



Clinical trial results:

A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of the Effects of Ranolazine on Major Adverse Cardiovascular Events in Subjects with a History of Chronic Angina Who Undergo Percutaneous Coronary Intervention with Incomplete Revascularization

Summary

EudraCT number	2011-002507-15
Trial protocol	DE SE CZ AT GB BE NL ES IT
Global end of trial date	09 February 2015

Results information

Result version number	v1 (current)
This version publication date	25 February 2016
First version publication date	25 February 2016

Trial information

Trial identification

Sponsor protocol code	GS-US-259-0116
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01442038
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Gilead Sciences
Sponsor organisation address	333 Lakeside Drive, Foster City, CA, United States, 94404
Public contact	Clinical Trial Mailbox, Gilead Sciences International Ltd, ClinicalTrialDisclosures@gilead.com
Scientific contact	Clinical Trial Mailbox, Gilead Sciences International Ltd, ClinicalTrialDisclosures@gilead.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	09 February 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	09 February 2015
Global end of trial reached?	Yes
Global end of trial date	09 February 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to evaluate the efficacy of ranolazine as compared with placebo when used as part of standard medical therapy in chronic angina subjects with incomplete revascularization post-PCI on the composite of ischemia-driven revascularization or ischemia-driven hospitalization without revascularization.

Protection of trial subjects:

The protocol and consent/assent forms were submitted by each investigator to a duly constituted Independent Ethics Committee (IEC) or Institutional Review Board (IRB) for review and approval before study initiation. All revisions to the consent/assent forms (if applicable) after initial IEC/IRB approval were submitted by the investigator to the IEC/IRB for review and approval before implementation in accordance with regulatory requirements.

This study was conducted in accordance with recognized international scientific and ethical standards, including but not limited to the International Conference on Harmonization guideline for Good Clinical Practice (ICH GCP) and the original principles embodied in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 November 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Netherlands: 26
Country: Number of subjects enrolled	Poland: 375
Country: Number of subjects enrolled	Spain: 167
Country: Number of subjects enrolled	Sweden: 44
Country: Number of subjects enrolled	United Kingdom: 33
Country: Number of subjects enrolled	Austria: 27
Country: Number of subjects enrolled	Belgium: 41
Country: Number of subjects enrolled	Czech Republic: 75
Country: Number of subjects enrolled	France: 37
Country: Number of subjects enrolled	Germany: 61
Country: Number of subjects enrolled	Italy: 61
Country: Number of subjects enrolled	United States: 965
Country: Number of subjects enrolled	Russian Federation: 322
Country: Number of subjects enrolled	Israel: 220

Country: Number of subjects enrolled	Canada: 165
Worldwide total number of subjects	2619
EEA total number of subjects	947

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)	1433
From 65 to 84 years	1155
85 years and over	31

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at study sites in the United States, Canada, Europe, Russia, and Israel. The first participant was screened on 03 November 2011. The last study visit occurred on 09 February 2015.

Pre-assignment

Screening details:

2734 participants were screened

Period 1

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

Arms

Are arms mutually exclusive?	Yes
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Arm title	Ranolazine
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Arm description:

Ranolazine 500 mg (1 x 500 mg tablet) for 7 days, followed by ranolazine 1000 mg (2 x 500 mg tablet) for the duration of the study (participants receiving a moderate CYP3A4 inhibitor continued to receive ranolazine 500 mg (1 x 500 mg tablet) for the duration of the study)

Arm type	Experimental
Investigational medicinal product name	Ranolazine
Investigational medicinal product code	
Other name	Ranexa®
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Ranolazine 500 mg tablet(s) administered twice daily

Arm title	Placebo
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Arm description:

Ranolazine placebo (1 tablet) for 7 days, followed by ranolazine placebo (2 tablets) for the duration of the study (participants receiving a moderate CYP3A4 inhibitor continued to receive ranolazine placebo (1 tablet) for the duration of the study)

Arm type	Placebo
Investigational medicinal product name	Ranolazine Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Ranolazine placebo tablet(s) administered twice daily

Number of subjects in period 1	Ranolazine	Placebo
Started	1322	1297
Completed	1029	1039
Not completed	293	258
Participant withdrew consent	136	97
Adverse event, non-fatal	26	15
Death	34	29
Investigator-initiated early site closure	44	43
Lost to follow-up	37	51
Investigator's discretion	13	16
Protocol deviation	3	7

Baseline characteristics

Reporting groups

Reporting group title	Ranolazine
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Reporting group description:

Ranolazine 500 mg (1 x 500 mg tablet) for 7 days, followed by ranolazine 1000 mg (2 x 500 mg tablet) for the duration of the study (participants receiving a moderate CYP3A4 inhibitor continued to receive ranolazine 500 mg (1 x 500 mg tablet) for the duration of the study)

Reporting group title	Placebo
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Reporting group description:

Ranolazine placebo (1 tablet) for 7 days, followed by ranolazine placebo (2 tablets) for the duration of the study (participants receiving a moderate CYP3A4 inhibitor continued to receive ranolazine placebo (1 tablet) for the duration of the study)

Reporting group values	Ranolazine	Placebo	Total
Number of subjects	1322	1297	2619
Age categorical Units: Subjects			
< 65 Years	714	719	1433
65-74 Years	402	383	785
≥ 75 Years	206	195	401
Age continuous Units: years			
arithmetic mean	63.4	63.4	
standard deviation	± 10.51	± 10.06	-
Gender categorical Units: Subjects			
Female	276	260	536
Male	1046	1037	2083
Race Units: Subjects			
American Indian or Alaska native	0	3	3
Asian	16	10	26
Black or African American	49	43	92
Native Hawaiian or Pacific Islander	2	1	3
White	1203	1196	2399
Other	29	28	57
Not permitted	23	16	39
Ethnicity Units: Subjects			
Hispanic or Latino	72	64	136
Not Hispanic or Latino	1219	1208	2427
Not reported	28	24	52
Unknown	3	1	4

End points

End points reporting groups

Reporting group title	Ranolazine
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Reporting group description:

Ranolazine 500 mg (1 x 500 mg tablet) for 7 days, followed by ranolazine 1000 mg (2 x 500 mg tablet) for the duration of the study (participants receiving a moderate CYP3A4 inhibitor continued to receive ranolazine 500 mg (1 x 500 mg tablet) for the duration of the study)

Reporting group title	Placebo
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Reporting group description:

Ranolazine placebo (1 tablet) for 7 days, followed by ranolazine placebo (2 tablets) for the duration of the study (participants receiving a moderate CYP3A4 inhibitor continued to receive ranolazine placebo (1 tablet) for the duration of the study)

Primary: Time From Randomization to First Occurrence of Ischemia-driven Revascularization or Ischemia-driven Hospitalization Without Revascularization

End point title	Time From Randomization to First Occurrence of Ischemia-driven Revascularization or Ischemia-driven Hospitalization Without Revascularization
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End point description:

999 = not calculable. Full Analysis Set: all participants in the Safety Analysis Set (randomized and received at least on dose of study drug), except participants with no qualifying percutaneous coronary intervention (PCI; formerly known as angioplasty with stent). Time to event distributions were estimated by the Kaplan-Meier (KM) method. 1 month = 28 days; 1 calendar year = 365 days.

End point type	Primary
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End point timeframe:

Baseline through end of study (average 90 weeks)

End point values	Ranolazine	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1317	1287		
Units: percentage of participants				
number (not applicable)				
KM Estimate: 1 Month	3.4	2.3		
KM Estimate: 6 Months	11.3	10		
KM Estimate: 12 Months	19.1	17.3		
KM Estimate: 1 Calendar Year	20.2	18.9		
KM Estimate: 18 Months	23.8	25.3		
KM Estimate: 24 Months	27.6	29.4		
KM Estimate: 2 Calendar Years	30.7	31		
KM Estimate: 30 Months	31.1	33.8		
KM Estimate: 36 Months	32.2	37.8		
KM Estimate: 3 Calendar Years	999	37.8		

Statistical analyses

Statistical analysis title	Difference in KM percentages
Comparison groups	Ranolazine v Placebo
Number of subjects included in analysis	2604
Analysis specification	Pre-specified
Analysis type	other ^[1]
P-value	= 0.48 ^[2]
Method	Cox Proportional Hazards Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.948
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.818
upper limit	1.099

Notes:

[1] - Comparative analysis

[2] - The p-value and hazard ratio are from Cox proportional hazards model stratifying by reason for qualifying percutaneous coronary intervention (PCI): acute coronary syndrome (ACS) versus non-ACS indication, and history of diabetes (yes versus no).

Secondary: Time From Randomization to Sudden Cardiac Death

End point title	Time From Randomization to Sudden Cardiac Death
End point description:	
Full Analysis Set. Time to event distributions were estimated by the Kaplan-Meier method. 1 month = 28 days; 1 calendar year = 365 days.	
End point type	Secondary
End point timeframe:	
Baseline through end of study (average 90 weeks)	

End point values	Ranolazine	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1317	1287		
Units: percentage of participants				
number (not applicable)				
KM Estimate: 1 Month	0.2	0.1		
KM Estimate: 6 Months	0.5	0.2		
KM Estimate: 12 Months	0.5	0.5		
KM Estimate: 1 Calendar Year	0.5	0.5		
KM Estimate: 18 Months	0.5	0.8		
KM Estimate: 24 Months	0.5	0.9		
KM Estimate: 2 Calendar Years	0.7	0.9		
KM Estimate: 30 Months	0.7	0.9		
KM Estimate: 36 Months	0.7	0.9		
KM Estimate: 3 Calendar Years	0.7	0.9		

Statistical analyses

Statistical analysis title	Difference in percentages
Comparison groups	Ranolazine v Placebo
Number of subjects included in analysis	2604
Analysis specification	Pre-specified
Analysis type	other ^[3]
P-value	= 0.4 ^[4]
Method	Cox Proportional Hazards Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.665
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.244
upper limit	1.691

Notes:

[3] - Comparative analysis

[4] - The p-value and hazard ratio are from Cox proportional hazards model stratifying by reason for qualifying PCI: ACS versus non-ACS indication, and history of diabetes (yes versus no).

Secondary: Time From Randomization to Cardiovascular Death

End point title	Time From Randomization to Cardiovascular Death
End point description:	
Full Analysis Set. Time to event distributions were estimated by the Kaplan-Meier method. 1 month = 28 days; 1 calendar year = 365 days.	
End point type	Secondary
End point timeframe:	
Baseline through end of study (average 90 weeks)	

End point values	Ranolazine	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1317	1287		
Units: percentage of participants				
number (not applicable)				
KM Estimate: 1 Month	0.2	0.1		
KM Estimate: 6 Months	0.6	0.4		
KM Estimate: 12 Months	1	0.9		
KM Estimate: 1 Calendar Year	1.1	1		
KM Estimate: 18 Months	1.5	1.4		
KM Estimate: 24 Months	1.7	1.7		
KM Estimate: 2 Calendar Years	1.9	1.7		
KM Estimate: 30 months	1.9	1.7		
KM Estimate: 36 months	1.9	1.7		
KM Estimate: 3 Calendar Years	1.9	1.7		

Statistical analyses

Statistical analysis title	Difference in KM percentages
Comparison groups	Ranolazine v Placebo
Number of subjects included in analysis	2604
Analysis specification	Pre-specified
Analysis type	other ^[5]
P-value	= 0.82 ^[6]
Method	Cox Proportional Hazards Model
Parameter estimate	Hazard ratio (HR)
Point estimate	1.073
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.579
upper limit	1.994

Notes:

[5] - Comparative analysis

[6] - The p-value and hazard ratio are from Cox proportional hazards model stratifying by reason for qualifying PCI: ACS versus non-ACS indication, and history of diabetes (yes versus no).

Secondary: Time From Randomization to Myocardial Infarction

End point title	Time From Randomization to Myocardial Infarction
End point description:	
Full Analysis Set. Time to event distributions were estimated by the Kaplan-Meier method. 1 month = 28 days; 1 calendar year = 365 days.	
End point type	Secondary
End point timeframe:	
Baseline through end of study (average 90 weeks)	

End point values	Ranolazine	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1317	1287		
Units: percentage of participants				
number (not applicable)				
KM Estimate: 1 Month	1.2	0.6		
KM Estimate: 6 Months	3.8	3.3		
KM Estimate: 12 Months	5.8	5.7		
KM Estimate: 1 Calendar Year	6.2	6.2		
KM Estimate: 18 Months	7.3	8.5		
KM Estimate: 24 Months	8.7	9.4		
KM Estimate: 2 Calendar Years	10	9.4		
KM Estimate: 30 months	10.9	10.1		
KM Estimate: 36 months	10.9	13.4		
KM Estimate: 3 Calendar Years	10.9	13.4		

Statistical analyses

Statistical analysis title	Difference in KM percentages
Comparison groups	Ranolazine v Placebo
Number of subjects included in analysis	2604
Analysis specification	Pre-specified
Analysis type	other ^[7]
P-value	= 0.81 ^[8]
Method	Cox Proportional Hazards Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.968
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.745
upper limit	1.256

Notes:

[7] - Comparative analysis

[8] - The p-value and hazard ratio are from Cox proportional hazards model stratifying by reason for qualifying PCI: ACS versus non-ACS indication, and history of diabetes (yes versus no).

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline through end of study drug treatment (average exposure 72 weeks) plus 30 days

Adverse event reporting additional description:

Safety Analysis Set: participants who were randomized and received at least one dose of study drug

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	17.1
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Reporting groups

Reporting group title	Ranolazine
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Reporting group description:

Ranolazine 500 mg (1 x 500 mg tablet) for 7 days, followed by ranolazine 1000 mg (2 x 500 mg tablet) for the duration of the study (participants receiving a moderate CYP3A4 inhibitor continued to receive ranolazine 500 mg (1 x 500 mg tablet) for the duration of the study)

Reporting group title	Placebo
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Reporting group description:

Ranolazine placebo (1 tablet) for 7 days, followed by ranolazine placebo (2 tablets) for the duration of the study (participants receiving a moderate CYP3A4 inhibitor continued to receive ranolazine placebo (1 tablet) for the duration of the study)

Serious adverse events	Ranolazine	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	516 / 1322 (39.03%)	485 / 1297 (37.39%)	
number of deaths (all causes)	34	29	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Prostate cancer			
subjects affected / exposed	3 / 1322 (0.23%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder adenocarcinoma stage unspecified			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neoplasm			

subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma		
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1297 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma		
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma		
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of skin		
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine cancer		
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma of colon		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adrenal adenoma		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer		

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer stage 0, with cancer in situ		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial carcinoma		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangiocarcinoma		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colon neoplasm		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial cancer		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial cancer stage I		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fibrous histiocytoma		

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Glioblastoma		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Leukaemia		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Lung adenocarcinoma		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung neoplasm		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Lung neoplasm malignant		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to peritoneum		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm malignant		

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal adenocarcinoma		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal carcinoma		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic carcinoma metastatic		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Plasma cell myeloma		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cell carcinoma		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland neoplasm		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell lung cancer		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Testis cancer		

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid neoplasm			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Peripheral ischaemia			
subjects affected / exposed	6 / 1322 (0.45%)	7 / 1297 (0.54%)	
occurrences causally related to treatment / all	0 / 8	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 2	
Hypertension			
subjects affected / exposed	9 / 1322 (0.68%)	3 / 1297 (0.23%)	
occurrences causally related to treatment / all	0 / 10	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			
subjects affected / exposed	4 / 1322 (0.30%)	7 / 1297 (0.54%)	
occurrences causally related to treatment / all	0 / 6	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral vascular disorder			
subjects affected / exposed	4 / 1322 (0.30%)	5 / 1297 (0.39%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	7 / 1322 (0.53%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	1 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm			

subjects affected / exposed	5 / 1322 (0.38%)	2 / 1297 (0.15%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Deep vein thrombosis		
subjects affected / exposed	4 / 1322 (0.30%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic hypotension		
subjects affected / exposed	4 / 1322 (0.30%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic stenosis		
subjects affected / exposed	3 / 1322 (0.23%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive crisis		
subjects affected / exposed	1 / 1322 (0.08%)	2 / 1297 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intermittent claudication		
subjects affected / exposed	3 / 1322 (0.23%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery stenosis		
subjects affected / exposed	1 / 1322 (0.08%)	2 / 1297 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombosis		
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive emergency		

subjects affected / exposed	2 / 1322 (0.15%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant hypertension		
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial stenosis		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerosis		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Extremity necrosis		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral artery occlusion		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemic shock		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Ischaemia		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphorrhoea		

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery thrombosis			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renovascular hypertension			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subclavian vein thrombosis			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose vein			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	37 / 1322 (2.80%)	24 / 1297 (1.85%)	
occurrences causally related to treatment / all	0 / 39	0 / 27	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	19 / 1322 (1.44%)	19 / 1297 (1.46%)	
occurrences causally related to treatment / all	0 / 20	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	2 / 1322 (0.15%)	3 / 1297 (0.23%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			

subjects affected / exposed	2 / 1322 (0.15%)	2 / 1297 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Asthenia		
subjects affected / exposed	3 / 1322 (0.23%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery restenosis		
subjects affected / exposed	1 / 1322 (0.08%)	2 / 1297 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Multi-organ failure		
subjects affected / exposed	0 / 1322 (0.00%)	3 / 1297 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2
Sudden cardiac death		
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1
Arterial restenosis		
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1297 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Death		
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Fatigue		
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery restenosis		

subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery restenosis		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Device extrusion		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device malfunction		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Face oedema		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired healing		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Multi-organ disorder		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Oedema peripheral		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombosis in device		

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcer haemorrhage			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 1322 (0.00%)	4 / 1297 (0.31%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymal cyst			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	13 / 1322 (0.98%)	13 / 1297 (1.00%)	
occurrences causally related to treatment / all	0 / 15	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 1	
Chronic obstructive pulmonary disease			

subjects affected / exposed	5 / 1322 (0.38%)	7 / 1297 (0.54%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 0
Dyspnoea exertional		
subjects affected / exposed	2 / 1322 (0.15%)	4 / 1297 (0.31%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary oedema		
subjects affected / exposed	2 / 1322 (0.15%)	4 / 1297 (0.31%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Epistaxis		
subjects affected / exposed	1 / 1322 (0.08%)	2 / 1297 (0.15%)
occurrences causally related to treatment / all	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural effusion		
subjects affected / exposed	1 / 1322 (0.08%)	2 / 1297 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax		
subjects affected / exposed	1 / 1322 (0.08%)	2 / 1297 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary embolism		
subjects affected / exposed	1 / 1322 (0.08%)	2 / 1297 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory failure		
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute respiratory failure		

subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Asthma		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis chronic		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoptysis		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxia		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal stenosis		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung consolidation		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngeal haemorrhage		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia aspiration		

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax spontaneous		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary congestion		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary fibrosis		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary hypertension		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Respiratory disorder		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory distress		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Tonsillar hypertrophy		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheal stenosis		

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	2 / 1322 (0.15%)	4 / 1297 (0.31%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	3 / 1322 (0.23%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delusional disorder, unspecified type			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major depression			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Cardiac stress test abnormal			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ejection fraction decreased			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram ST segment			

depression			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	3 / 1322 (0.23%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Laceration			
subjects affected / exposed	1 / 1322 (0.08%)	2 / 1297 (0.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Anaemia postoperative			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest injury			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral injury			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial bones fracture			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Graft thrombosis			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Humerus fracture		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Limb injury		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lower limb fracture		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar vertebral fracture		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle rupture		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic fracture		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Periorbital haematoma		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial reocclusion		

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural complication		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural fistula		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematoma		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haemorrhage		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative hernia		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound complication		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postpericardiotomy syndrome		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural pain		

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pubis fracture			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous haematoma			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haemorrhage			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft complication			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular pseudoaneurysm			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Atrial septal defect			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	125 / 1322 (9.46%)	114 / 1297 (8.79%)	
occurrences causally related to treatment / all	0 / 146	0 / 135	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	58 / 1322 (4.39%)	71 / 1297 (5.47%)	
occurrences causally related to treatment / all	0 / 66	0 / 79	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	28 / 1322 (2.12%)	29 / 1297 (2.24%)	
occurrences causally related to treatment / all	0 / 31	0 / 31	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	18 / 1322 (1.36%)	18 / 1297 (1.39%)	
occurrences causally related to treatment / all	0 / 19	0 / 19	
deaths causally related to treatment / all	0 / 5	0 / 2	
Atrial fibrillation			
subjects affected / exposed	12 / 1322 (0.91%)	14 / 1297 (1.08%)	
occurrences causally related to treatment / all	0 / 14	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			
subjects affected / exposed	20 / 1322 (1.51%)	6 / 1297 (0.46%)	
occurrences causally related to treatment / all	0 / 28	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 1	
Coronary artery disease			
subjects affected / exposed	14 / 1322 (1.06%)	11 / 1297 (0.85%)	
occurrences causally related to treatment / all	0 / 15	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac failure			

subjects affected / exposed	11 / 1322 (0.83%)	12 / 1297 (0.93%)
occurrences causally related to treatment / all	0 / 14	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial ischaemia		
subjects affected / exposed	8 / 1322 (0.61%)	12 / 1297 (0.93%)
occurrences causally related to treatment / all	0 / 8	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Acute coronary syndrome		
subjects affected / exposed	2 / 1322 (0.15%)	9 / 1297 (0.69%)
occurrences causally related to treatment / all	0 / 2	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular tachycardia		
subjects affected / exposed	5 / 1322 (0.38%)	4 / 1297 (0.31%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Bradycardia		
subjects affected / exposed	5 / 1322 (0.38%)	3 / 1297 (0.23%)
occurrences causally related to treatment / all	0 / 5	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac arrest		
subjects affected / exposed	5 / 1322 (0.38%)	3 / 1297 (0.23%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 4	0 / 3
Ischaemic cardiomyopathy		
subjects affected / exposed	2 / 1322 (0.15%)	4 / 1297 (0.31%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Atrial flutter		
subjects affected / exposed	5 / 1322 (0.38%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure acute		

subjects affected / exposed	2 / 1322 (0.15%)	2 / 1297 (0.15%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	2 / 1322 (0.15%)	2 / 1297 (0.15%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve incompetence			
subjects affected / exposed	3 / 1322 (0.23%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	1 / 1322 (0.08%)	2 / 1297 (0.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Arrhythmia supraventricular			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1297 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Atrioventricular block			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block second degree			

subjects affected / exposed	0 / 1322 (0.00%)	2 / 1297 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure chronic			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1297 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-respiratory arrest			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cardiogenic shock			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Coronary artery occlusion			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular dysfunction			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postinfarction angina			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular arrhythmia			

subjects affected / exposed	0 / 1322 (0.00%)	2 / 1297 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Arrhythmia		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block complete		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block first degree		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac tamponade		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiopulmonary failure		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cardiorenal syndrome		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Conduction disorder		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cor pulmonale		

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Coronary artery insufficiency		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Myocardial rupture		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Palpitations		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Right ventricular dysfunction		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus arrest		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus arrhythmia		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus bradycardia		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus tachycardia		

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular dysfunction			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachyarrhythmia			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wolff-Parkinson-White syndrome			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Syncope			
subjects affected / exposed	25 / 1322 (1.89%)	13 / 1297 (1.00%)	
occurrences causally related to treatment / all	3 / 30	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	12 / 1322 (0.91%)	9 / 1297 (0.69%)	
occurrences causally related to treatment / all	0 / 12	0 / 9	
deaths causally related to treatment / all	0 / 3	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	12 / 1322 (0.91%)	3 / 1297 (0.23%)	
occurrences causally related to treatment / all	0 / 14	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			

subjects affected / exposed	9 / 1322 (0.68%)	2 / 1297 (0.15%)
occurrences causally related to treatment / all	1 / 10	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery stenosis		
subjects affected / exposed	8 / 1322 (0.61%)	2 / 1297 (0.15%)
occurrences causally related to treatment / all	0 / 9	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		
subjects affected / exposed	5 / 1322 (0.38%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	1 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic stroke		
subjects affected / exposed	5 / 1322 (0.38%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Headache		
subjects affected / exposed	2 / 1322 (0.15%)	2 / 1297 (0.15%)
occurrences causally related to treatment / all	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral infarction		
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Lacunar infarction		
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1297 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Loss of consciousness		
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myelopathy		

subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Balance disorder		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain oedema		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Carotid artery aneurysm		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery dissection		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery occlusion		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar infarction		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haematoma		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haemorrhage		

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dysarthria		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Generalised tonic-clonic seizure		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Guillain-Barre syndrome		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic transformation stroke		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial pressure increased		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Lateral medullary syndrome		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar radiculopathy		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mononeuropathy		

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle contractions involuntary		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myasthenia gravis		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paraesthesia		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Radicular pain		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sciatica		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subarachnoid haemorrhage		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Toxic encephalopathy		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tremor		

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral artery stenosis			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	10 / 1322 (0.76%)	3 / 1297 (0.23%)	
occurrences causally related to treatment / all	0 / 10	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukocytosis			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normochromic normocytic anaemia			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Platelet dysfunction			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	1 / 1322 (0.08%)	3 / 1297 (0.23%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Cataract			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyphaema			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Gastrointestinal haemorrhage			
subjects affected / exposed	8 / 1322 (0.61%)	13 / 1297 (1.00%)	
occurrences causally related to treatment / all	0 / 9	0 / 15	
deaths causally related to treatment / all	0 / 1	0 / 0	
Vomiting			
subjects affected / exposed	4 / 1322 (0.30%)	3 / 1297 (0.23%)	
occurrences causally related to treatment / all	1 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	6 / 1322 (0.45%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 6	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Abdominal pain			
subjects affected / exposed	3 / 1322 (0.23%)	2 / 1297 (0.15%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	4 / 1322 (0.30%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	1 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	2 / 1322 (0.15%)	2 / 1297 (0.15%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			
subjects affected / exposed	3 / 1322 (0.23%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	3 / 1322 (0.23%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer			
subjects affected / exposed	1 / 1322 (0.08%)	2 / 1297 (0.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			

subjects affected / exposed	2 / 1322 (0.15%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenitis		
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis		
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal perforation		
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Lower gastrointestinal haemorrhage		
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal haematoma		
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal discomfort		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal hernia		

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain lower			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fissure			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic gastrointestinal bleeding			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Crohn's disease			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticular perforation			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal			

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysphagia		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis erosive		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal perforation		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal polyp haemorrhage		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrooesophageal reflux disease		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematemesis		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematochezia		

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus paralytic		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal angina		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal haemorrhage		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal mass		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal obstruction		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intra-abdominal haemorrhage		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Large intestine polyp		

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lip disorder		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric artery thrombosis		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis acute		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis chronic		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Proctitis		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radicular cyst		

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal ulcer haemorrhage			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	1 / 1322 (0.08%)	2 / 1297 (0.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			

Angioedema			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dry gangrene			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperhidrosis			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriasis			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash generalised			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin lesion			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Renal failure acute			
subjects affected / exposed	5 / 1322 (0.38%)	6 / 1297 (0.46%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	1 / 1322 (0.08%)	4 / 1297 (0.31%)	
occurrences causally related to treatment / all	0 / 1	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	4 / 1322 (0.30%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	1 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1297 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder outlet obstruction			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic nephropathy			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephropathy			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrotic syndrome			

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal artery stenosis			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure chronic			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Renal infarct			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary incontinence			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal insufficiency			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			

Osteoarthritis			
subjects affected / exposed	5 / 1322 (0.38%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	2 / 1322 (0.15%)	2 / 1297 (0.15%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	2 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal column stenosis			
subjects affected / exposed	0 / 1322 (0.00%)	3 / 1297 (0.23%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			

subjects affected / exposed	2 / 1322 (0.15%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neck pain		
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal osteoarthritis		
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical spinal stenosis		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc protrusion		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myalgia		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neck mass		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteochondrosis		

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyarthritis			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriatic arthropathy			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal disorder			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			
subjects affected / exposed	14 / 1322 (1.06%)	12 / 1297 (0.93%)	
occurrences causally related to treatment / all	0 / 14	0 / 12	
deaths causally related to treatment / all	0 / 1	0 / 0	
Urinary tract infection			
subjects affected / exposed	2 / 1322 (0.15%)	6 / 1297 (0.46%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	5 / 1322 (0.38%)	2 / 1297 (0.15%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	6 / 1322 (0.45%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			

subjects affected / exposed	3 / 1322 (0.23%)	3 / 1297 (0.23%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis		
subjects affected / exposed	1 / 1322 (0.08%)	4 / 1297 (0.31%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis		
subjects affected / exposed	4 / 1322 (0.30%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis		
subjects affected / exposed	3 / 1322 (0.23%)	2 / 1297 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis acute		
subjects affected / exposed	1 / 1322 (0.08%)	3 / 1297 (0.23%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Septic shock		
subjects affected / exposed	3 / 1322 (0.23%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Abscess limb		
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis		
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urosepsis		

subjects affected / exposed	2 / 1322 (0.15%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Wound infection		
subjects affected / exposed	1 / 1322 (0.08%)	2 / 1297 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchopneumonia		
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bursitis infective		
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1297 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Device related infection		
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1297 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Erysipelas		
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis viral		
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1297 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza		
subjects affected / exposed	1 / 1322 (0.08%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal wall abscess		

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abscess neck		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis perforated		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis bacterial		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis infective		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile colitis		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile infection		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Creutzfeldt-Jakob disease		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cystitis		

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea infectious		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis bacterial		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis bacterial		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gingival abscess		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Groin abscess		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster oticus		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infection		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Localised infection		

subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Orchitis		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis acute		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis externa		
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative abscess		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound infection		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary tuberculosis		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection viral		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sepsis syndrome		

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin infection			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculosis			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection bacterial			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	4 / 1322 (0.30%)	2 / 1297 (0.15%)	
occurrences causally related to treatment / all	4 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	4 / 1322 (0.30%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			

subjects affected / exposed	4 / 1322 (0.30%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dehydration		
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		
subjects affected / exposed	2 / 1322 (0.15%)	1 / 1297 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		
subjects affected / exposed	0 / 1322 (0.00%)	2 / 1297 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemia		
subjects affected / exposed	2 / 1322 (0.15%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus inadequate control		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ketoacidosis		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Electrolyte imbalance		
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid overload		

subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gout			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypomagnesaemia			
subjects affected / exposed	1 / 1322 (0.08%)	0 / 1297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 1322 (0.00%)	1 / 1297 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Ranolazine	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	655 / 1322 (49.55%)	531 / 1297 (40.94%)	
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	161 / 1322 (12.18%)	156 / 1297 (12.03%)	
occurrences (all)	211	199	
Nervous system disorders			
Dizziness			
subjects affected / exposed	240 / 1322 (18.15%)	119 / 1297 (9.18%)	
occurrences (all)	275	135	
Headache			
subjects affected / exposed	98 / 1322 (7.41%)	89 / 1297 (6.86%)	
occurrences (all)	113	101	
General disorders and administration site conditions			

Chest pain subjects affected / exposed occurrences (all)	97 / 1322 (7.34%) 115	92 / 1297 (7.09%) 105	
Fatigue subjects affected / exposed occurrences (all)	99 / 1322 (7.49%) 104	74 / 1297 (5.71%) 77	
Gastrointestinal disorders Constipation subjects affected / exposed occurrences (all)	167 / 1322 (12.63%) 184	71 / 1297 (5.47%) 73	
Nausea subjects affected / exposed occurrences (all)	123 / 1322 (9.30%) 137	63 / 1297 (4.86%) 69	
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all)	89 / 1322 (6.73%) 104	89 / 1297 (6.86%) 98	
Cough subjects affected / exposed occurrences (all)	69 / 1322 (5.22%) 72	51 / 1297 (3.93%) 56	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 September 2011	Clarified that the primary and secondary endpoint events were adjudicated; included a more conservative statistical approach to multiple testing of the secondary endpoints.
29 November 2011	Included a recommendation for investigators to closely monitor subjects concomitantly taking drugs that were known to affect the QTc intervals; included a recommendations for investigators to exercise caution when administering ranolazine in subjects with a history of congenital or a family history of a long QT syndrome as well as in subjects with known acquired QT interval prolongation.
15 February 2012	Revised and clarified the primary and secondary endpoint events adjudication; added heart failure hospitalizations as a safety endpoint; added new inclusion criterion to clarify that subjects must have been randomized within 14 days of the index PCI; added new exclusion criterion to prohibit concomitant use of metformin at total daily doses > 1000 mg; clarified the requirements for creatinine kinase-MB (CK-MB) and troponin I/T testing; clarified the study drug dosing restrictions in subjects who received any moderate cytochrome P450 enzyme (CYP) 3A4 inhibitor, not just verapamil or diltiazem; added the submission to the core laboratory of written results for stress tests performed within 3 months prior to the index PCI.
25 October 2012	Broadened the qualifying time frame for establishing a history of chronic angina; allowed incomplete revascularization in a single coronary territory to qualify in the absence of additional enriching criteria for subjects undergoing index percutaneous coronary intervention for non-acute coronary syndrome

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

There were no limitations affecting the analysis or results.

Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/24268208>

<http://www.ncbi.nlm.nih.gov/pubmed/26474810>

<http://www.ncbi.nlm.nih.gov/pubmed/26555329>