcalcetide	20120359 Etelcalcetide	Total
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	341	332	106	779
Units: percentage of participants				
number (confidence interval 95%)	81.2 (76.7 to 85.2)	54.5 (49 to 60)	65.1 (55.2 to 74.1)	67.7 (64.2 to 70.9)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With > 30% Reduction From Baseline in PTH During the EAP12

End point title	Percentage of Participants With > 30% Reduction From Baseline in PTH During the EAP12
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End point description:

The efficacy assessment phase at 12 months (EAP12) was defined as the period from week 46 to 53 (inclusive). If multiple assessments were available during the EAP12, values were averaged.
Participants with pre-dialysis PTH assessment at baseline and during EAP12 were included in the

analysis.

End point type	Secondary
End point timeframe:	
Baseline and the efficacy assessment phase at month 12 (weeks 46-53)	

End point values	20120229 / 20120230 Placebo	20120229 / 20120230 Etelcalcetide	20120359 Etelcalcetide	Total
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	302	300	74	676
Units: percentage of participants				
number (confidence interval 95%)	82.5 (77.7 to 86.6)	53.3 (47.5 to 59.1)	63.5 (51.5 to 74.4)	67.5 (63.8 to 71)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With PTH ≤ 300 pg/mL During the EAP

End point title	Percentage of Participants With PTH ≤ 300 pg/mL During the EAP
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End point description:

Participants with predialysis PTH assessment during the EAP who completed a minimum of 8 weeks of treatment with etelcalcetide were included in the analysis.

End point type	Secondary
End point timeframe:	
Baseline and the efficacy assessment phase (defined as the last 6 weeks prior to ending treatment for participants who completed a minimum of 8 weeks of treatment)	

End point values	20120229 / 20120230 Placebo	20120229 / 20120230 Etelcalcetide	20120359 Etelcalcetide	Total
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	352	355	108	815
Units: percentage of participants				
number (confidence interval 95%)	55.7 (50.3 to 60.9)	59.7 (54.4 to 64.9)	54.6 (44.8 to 64.2)	57.3 (53.8 to 60.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With PTH ≤ 300 pg/mL During the EAP12

End point title	Percentage of Participants With PTH ≤ 300 pg/mL During the
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End point description:

Participants with predialysis PTH assessment during the EAP12 are included in the analysis.

End point type Secondary

End point timeframe:

Week 46 to 53

End point values	20120229 / 20120230 Placebo	20120229 / 20120230 Etelcalcetide	20120359 Etelcalcetide	Total
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	312	321	75	708
Units: percentage of participants				
number (confidence interval 95%)	54.8 (49.1 to 60.4)	61.1 (55.5 to 66.4)	42.7 (31.3 to 54.6)	56.4 (52.6 to 60)

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Mean PTH During the EAP

End point title Percent Change From Baseline in Mean PTH During the EAP

End point description:

Participants with available data are included in the analysis.

End point type Secondary

End point timeframe:

Baseline and the efficacy assessment phase (defined as the last 6 weeks prior to ending treatment for participants who completed a minimum of 8 weeks of treatment)

End point values	20120229 / 20120230 Placebo	20120229 / 20120230 Etelcalcetide	20120359 Etelcalcetide	Total
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	341	332	106	779
Units: percent change				
arithmetic mean (standard error)	-54.55 ($\pm$ 2.12)	3.92 ($\pm$ 8.68)	-28.4 ($\pm$ 6.96)	-26.07 ($\pm$ 4.04)

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Mean PTH During the EAP12

End point title	Percent Change From Baseline in Mean PTH During the EAP12
End point description: Participants with available data are included in the analysis.	
End point type	Secondary
End point timeframe: Baseline and the efficacy assessment phase at month 12 (weeks 46-53)	

End point values	20120229 / 20120230 Placebo	20120229 / 20120230 Etelcalcetide	20120359 Etelcalcetide	Total
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	302	300	74	676
Units: percent change				
arithmetic mean (standard error)	-55.41 ($\pm$ 2.2)	4.78 ($\pm$ 9.62)	-27.05 ($\pm$ 7.57)	-25.59 ($\pm$ 4.59)

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Mean Corrected Calcium During the EAP

End point title	Percent Change From Baseline in Mean Corrected Calcium During the EAP
End point description: Participants with available data are included in the analysis.	
End point type	Secondary
End point timeframe: Baseline and the efficacy assessment phase (defined as the last 6 weeks prior to ending treatment for participants who completed a minimum of 8 weeks of treatment)	

End point values	20120229 / 20120230 Placebo	20120229 / 20120230 Etelcalcetide	20120359 Etelcalcetide	Total
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	352	352	103	807
Units: percent change				
arithmetic mean (standard error)	-10.01 ($\pm$ 0.52)	-6.74 ($\pm$ 0.47)	-8.65 ($\pm$ 1.04)	-8.41 ($\pm$ 0.34)

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Mean Corrected Calcium During the EAP12

End point title	Percent Change From Baseline in Mean Corrected Calcium During the EAP12
End point description: Participants with available data are included in the analysis.	
End point type	Secondary
End point timeframe: Baseline and the efficacy assessment phase at month 12 (weeks 46-53)	

End point values	20120229 / 20120230 Placebo	20120229 / 20120230 Etelcalcetide	20120359 Etelcalcetide	Total
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	310	319	75	704
Units: percent change				
arithmetic mean (standard error)	-9.76 ($\pm$ 0.52)	-6.43 ($\pm$ 0.45)	-9.73 ($\pm$ 1.14)	-8.25 ($\pm$ 0.34)

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Mean Corrected Calcium Phosphorus Product During the EAP

End point title	Percent Change From Baseline in Mean Corrected Calcium Phosphorus Product During the EAP
End point description: Participants with available data are included in the analysis.	
End point type	Secondary
End point timeframe: Baseline and the efficacy assessment phase (defined as the last 6 weeks prior to ending treatment for participants who completed a minimum of 8 weeks of treatment)	

End point values	20120229 / 20120230 Placebo	20120229 / 20120230 Etelcalcetide	20120359 Etelcalcetide	Total
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	342	345	99	786
Units: percent change				
arithmetic mean (standard error)	-15.26 ($\pm$ 1.58)	-10.41 ($\pm$ 1.61)	-6.58 ($\pm$ 4.28)	-12.04 ($\pm$ 1.13)

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Mean Corrected Calcium Phosphorus Product During the EAP12

End point title	Percent Change From Baseline in Mean Corrected Calcium Phosphorus Product During the EAP12
End point description: Participants with available data are included in the analysis.	
End point type	Secondary
End point timeframe: Baseline and the efficacy assessment phase at month 12 (weeks 46-53)	

End point values	20120229 / 20120230 Placebo	20120229 / 20120230 Etelcalcetide	20120359 Etelcalcetide	Total
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	309	317	75	701
Units: percent change				
arithmetic mean (standard error)	-15.3 (± 1.53)	-9.78 (± 1.62)	-7.29 (± 4.82)	-11.95 (± 1.13)

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Mean Phosphorus During the EAP

End point title	Percent Change From Baseline in Mean Phosphorus During the EAP
End point description: Participants with available data are included in the analysis.	
End point type	Secondary
End point timeframe: Baseline and the efficacy assessment phase (defined as the last 6 weeks prior to ending treatment for participants who completed a minimum of 8 weeks of treatment)	

End point values	20120229 / 20120230 Placebo	20120229 / 20120230 Etelcalcetide	20120359 Etelcalcetide	Total
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	343	348	105	796
Units: percent change				
arithmetic mean (standard error)	-5.71 (± 1.71)	-3.5 (± 1.68)	2.82 (± 4.56)	-3.62 (± 1.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Mean Phosphorus During the EAP12

End point title	Percent Change From Baseline in Mean Phosphorus During the EAP12
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End point description:

Participants with available data are included in the analysis.

End point type	Secondary
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End point timeframe:

Baseline and the efficacy assessment phase at month 12 (weeks 46-53)

End point values	20120229 / 20120230 Placebo	20120229 / 20120230 Etelcalcetide	20120359 Etelcalcetide	Total
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	309	319	75	703
Units: percent change				
arithmetic mean (standard error)	-5.87 (± 1.65)	-3.06 (± 1.73)	3.53 (± 5.46)	-3.59 (± 1.22)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose until 30 days after last dose; the treatment period was 52 weeks.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	18.0
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Reporting groups

Reporting group title	20120229 / 20120230 Placebo
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Reporting group description:

Participants who received placebo in parent study 20120229 or 20120230 received etelcalcetide at a starting dose of 5 mg three times a week (TIW) for up to 52 weeks in the extension study. Etelcalcetide dose could be increased at weeks 5, 9, 17, 25, 33, 41, and 49 to a maximum dose of 15 mg to achieve predialysis serum parathyroid hormone levels ≤ 300 pg/mL.

Reporting group title	20120229 / 20120230 Etelcalcetide
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Reporting group description:

Participants who received etelcalcetide in parent study 20120229 or 20120230 received etelcalcetide at a starting dose of 5 mg TIW for up to 52 weeks in the extension study. Etelcalcetide dose could be increased at weeks 5, 9, 17, 25, 33, 41, and 49 to a maximum dose of 15 mg to achieve predialysis serum parathyroid hormone levels ≤ 300 pg/mL.

Reporting group title	20120359 Etelcalcetide
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Reporting group description:

Participants who received etelcalcetide in parent study 20120359 received etelcalcetide at a starting dose of 5 mg TIW for up to 52 weeks in the extension study. Etelcalcetide dose could be increased at weeks 5, 9, 17, 25, 33, 41, and 49 to a maximum dose of 15 mg to achieve predialysis serum parathyroid hormone levels ≤ 300 pg/mL.

Reporting group title	Total
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Reporting group description:

Participants received etelcalcetide at a starting dose of 5 mg three times a week (TIW) for up to 52 weeks. Etelcalcetide dose could be increased at weeks 5, 9, 17, 25, 33, 41, and 49 to a maximum dose of 15 mg to achieve predialysis serum parathyroid hormone levels ≤ 300 pg/mL.

Serious adverse events	20120229 / 20120230 Placebo	20120229 / 20120230 Etelcalcetide	20120359 Etelcalcetide
Total subjects affected by serious adverse events			
subjects affected / exposed	161 / 383 (42.04%)	142 / 384 (36.98%)	53 / 123 (43.09%)
number of deaths (all causes)	27	16	8
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder adenocarcinoma stage			

unspecified				
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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	
Breast cancer				
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0	
Clear cell renal cell carcinoma				
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Colon cancer stage II				
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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	
Lung cancer metastatic				
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0	
Metastases to spine				
subjects affected / exposed	2 / 383 (0.52%)	0 / 384 (0.00%)	0 / 123 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Neoplasm malignant				
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0	
Pancreatic carcinoma				
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0	
Prostate cancer				

subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sarcoma			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Thyroid neoplasm			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic stenosis			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial occlusive disease			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	2 / 383 (0.52%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dry gangrene			

subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity necrosis			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	2 / 383 (0.52%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Hypertension			
subjects affected / exposed	5 / 383 (1.31%)	4 / 384 (1.04%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive emergency			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Hypotension			
subjects affected / exposed	5 / 383 (1.31%)	4 / 384 (1.04%)	2 / 123 (1.63%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Jugular vein thrombosis			

subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant hypertension			
subjects affected / exposed	0 / 383 (0.00%)	2 / 384 (0.52%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	2 / 383 (0.52%)	1 / 384 (0.26%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral vascular disorder			
subjects affected / exposed	2 / 383 (0.52%)	4 / 384 (1.04%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Shock haemorrhagic			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Steal syndrome			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Surgical and medical procedures			
Arteriovenous graft			

subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Therapy cessation			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	2 / 383 (0.52%)	2 / 384 (0.52%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	3 / 383 (0.78%)	7 / 384 (1.82%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 3	0 / 8	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device occlusion			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug resistance			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic cyst			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Hyperthermia			

subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthermia malignant			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothermia			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired healing			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Non-cardiac chest pain			
subjects affected / exposed	6 / 383 (1.57%)	5 / 384 (1.30%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	2 / 383 (0.52%)	2 / 384 (0.52%)	3 / 123 (2.44%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	1 / 383 (0.26%)	1 / 384 (0.26%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Thrombosis in device			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	2 / 123 (1.63%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Drug hypersensitivity			

subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seasonal allergy			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Menorrhagia			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Pelvic haemorrhage			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	1 / 383 (0.26%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Acute respiratory failure				
subjects affected / exposed	2 / 383 (0.52%)	1 / 384 (0.26%)	0 / 123 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0	
Aspiration				
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0	
Asthma				
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Bronchospasm				
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Chronic obstructive pulmonary disease				
subjects affected / exposed	1 / 383 (0.26%)	1 / 384 (0.26%)	0 / 123 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Cough				
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Dyspnoea				
subjects affected / exposed	0 / 383 (0.00%)	3 / 384 (0.78%)	1 / 123 (0.81%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Dyspnoea exertional				
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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	
Epistaxis				

subjects affected / exposed	1 / 383 (0.26%)	1 / 384 (0.26%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Pleural effusion			
subjects affected / exposed	2 / 383 (0.52%)	2 / 384 (0.52%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary cavitation			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Pulmonary congestion			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 383 (0.26%)	2 / 384 (0.52%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pulmonary infarction			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mass			

subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	1 / 383 (0.26%)	3 / 384 (0.78%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Respiratory failure			
subjects affected / exposed	3 / 383 (0.78%)	2 / 384 (0.52%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Stridor			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Throat tightness			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	2 / 383 (0.52%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			

subjects affected / exposed	0 / 383 (0.00%)	2 / 384 (0.52%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression suicidal			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Hallucination, visual			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	6 / 383 (1.57%)	0 / 384 (0.00%)	2 / 123 (1.63%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anticoagulation drug level below therapeutic			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 383 (0.52%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bilirubin conjugated increased			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			

subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood calcium decreased			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood pressure increased			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Hepatitis C antibody positive			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
International normalised ratio increased			
subjects affected / exposed	1 / 383 (0.26%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin increased			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Weight decreased			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Ankle fracture			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriovenous fistula occlusion			
subjects affected / exposed	0 / 383 (0.00%)	2 / 384 (0.52%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriovenous fistula site complication			
subjects affected / exposed	7 / 383 (1.83%)	6 / 384 (1.56%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 11	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriovenous fistula site haemorrhage			
subjects affected / exposed	3 / 383 (0.78%)	4 / 384 (1.04%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 3	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriovenous fistula thrombosis			
subjects affected / exposed	4 / 383 (1.04%)	6 / 384 (1.56%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 9	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Complications of transplanted kidney			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Compression fracture			

subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary bypass thrombosis			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Dialysis related complication			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 383 (0.00%)	2 / 384 (0.52%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Foot fracture			

subjects affected / exposed	3 / 383 (0.78%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft thrombosis			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemodialysis-induced symptom			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional overdose			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw fracture			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Lower limb fracture			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			

subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple fractures			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Patella fracture			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Peripheral arterial reocclusion			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirenal haematoma			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Post procedural haematoma			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative respiratory failure			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Procedural hypotension			

subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Radius fracture			
subjects affected / exposed	0 / 383 (0.00%)	2 / 384 (0.52%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shunt stenosis			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shunt thrombosis			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Soft tissue injury			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Splenic injury			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Stoma site pain			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	1 / 383 (0.26%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			

subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Toxicity to various agents			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular access complication			
subjects affected / exposed	0 / 383 (0.00%)	2 / 384 (0.52%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular graft complication			
subjects affected / exposed	0 / 383 (0.00%)	2 / 384 (0.52%)	2 / 123 (1.63%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular graft thrombosis			
subjects affected / exposed	4 / 383 (1.04%)	2 / 384 (0.52%)	2 / 123 (1.63%)
occurrences causally related to treatment / all	0 / 9	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular pseudoaneurysm			
subjects affected / exposed	1 / 383 (0.26%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication			

subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound haemorrhage			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	3 / 383 (0.78%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	5 / 383 (1.31%)	6 / 384 (1.56%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Angina pectoris			
subjects affected / exposed	2 / 383 (0.52%)	3 / 384 (0.78%)	2 / 123 (1.63%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	1 / 383 (0.26%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve disease			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve incompetence			

subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve stenosis			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	9 / 383 (2.35%)	4 / 384 (1.04%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 12	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	1 / 383 (0.26%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	1 / 383 (0.26%)	1 / 384 (0.26%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	2 / 383 (0.52%)	2 / 384 (0.52%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	6 / 383 (1.57%)	2 / 384 (0.52%)	4 / 123 (3.25%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 3	0 / 2	0 / 4
Cardiac disorder			

subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	2 / 383 (0.52%)	3 / 384 (0.78%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Cardiac failure acute			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac failure chronic			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	8 / 383 (2.09%)	7 / 384 (1.82%)	3 / 123 (2.44%)
occurrences causally related to treatment / all	0 / 11	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiac valve disease			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	1 / 383 (0.26%)	3 / 384 (0.78%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 0
Cardiogenic shock			
subjects affected / exposed	1 / 383 (0.26%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiomyopathy			

subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiovascular insufficiency			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	3 / 383 (0.78%)	6 / 384 (1.56%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	3 / 383 (0.78%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve incompetence			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	2 / 383 (0.52%)	4 / 384 (1.04%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	2 / 383 (0.52%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Palpitations			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			

subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus node dysfunction			
subjects affected / exposed	0 / 383 (0.00%)	2 / 384 (0.52%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	1 / 383 (0.26%)	2 / 384 (0.52%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Torsade de pointes			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tricuspid valve incompetence			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			
subjects affected / exposed	2 / 383 (0.52%)	2 / 384 (0.52%)	2 / 123 (1.63%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	0 / 383 (0.00%)	2 / 384 (0.52%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ataxia			

subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	3 / 383 (0.78%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Encephalopathy			
subjects affected / exposed	0 / 383 (0.00%)	3 / 384 (0.78%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			

subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Headache			
subjects affected / exposed	2 / 383 (0.52%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			
subjects affected / exposed	0 / 383 (0.00%)	2 / 384 (0.52%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meralgia paraesthetica			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Migraine			

subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 383 (0.00%)	2 / 384 (0.52%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	3 / 383 (0.78%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Syncope			
subjects affected / exposed	6 / 383 (1.57%)	2 / 384 (0.52%)	3 / 123 (2.44%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	1 / 383 (0.26%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tremor			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 383 (0.78%)	1 / 384 (0.26%)	2 / 123 (1.63%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia of chronic disease			

subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic anaemia			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Leukocytosis			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Nephrogenic anaemia			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Deafness neurosensory			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Vertigo			
subjects affected / exposed	2 / 383 (0.52%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			

Cataract			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Diplopia			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lens dislocation			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic neuropathy			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Abdominal pain			
subjects affected / exposed	3 / 383 (0.78%)	3 / 384 (0.78%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	1 / 383 (0.26%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall haematoma			

subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anorectal varices haemorrhage			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Colitis ischaemic			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 383 (0.26%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dental caries			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Diabetic gastroparesis			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			

subjects affected / exposed	2 / 383 (0.52%)	2 / 384 (0.52%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticular perforation			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocutaneous fistula			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric antral vascular ectasia			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric disorder			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			

subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Gastritis			
subjects affected / exposed	2 / 383 (0.52%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis erosive			
subjects affected / exposed	1 / 383 (0.26%)	2 / 384 (0.52%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis haemorrhagic			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	2 / 123 (1.63%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	2 / 383 (0.52%)	4 / 384 (1.04%)	4 / 123 (3.25%)
occurrences causally related to treatment / all	0 / 4	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal necrosis			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal vascular malformation			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			

subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Haemorrhoids			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Ileus			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	3 / 383 (0.78%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine polyp			

subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Megacolon			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic duct obstruction			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Pancreatitis acute			
subjects affected / exposed	2 / 383 (0.52%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			

subjects affected / exposed	1 / 383 (0.26%)	2 / 384 (0.52%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	3 / 383 (0.78%)	1 / 384 (0.26%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary colic			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis acute			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Cholecystitis			
subjects affected / exposed	2 / 383 (0.52%)	3 / 384 (0.78%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			

subjects affected / exposed	1 / 383 (0.26%)	2 / 384 (0.52%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cirrhosis			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Hepatitis acute			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Hepatotoxicity			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decubitus ulcer			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot			
subjects affected / exposed	1 / 383 (0.26%)	2 / 384 (0.52%)	2 / 123 (1.63%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Henoch-Schonlein purpura			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Purpura			

subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	1 / 383 (0.26%)	5 / 384 (1.30%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitic rash			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Azotaemia			
subjects affected / exposed	2 / 383 (0.52%)	2 / 384 (0.52%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrosclerosis			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			

subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cyst haemorrhage			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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 impairment			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Endocrine disorders			
Goitre			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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

Flank pain			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Joint swelling			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 383 (0.00%)	2 / 384 (0.52%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathic arthropathy			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	1 / 383 (0.26%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			

subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	2 / 383 (0.52%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal pain			
subjects affected / exposed	2 / 383 (0.52%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal wall abscess			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acinetobacter bacteraemia			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acinetobacter infection			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Appendicitis			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriovenous graft site infection			

subjects affected / exposed	1 / 383 (0.26%)	1 / 384 (0.26%)	2 / 123 (1.63%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	2 / 383 (0.52%)	2 / 384 (0.52%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial tracheitis			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	1 / 383 (0.26%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	8 / 383 (2.09%)	4 / 384 (1.04%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 8	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			

subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Cystitis			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Device related infection			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	1 / 383 (0.26%)	1 / 384 (0.26%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic gangrene			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	1 / 383 (0.26%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis infectious			

subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Escherichia bacteraemia			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	2 / 123 (1.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	6 / 383 (1.57%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital abscess			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft infection			
subjects affected / exposed	0 / 383 (0.00%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Helicobacter gastritis			

subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Herpes zoster			
subjects affected / exposed	2 / 383 (0.52%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected skin ulcer			
subjects affected / exposed	3 / 383 (0.78%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious mononucleosis			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Influenza			
subjects affected / exposed	3 / 383 (0.78%)	1 / 384 (0.26%)	2 / 123 (1.63%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral discitis			
subjects affected / exposed	2 / 383 (0.52%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	2 / 383 (0.52%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			

subjects affected / exposed	4 / 383 (1.04%)	3 / 384 (0.78%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis acute			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal abscess			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Peritonitis			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	7 / 383 (1.83%)	5 / 384 (1.30%)	3 / 123 (2.44%)
occurrences causally related to treatment / all	0 / 8	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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 cyst infection			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Respiratory tract infection			

subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	10 / 383 (2.61%)	2 / 384 (0.52%)	3 / 123 (2.44%)
occurrences causally related to treatment / all	0 / 12	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 0
Septic shock			
subjects affected / exposed	3 / 383 (0.78%)	1 / 384 (0.26%)	2 / 123 (1.63%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Shunt infection			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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
Skin infection			
subjects affected / exposed	1 / 383 (0.26%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	1 / 383 (0.26%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheitis			

subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	2 / 383 (0.52%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	1 / 383 (0.26%)	1 / 384 (0.26%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 383 (0.26%)	2 / 384 (0.52%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	1 / 383 (0.26%)	2 / 384 (0.52%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	2 / 383 (0.52%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound sepsis			

subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Fluid overload			
subjects affected / exposed	3 / 383 (0.78%)	8 / 384 (2.08%)	4 / 123 (3.25%)
occurrences causally related to treatment / all	0 / 5	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	14 / 383 (3.66%)	10 / 384 (2.60%)	5 / 123 (4.07%)
occurrences causally related to treatment / all	0 / 14	0 / 11	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypervolaemia			
subjects affected / exposed	1 / 383 (0.26%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			

subjects affected / exposed	2 / 383 (0.52%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	5 / 383 (1.31%)	4 / 384 (1.04%)	1 / 123 (0.81%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	1 / 383 (0.26%)	0 / 384 (0.00%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 383 (0.00%)	1 / 384 (0.26%)	0 / 123 (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	Total		
Total subjects affected by serious adverse events			
subjects affected / exposed	356 / 890 (40.00%)		
number of deaths (all causes)	51		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bladder adenocarcinoma stage unspecified			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Breast cancer				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Clear cell renal cell carcinoma				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Colon cancer stage II				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lung cancer metastatic				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Metastases to spine				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Neoplasm malignant				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Pancreatic carcinoma				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Prostate cancer				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sarcoma				

subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thyroid neoplasm			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aortic stenosis			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arterial occlusive disease			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Deep vein thrombosis			
subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Dry gangrene			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Extremity necrosis			

subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haematoma				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Haemorrhage				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypertension				
subjects affected / exposed	10 / 890 (1.12%)			
occurrences causally related to treatment / all	0 / 11			
deaths causally related to treatment / all	0 / 0			
Hypertensive crisis				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hypertensive emergency				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypotension				
subjects affected / exposed	11 / 890 (1.24%)			
occurrences causally related to treatment / all	0 / 11			
deaths causally related to treatment / all	0 / 1			
Jugular vein thrombosis				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Malignant hypertension				

subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Orthostatic hypotension			
subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Peripheral arterial occlusive disease			
subjects affected / exposed	4 / 890 (0.45%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Peripheral vascular disorder			
subjects affected / exposed	6 / 890 (0.67%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 1		
Shock haemorrhagic			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Steal syndrome			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vasculitis			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Arteriovenous graft			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Therapy cessation			

subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Asthenia			
subjects affected / exposed	5 / 890 (0.56%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Chest pain			
subjects affected / exposed	11 / 890 (1.24%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 0		
Device occlusion			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Drug resistance			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemorrhagic cyst			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperthermia			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperthermia malignant			

subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypothermia			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Impaired healing			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Non-cardiac chest pain			
subjects affected / exposed	12 / 890 (1.35%)		
occurrences causally related to treatment / all	0 / 13		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	7 / 890 (0.79%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Sudden death			
subjects affected / exposed	3 / 890 (0.34%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 3		
Thrombosis in device			
subjects affected / exposed	3 / 890 (0.34%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hypersensitivity			

subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Seasonal allergy			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Menorrhagia			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pelvic haemorrhage			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Postmenopausal haemorrhage			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Acute respiratory failure			
subjects affected / exposed	3 / 890 (0.34%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		

Aspiration				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Asthma				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bronchospasm				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Chronic obstructive pulmonary disease				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Cough				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	4 / 890 (0.45%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Dyspnoea exertional				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Epistaxis				
subjects affected / exposed	3 / 890 (0.34%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Hypoxia				

subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	4 / 890 (0.45%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Pneumonia aspiration				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary cavitation				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary congestion				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	4 / 890 (0.45%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 1			
Pulmonary infarction				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary mass				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary oedema				

subjects affected / exposed	4 / 890 (0.45%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Respiratory arrest			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			
subjects affected / exposed	5 / 890 (0.56%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 1		
Stridor			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Throat tightness			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Confusional state			
subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Delirium			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Depression			
subjects affected / exposed	3 / 890 (0.34%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Depression suicidal			

subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hallucination, visual			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mental status changes			
subjects affected / exposed	8 / 890 (0.90%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anticoagulation drug level below therapeutic			
subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Bilirubin conjugated increased			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood bilirubin increased			

subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood calcium decreased			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood pressure increased			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatitis C antibody positive			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
International normalised ratio increased			
subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Troponin increased			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Weight decreased			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Arteriovenous fistula occlusion			

subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Arteriovenous fistula site complication				
subjects affected / exposed	13 / 890 (1.46%)			
occurrences causally related to treatment / all	0 / 17			
deaths causally related to treatment / all	0 / 0			
Arteriovenous fistula site haemorrhage				
subjects affected / exposed	8 / 890 (0.90%)			
occurrences causally related to treatment / all	0 / 11			
deaths causally related to treatment / all	0 / 0			
Arteriovenous fistula thrombosis				
subjects affected / exposed	10 / 890 (1.12%)			
occurrences causally related to treatment / all	0 / 15			
deaths causally related to treatment / all	0 / 0			
Cervical vertebral fracture				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Clavicle fracture				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Complications of transplanted kidney				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Compression fracture				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Contusion				

subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Coronary bypass thrombosis				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dialysis related complication				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Facial bones fracture				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fall				
subjects affected / exposed	3 / 890 (0.34%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Femoral neck fracture				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Femur fracture				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Foot fracture				
subjects affected / exposed	3 / 890 (0.34%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Graft thrombosis				

subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemodialysis-induced symptom				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Hip fracture				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Humerus fracture				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intentional overdose				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Jaw fracture				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lower limb fracture				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lumbar vertebral fracture				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Multiple fractures				

subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Patella fracture			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral arterial reocclusion			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Perirenal haematoma			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural complication			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural haematoma			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Postoperative respiratory failure			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Procedural hypotension			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Radius fracture			

subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Shunt stenosis			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Shunt thrombosis			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Soft tissue injury			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Splenic injury			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Stoma site pain			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subdural haematoma			
subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Thermal burn			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tibia fracture			

subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Toxicity to various agents				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vascular access complication				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Vascular graft complication				
subjects affected / exposed	4 / 890 (0.45%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Vascular graft thrombosis				
subjects affected / exposed	8 / 890 (0.90%)			
occurrences causally related to treatment / all	0 / 14			
deaths causally related to treatment / all	0 / 0			
Vascular pseudoaneurysm				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Wound				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Wound complication				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Wound dehiscence				

subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wound haemorrhage			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	4 / 890 (0.45%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Acute myocardial infarction			
subjects affected / exposed	11 / 890 (1.24%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 2		
Angina pectoris			
subjects affected / exposed	7 / 890 (0.79%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Angina unstable			
subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Aortic valve disease			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aortic valve incompetence			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aortic valve stenosis			

subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Arrhythmia				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Atrial fibrillation				
subjects affected / exposed	13 / 890 (1.46%)			
occurrences causally related to treatment / all	0 / 16			
deaths causally related to treatment / all	0 / 0			
Atrial flutter				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block complete				
subjects affected / exposed	3 / 890 (0.34%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Bradycardia				
subjects affected / exposed	5 / 890 (0.56%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	12 / 890 (1.35%)			
occurrences causally related to treatment / all	0 / 12			
deaths causally related to treatment / all	0 / 9			
Cardiac disorder				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Cardiac failure				

subjects affected / exposed	5 / 890 (0.56%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 2			
Cardiac failure acute				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Cardiac failure chronic				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac failure congestive				
subjects affected / exposed	18 / 890 (2.02%)			
occurrences causally related to treatment / all	0 / 23			
deaths causally related to treatment / all	0 / 1			
Cardiac valve disease				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardio-respiratory arrest				
subjects affected / exposed	4 / 890 (0.45%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 3			
Cardiogenic shock				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Cardiomyopathy				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiovascular insufficiency				

subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Coronary artery disease				
subjects affected / exposed	9 / 890 (1.01%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 0			
Coronary artery stenosis				
subjects affected / exposed	3 / 890 (0.34%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Mitral valve incompetence				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				
subjects affected / exposed	7 / 890 (0.79%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 0			
Myocardial ischaemia				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Palpitations				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pericardial effusion				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sinus node dysfunction				

subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Supraventricular tachycardia			
subjects affected / exposed	3 / 890 (0.34%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Tachycardia			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Torsade de pointes			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tricuspid valve incompetence			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ventricular fibrillation			
subjects affected / exposed	6 / 890 (0.67%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 3		
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Ataxia			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Carotid artery stenosis			

subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebral haemorrhage			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Cerebral infarction			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	4 / 890 (0.45%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Dizziness			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Encephalopathy			
subjects affected / exposed	4 / 890 (0.45%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Generalised tonic-clonic seizure			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemorrhage intracranial			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Headache			

subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hemiparesis				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypoaesthesia				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hypoxic-ischaemic encephalopathy				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Loss of consciousness				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Meralgia paraesthetica				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolic encephalopathy				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Migraine				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Presyncope				

subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	4 / 890 (0.45%)		
occurrences causally related to treatment / all	1 / 4		
deaths causally related to treatment / all	0 / 0		
Subarachnoid haemorrhage			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	11 / 890 (1.24%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Transient ischaemic attack			
subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Tremor			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	6 / 890 (0.67%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Anaemia of chronic disease			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemorrhagic anaemia			

subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Leukocytosis			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lymphadenopathy			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nephrogenic anaemia			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Deafness neurosensory			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vertigo			
subjects affected / exposed	3 / 890 (0.34%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Cataract			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diplopia			

subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lens dislocation			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Optic neuropathy			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			
subjects affected / exposed	7 / 890 (0.79%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Abdominal pain lower			
subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Abdominal pain upper			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal wall haematoma			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anorectal varices haemorrhage			

subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ascites				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Colitis				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Colitis ischaemic				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Dental caries				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diabetic gastroparesis				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	4 / 890 (0.45%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Diverticular perforation				

subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diverticulum intestinal				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Duodenal ulcer				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Enteritis				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Enterocutaneous fistula				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastric antral vascular ectasia				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Gastric disorder				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastric haemorrhage				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastritis				

subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Gastritis erosive				
subjects affected / exposed	3 / 890 (0.34%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Gastritis haemorrhagic				
subjects affected / exposed	3 / 890 (0.34%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				
subjects affected / exposed	10 / 890 (1.12%)			
occurrences causally related to treatment / all	0 / 14			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal necrosis				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal vascular malformation				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrooesophageal reflux disease				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haematemesis				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Haemorrhoidal haemorrhage				

subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemorrhoids				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Inguinal hernia				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intestinal ischaemia				
subjects affected / exposed	3 / 890 (0.34%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Intestinal perforation				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Large intestine perforation				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Large intestine polyp				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Megacolon				

subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Oesophagitis				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pancreatic duct obstruction				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pancreatitis acute				
subjects affected / exposed	3 / 890 (0.34%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Rectal haemorrhage				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Small intestinal obstruction				
subjects affected / exposed	4 / 890 (0.45%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Subileus				

subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage			
subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	5 / 890 (0.56%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Biliary colic			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholangitis acute			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholecystitis			
subjects affected / exposed	5 / 890 (0.56%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	3 / 890 (0.34%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Hepatic cirrhosis			

subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatitis acute			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatotoxicity			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Decubitus ulcer			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetic foot			
subjects affected / exposed	5 / 890 (0.56%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Henoch-Schonlein purpura			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Purpura			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Skin ulcer			

subjects affected / exposed	6 / 890 (0.67%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Vasculitic rash			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Azotaemia			
subjects affected / exposed	4 / 890 (0.45%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Chronic kidney disease			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haematuria			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nephrolithiasis			
subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Nephrosclerosis			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal colic			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal cyst haemorrhage			

subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal impairment			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Goitre			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Arthritis			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bone pain			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Bursitis			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Flank pain			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Joint swelling				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal chest pain				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal pain				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Neuropathic arthropathy				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Osteoarthritis				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pain in extremity				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Rhabdomyolysis				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rotator cuff syndrome				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Spinal osteoarthritis				

subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Spinal pain			
subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abdominal wall abscess			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abscess limb			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acinetobacter bacteraemia			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acinetobacter infection			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Appendicitis			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arteriovenous graft site infection			
subjects affected / exposed	4 / 890 (0.45%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Bacteraemia			

subjects affected / exposed	4 / 890 (0.45%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Bacterial sepsis				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bacterial tracheitis				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bronchopneumonia				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Campylobacter gastroenteritis				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	13 / 890 (1.46%)			
occurrences causally related to treatment / all	0 / 14			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile colitis				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile infection				

subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cystitis				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Device related infection				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Device related sepsis				
subjects affected / exposed	3 / 890 (0.34%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Diabetic gangrene				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Endocarditis				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Enteritis infectious				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Erysipelas				

subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Escherichia bacteraemia				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gangrene				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	6 / 890 (0.67%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Genital abscess				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Graft infection				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Helicobacter gastritis				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Herpes zoster				

subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Infected skin ulcer				
subjects affected / exposed	4 / 890 (0.45%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Infectious mononucleosis				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	6 / 890 (0.67%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Intervertebral discitis				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Localised infection				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis				
subjects affected / exposed	8 / 890 (0.90%)			
occurrences causally related to treatment / all	0 / 10			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis acute				

subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Perirectal abscess				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peritonitis				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	15 / 890 (1.69%)			
occurrences causally related to treatment / all	0 / 17			
deaths causally related to treatment / all	0 / 0			
Pneumonia bacterial				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Postoperative wound infection				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal cyst infection				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Sepsis				

subjects affected / exposed	15 / 890 (1.69%)		
occurrences causally related to treatment / all	0 / 18		
deaths causally related to treatment / all	0 / 3		
Septic shock			
subjects affected / exposed	6 / 890 (0.67%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 2		
Shunt infection			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin infection			
subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Staphylococcal bacteraemia			
subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Staphylococcal sepsis			
subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Subcutaneous abscess			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tracheitis			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tracheobronchitis			

subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			
subjects affected / exposed	3 / 890 (0.34%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	4 / 890 (0.45%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	3 / 890 (0.34%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Viral infection			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wound infection			
subjects affected / exposed	2 / 890 (0.22%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Wound sepsis			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diabetes mellitus				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diabetic ketoacidosis				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Failure to thrive				
subjects affected / exposed	1 / 890 (0.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Fluid overload				
subjects affected / exposed	15 / 890 (1.69%)			
occurrences causally related to treatment / all	0 / 17			
deaths causally related to treatment / all	0 / 0			
Hyperkalaemia				
subjects affected / exposed	29 / 890 (3.26%)			
occurrences causally related to treatment / all	0 / 32			
deaths causally related to treatment / all	0 / 0			
Hypervolaemia				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Hypocalcaemia				
subjects affected / exposed	2 / 890 (0.22%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Hypoglycaemia				

subjects affected / exposed	10 / 890 (1.12%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Hypophosphataemia			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Malnutrition			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolic acidosis			
subjects affected / exposed	1 / 890 (0.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	20120229 / 20120230 Placebo	20120229 / 20120230 Etelcalcetide	20120359 Etelcalcetide
Total subjects affected by non-serious adverse events			
subjects affected / exposed	289 / 383 (75.46%)	249 / 384 (64.84%)	75 / 123 (60.98%)
Investigations			
Blood calcium decreased			
subjects affected / exposed	226 / 383 (59.01%)	129 / 384 (33.59%)	30 / 123 (24.39%)
occurrences (all)	337	192	44
Injury, poisoning and procedural complications			
Arteriovenous fistula site complication			
subjects affected / exposed	22 / 383 (5.74%)	27 / 384 (7.03%)	8 / 123 (6.50%)
occurrences (all)	39	31	13
Fall			
subjects affected / exposed	22 / 383 (5.74%)	14 / 384 (3.65%)	6 / 123 (4.88%)
occurrences (all)	26	18	7
Procedural hypotension			

subjects affected / exposed occurrences (all)	17 / 383 (4.44%) 27	8 / 384 (2.08%) 10	8 / 123 (6.50%) 47
Vascular disorders			
Hypertension			
subjects affected / exposed	30 / 383 (7.83%)	18 / 384 (4.69%)	10 / 123 (8.13%)
occurrences (all)	36	36	18
Hypotension			
subjects affected / exposed	36 / 383 (9.40%)	25 / 384 (6.51%)	5 / 123 (4.07%)
occurrences (all)	60	41	5
Nervous system disorders			
Headache			
subjects affected / exposed	25 / 383 (6.53%)	25 / 384 (6.51%)	2 / 123 (1.63%)
occurrences (all)	31	29	2
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	22 / 383 (5.74%)	12 / 384 (3.13%)	3 / 123 (2.44%)
occurrences (all)	23	14	3
Diarrhoea			
subjects affected / exposed	41 / 383 (10.70%)	46 / 384 (11.98%)	8 / 123 (6.50%)
occurrences (all)	53	63	14
Nausea			
subjects affected / exposed	43 / 383 (11.23%)	27 / 384 (7.03%)	13 / 123 (10.57%)
occurrences (all)	51	37	16
Vomiting			
subjects affected / exposed	40 / 383 (10.44%)	37 / 384 (9.64%)	11 / 123 (8.94%)
occurrences (all)	53	46	13
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	21 / 383 (5.48%)	20 / 384 (5.21%)	13 / 123 (10.57%)
occurrences (all)	23	22	15
Dyspnoea			
subjects affected / exposed	24 / 383 (6.27%)	17 / 384 (4.43%)	5 / 123 (4.07%)
occurrences (all)	43	20	12
Psychiatric disorders			
Anxiety			

subjects affected / exposed occurrences (all)	8 / 383 (2.09%) 8	10 / 384 (2.60%) 12	7 / 123 (5.69%) 8
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	19 / 383 (4.96%)	18 / 384 (4.69%)	10 / 123 (8.13%)
occurrences (all)	21	20	10
Back pain			
subjects affected / exposed	26 / 383 (6.79%)	20 / 384 (5.21%)	4 / 123 (3.25%)
occurrences (all)	27	22	4
Muscle spasms			
subjects affected / exposed	36 / 383 (9.40%)	33 / 384 (8.59%)	10 / 123 (8.13%)
occurrences (all)	55	51	30
Pain in extremity			
subjects affected / exposed	16 / 383 (4.18%)	23 / 384 (5.99%)	6 / 123 (4.88%)
occurrences (all)	24	29	11
Infections and infestations			
Bronchitis			
subjects affected / exposed	20 / 383 (5.22%)	6 / 384 (1.56%)	2 / 123 (1.63%)
occurrences (all)	21	8	3
Nasopharyngitis			
subjects affected / exposed	19 / 383 (4.96%)	21 / 384 (5.47%)	3 / 123 (2.44%)
occurrences (all)	25	28	3
Upper respiratory tract infection			
subjects affected / exposed	20 / 383 (5.22%)	14 / 384 (3.65%)	20 / 123 (16.26%)
occurrences (all)	21	17	24

Non-serious adverse events	Total		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	613 / 890 (68.88%)		
Investigations			
Blood calcium decreased			
subjects affected / exposed	385 / 890 (43.26%)		
occurrences (all)	573		
Injury, poisoning and procedural complications			
Arteriovenous fistula site complication			

subjects affected / exposed occurrences (all)	57 / 890 (6.40%) 83		
Fall subjects affected / exposed occurrences (all)	42 / 890 (4.72%) 51		
Procedural hypotension subjects affected / exposed occurrences (all)	33 / 890 (3.71%) 84		
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	58 / 890 (6.52%) 90		
Hypotension subjects affected / exposed occurrences (all)	66 / 890 (7.42%) 106		
Nervous system disorders Headache subjects affected / exposed occurrences (all)	52 / 890 (5.84%) 62		
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all)	37 / 890 (4.16%) 40		
Diarrhoea subjects affected / exposed occurrences (all)	95 / 890 (10.67%) 130		
Nausea subjects affected / exposed occurrences (all)	83 / 890 (9.33%) 104		
Vomiting subjects affected / exposed occurrences (all)	88 / 890 (9.89%) 112		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	54 / 890 (6.07%) 60		

Dyspnoea subjects affected / exposed occurrences (all)	46 / 890 (5.17%) 75		
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all)	25 / 890 (2.81%) 28		
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all) Muscle spasms subjects affected / exposed occurrences (all) Pain in extremity subjects affected / exposed occurrences (all)	47 / 890 (5.28%) 51 50 / 890 (5.62%) 53 79 / 890 (8.88%) 136 45 / 890 (5.06%) 64		
Infections and infestations Bronchitis subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all)	28 / 890 (3.15%) 32 43 / 890 (4.83%) 56 54 / 890 (6.07%) 62		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 March 2013	- Allowed initiation of etelcalcetide administration Monday to Friday, instead of the previous restriction of Wednesday or Thursday only - Clarified that etelcalcetide should not be administered subcutaneously or through any other route other than IV, and that it should not be administered concurrently with other IV medications. - Clarified that if suspended for symptomatic hypocalcemia, dosing should only resume after checking cCa levels, in addition to the currently stated resolution of symptomatic hypocalcemia. - Allowed adjustment of vitamin D for hypocalcemia during the study. - Provided recommended interventions for treating hypocalcemia with modification of oral calcium supplements, dialysate calcium concentration, and vitamin D. - Eliminated 4 hematology, 5 PTH, and 6 albumin/ calcium/ phosphorous assays in the dose maintenance phase. - Provided a sample Serious Adverse Event Form. - Increased pregnancy testing for women of childbearing potential from 2 times in total (before study start and at end of study), to 5 times in total (every 12 weeks).
19 August 2013	- Removed requirement for male contraception „ - Added text describing the new liquid formulation of etelcalcetide - Reduced the dose titration portion to the first 9 weeks, and commensurately increased the dose maintenance phase (entire study duration was unchanged) - Excluded the use of any concomitant medications known to be associated with hypocalcemia - Added a + 1 week window for the dose titration phase and a +/- 2 week window for the dose maintenance phase - Revised and reduced the assessments to reflect the new titration versus maintenance weeks - Eliminated all electrocardiogram measurements - Added new standard text for serious adverse event reporting procedures

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported