



Clinical trial results: Early treatment of Atrial fibrillation for Stroke prevention Trial (EAST) Summary

EudraCT number	2010-021258-20
Trial protocol	DE DK NL CZ BE ES PL IT
Global end of trial date	29 May 2020

Results information

Result version number	v1 (current)
This version publication date	27 May 2022
First version publication date	27 May 2022
Summary attachment (see zip file)	Final study report - EAST - AFNET 4 - 2010-021258-20 (EAST_AFNET4_CSR_complete_final_signed_20210224.pdf)

Trial information

Trial identification

Sponsor protocol code	EAST-AFNET 4
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Additional study identifiers

ISRCTN number	ISRCTN04708680
ClinicalTrials.gov id (NCT number)	NCT01288352
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Kompetenznetz Vorhofflimmern e.V. (AFNET)
Sponsor organisation address	Mendelstraße 11 , Münster, Germany, 48149
Public contact	Clinical Trials Information, Kompetenznetz Vorhofflimmern e.V. (AFNET), +49 251980 1340, info@kompetenznetz-vorhofflimmern.de
Scientific contact	Clinical Trials Information, Kompetenznetz Vorhofflimmern e.V. (AFNET), +49 251980 1340, info@kompetenznetz-vorhofflimmern.de

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	29 May 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 May 2020
Global end of trial reached?	Yes
Global end of trial date	29 May 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To test whether an early and comprehensive rhythm control therapy can prevent adverse cardiovascular outcomes in patients with atrial fibrillation (AF) compared to usual care.

Protection of trial subjects:

No IMP was in use.

Risk-Assessment regarding Covid-19-Pandemic: Due to End of Observation being set to 06.03.2020 and to collection of last FU information via postal questionnaires (no personal visits), the safety of study participants was not affected by the current pandemic.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 June 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: 180
Country: Number of subjects enrolled	Poland: 163
Country: Number of subjects enrolled	Spain: 129
Country: Number of subjects enrolled	Belgium: 143
Country: Number of subjects enrolled	Czechia: 35
Country: Number of subjects enrolled	Denmark: 53
Country: Number of subjects enrolled	Germany: 1664
Country: Number of subjects enrolled	Italy: 125
Country: Number of subjects enrolled	United Kingdom: 248
Country: Number of subjects enrolled	Switzerland: 46
Country: Number of subjects enrolled	France: 3
Worldwide total number of subjects	2789
EEA total number of subjects	2495

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)	585
From 65 to 84 years	2127
85 years and over	77

Subject disposition

Recruitment

Recruitment details:

We enrolled adults (≥ 18 years of age) who had early AF (defined as atrial fibrillation diagnosed ≤ 12 months before enrolment) and who were older than 75 years of age, have had a previous transient ischemic attack (TIA) or stroke, or met two of the following criteria: age greater than 65 years, female sex, heart failure, hypertension, diabetes

Pre-assignment

Screening details:

Recent onset AF, i.e. AF with known history of ≤ 1 year prior to random
Risk for stroke by EITHER

a) 1 of the following: age > 75 , prior stroke or transient ischemic attack
OR

b) 2 of the following: hypertension, diabetes mell, left ventricular hypertrophy, age > 65 , fem sex, peripheral artery dis, kidney dis, stable heart fail, s cor a di

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Early treatment

Arm description:

Patients will receive either catheter ablation, or adequate antiarrhythmic drug therapy at an early time point. The initial therapy will be decided by the local investigator. Upon recurrence of AF, both modalities will be combined.

Arm type	Experimental
Investigational medicinal product name	adequate antiarrhythmic therapy
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

according instructions

In Germany, Denmark, and Switzerland antiarrhythmic drugs (amiodarone, dronedarone, flecainide and propafenone) are considered investigational drugs whereas in the other countries these are not considered investigational drugs.

Arm title	Usual care
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Arm description:

conducted following the current ESC guidelines for AF treatment.

Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 1	Early treatment	Usual care
Started	1395	1394
Completed	1395	1394

Baseline characteristics

Reporting groups

Reporting group title	Early treatment
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Reporting group description:

Patients will receive either catheter ablation, or adequate antiarrhythmic drug therapy at an early time point. The initial therapy will be decided by the local investigator. Upon recurrence of AF, both modalities will be combined.

Reporting group title	Usual care
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Reporting group description:

conducted following the current ESC guidelines for AF treatment.

Reporting group values	Early treatment	Usual care	Total
Number of subjects	1395	1394	2789
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	306	279	585
From 65-84 years	1045	1082	2127
85 years and over	44	33	77
Gender categorical			
Units: Subjects			
Female	645	648	1293
Male	750	746	1496

End points

End points reporting groups

Reporting group title	Early treatment
Reporting group description: Patients will receive either catheter ablation, or adequate antiarrhythmic drug therapy at an early time point. The initial therapy will be decided by the local investigator. Upon recurrence of AF, both modalities will be combined.	
Reporting group title	Usual care
Reporting group description: conducted following the current ESC guidelines for AF treatment.	

Primary: First Primary Outcome

End point title	First Primary Outcome
End point description:	
End point type	Primary
End point timeframe:	
Overall trial	

End point values	Early treatment	Usual care		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1395	1394		
Units: Incidences	249	316		

Statistical analyses

Statistical analysis title	Regression analysis 1st primary outcome
Comparison groups	Usual care v Early treatment
Number of subjects included in analysis	2789
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Regression, Cox

Primary: Cardio vascular Death

End point title	Cardio vascular Death
End point description:	
End point type	Primary

End point timeframe:

Overall trial

End point values	Early treatment	Usual care		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1395	1394		
Units: Incidences	67	94		

Statistical analyses

Statistical analysis title	Regression analysis
Comparison groups	Early treatment v Usual care
Number of subjects included in analysis	2789
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.039
Method	Regression, Cox

Primary: Stroke

End point title	Stroke
End point description:	
End point type	Primary
End point timeframe:	
Overall Trial	

End point values	Early treatment	Usual care		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1395	1394		
Units: Incidences	40	62		

Statistical analyses

Statistical analysis title	Regression analysis Stroke
Comparison groups	Early treatment v Usual care

Number of subjects included in analysis	2789
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.035
Method	Regression, Cox

Primary: Worsening of Heart Failure

End point title	Worsening of Heart Failure
End point description:	
End point type	Primary
End point timeframe:	
Overall trial	

End point values	Early treatment	Usual care		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1395	1394		
Units: Incidences	139	169		

Statistical analyses

Statistical analysis title	Regression analysis heart Failure
Comparison groups	Early treatment v Usual care
Number of subjects included in analysis	2789
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.073
Method	Regression, Cox

Primary: Acute Coronary Syndrome

End point title	Acute Coronary Syndrome
End point description:	
End point type	Primary
End point timeframe:	
Overall Trial	

End point values	Early treatment	Usual care		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1395	1394		
Units: Incidences	53	65		

Statistical analyses

Statistical analysis title	Regression analysis Corobary Heart Syndrome
Comparison groups	Early treatment v Usual care
Number of subjects included in analysis	2789
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.309
Method	Regression, Cox

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Timeframe for AE

Adverse event reporting additional description:

AE additional description

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	19.0
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Reporting groups

Reporting group title	Early rhythm control
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Reporting group description: -

Reporting group title	Usual care
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Reporting group description: -

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: The trial tests a therapeutic strategy evaluating approved therapies in their approved indication. Therefore, the collection of adverse events was limited to SUSARs and to events related to the intervention. Details have been published in the trial protocol (refer to NEJM online appendix).

Serious adverse events	Early rhythm control	Usual care	
Total subjects affected by serious adverse events			
subjects affected / exposed	978 / 1395 (70.11%)	999 / 1394 (71.66%)	
number of deaths (all causes)	138	165	
number of deaths resulting from adverse events	138	165	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Abdominal neoplasm	Additional description: Abdominal neoplasm		
subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute lymphocytic leukaemia	Additional description: Acute lymphocytic leukaemia		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Acute myeloid leukaemia	Additional description: Acute myeloid leukaemia		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma gastric	Additional description: Adenocarcinoma gastric		

subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Adenoma benign	Additional description: Adenoma benign		
subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal adenoma	Additional description: Adrenal adenoma		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal cancer	Additional description: Anal cancer		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Angiosarcoma	Additional description: Angiosarcoma		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Basal cell carcinoma	Additional description: Basal cell carcinoma		
subjects affected / exposed	5 / 1395 (0.36%)	13 / 1394 (0.93%)	
occurrences causally related to treatment / all	0 / 6	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basosquamous carcinoma of skin	Additional description: Basosquamous carcinoma of skin		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder adenocarcinoma stage unspecified	Additional description: Bladder adenocarcinoma stage unspecified		
subjects affected / exposed	3 / 1395 (0.22%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bladder cancer	Additional description: Bladder cancer		

subjects affected / exposed	8 / 1395 (0.57%)	7 / 1394 (0.50%)	
occurrences causally related to treatment / all	0 / 10	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain neoplasm	Additional description: Brain neoplasm		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer	Additional description: Breast cancer		
subjects affected / exposed	10 / 1395 (0.72%)	13 / 1394 (0.93%)	
occurrences causally related to treatment / all	0 / 12	0 / 14	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bronchial carcinoma	Additional description: Bronchial carcinoma		
subjects affected / exposed	2 / 1395 (0.14%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Carcinoid tumour	Additional description: Carcinoid tumour		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carcinoma in situ	Additional description: Carcinoma in situ		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac myxoma	Additional description: Cardiac myxoma		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Central nervous system lymphoma	Additional description: Central nervous system lymphoma		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cervix carcinoma	Additional description: Cervix carcinoma		

subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic myeloid leukaemia	Additional description: Chronic myeloid leukaemia		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer	Additional description: Colon cancer		
subjects affected / exposed	10 / 1395 (0.72%)	17 / 1394 (1.22%)	
occurrences causally related to treatment / all	0 / 13	0 / 19	
deaths causally related to treatment / all	0 / 4	0 / 0	
Colorectal cancer	Additional description: Colorectal cancer		
subjects affected / exposed	4 / 1395 (0.29%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Endometrial cancer	Additional description: Endometrial cancer		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gallbladder cancer	Additional description: Gallbladder cancer		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder cancer metastatic	Additional description: Gallbladder cancer metastatic		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastric cancer	Additional description: Gastric cancer		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal neoplasm	Additional description: Gastrointestinal neoplasm		

subjects affected / exposed	0 / 1395 (0.00%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glioblastoma			
	Additional description: Glioblastoma		
subjects affected / exposed	1 / 1395 (0.07%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Hairy cell leukaemia			
	Additional description: Hairy cell leukaemia		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cancer			
	Additional description: Hepatic cancer		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatocellular carcinoma			
	Additional description: Hepatocellular carcinoma		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Intestinal adenocarcinoma			
	Additional description: Intestinal adenocarcinoma		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal cancer			
	Additional description: Laryngeal cancer		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukaemia			
	Additional description: Leukaemia		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lip and/or oral cavity cancer			
	Additional description: Lip and/or oral cavity cancer		

subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma	Additional description: Lung adenocarcinoma		
subjects affected / exposed	0 / 1395 (0.00%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung cancer metastatic	Additional description: Lung cancer metastatic		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung neoplasm	Additional description: Lung neoplasm		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung neoplasm malignant	Additional description: Lung neoplasm malignant		
subjects affected / exposed	10 / 1395 (0.72%)	11 / 1394 (0.79%)	
occurrences causally related to treatment / all	0 / 24	0 / 22	
deaths causally related to treatment / all	0 / 4	0 / 7	
Lymphoma	Additional description: Lymphoma		
subjects affected / exposed	3 / 1395 (0.22%)	8 / 1394 (0.57%)	
occurrences causally related to treatment / all	0 / 14	0 / 11	
deaths causally related to treatment / all	0 / 2	0 / 1	
Malignant ascites	Additional description: Malignant ascites		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma	Additional description: Malignant melanoma		
subjects affected / exposed	3 / 1395 (0.22%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Malignant neoplasm of thymus	Additional description: Malignant neoplasm of thymus		

subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Malignant neoplasm of uterine adnexa	Additional description: Malignant neoplasm of uterine adnexa		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinum neoplasm	Additional description: Mediastinum neoplasm		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Meningioma benign	Additional description: Meningioma benign		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesothelioma	Additional description: Mesothelioma		
subjects affected / exposed	3 / 1395 (0.22%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to lung	Additional description: Metastases to lung		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastasis	Additional description: Metastasis		
subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastatic neoplasm	Additional description: Metastatic neoplasm		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelodysplastic syndrome	Additional description: Myelodysplastic syndrome		

subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm	Additional description: Neoplasm		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Neoplasm malignant	Additional description: Neoplasm malignant		
subjects affected / exposed	1 / 1395 (0.07%)	5 / 1394 (0.36%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 3	
Neoplasm skin	Additional description: Neoplasm skin		
subjects affected / exposed	2 / 1395 (0.14%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine carcinoma of the skin	Additional description: Neuroendocrine carcinoma of the skin		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurofibrosarcoma	Additional description: Neurofibrosarcoma		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal carcinoma	Additional description: Oesophageal carcinoma		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cancer	Additional description: Ovarian cancer		
subjects affected / exposed	3 / 1395 (0.22%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Pancreatic carcinoma	Additional description: Pancreatic carcinoma		

subjects affected / exposed	9 / 1395 (0.65%)	11 / 1394 (0.79%)	
occurrences causally related to treatment / all	0 / 14	0 / 43	
deaths causally related to treatment / all	0 / 5	0 / 6	
Pancreatic carcinoma metastatic	Additional description: Pancreatic carcinoma metastatic		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Penile cancer	Additional description: Penile cancer		
subjects affected / exposed	0 / 1395 (0.00%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasma cell myeloma	Additional description: Plasma cell myeloma		
subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Prostate cancer	Additional description: Prostate cancer		
subjects affected / exposed	18 / 1395 (1.29%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 24	0 / 8	
deaths causally related to treatment / all	0 / 4	0 / 2	
Prostate cancer metastatic	Additional description: Prostate cancer metastatic		
subjects affected / exposed	2 / 1395 (0.14%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic adenoma	Additional description: Prostatic adenoma		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal adenocarcinoma	Additional description: Rectal adenocarcinoma		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal cancer	Additional description: Rectal cancer		

subjects affected / exposed	6 / 1395 (0.43%)	6 / 1394 (0.43%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer	Additional description: Renal cancer		
subjects affected / exposed	6 / 1395 (0.43%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Salivary gland neoplasm	Additional description: Salivary gland neoplasm		
subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin cancer	Additional description: Skin cancer		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin cancer metastatic	Additional description: Skin cancer metastatic		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestine carcinoma	Additional description: Small intestine carcinoma		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue neoplasm	Additional description: Soft tissue neoplasm		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of pharynx	Additional description: Squamous cell carcinoma of pharynx		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid adenoma	Additional description: Thyroid adenoma		

subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cancer	Additional description: Thyroid cancer		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsil cancer	Additional description: Tonsil cancer		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma	Additional description: Transitional cell carcinoma		
subjects affected / exposed	3 / 1395 (0.22%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Urethral cancer	Additional description: Urethral cancer		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine cancer	Additional description: Uterine cancer		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cancer	Additional description: Vulval cancer		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aortic aneurysm	Additional description: Aortic aneurysm		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Aortic dissection	Additional description: Aortic dissection		

subjects affected / exposed	2 / 1395 (0.14%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 2	
Aortic stenosis	Additional description: Aortic stenosis		
subjects affected / exposed	3 / 1395 (0.22%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula	Additional description: Arteriovenous fistula		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Circulatory collapse	Additional description: Circulatory collapse		
subjects affected / exposed	3 / 1395 (0.22%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis	Additional description: Deep vein thrombosis		
subjects affected / exposed	4 / 1395 (0.29%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism arterial	Additional description: Embolism arterial		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Haematoma	Additional description: Haematoma		
subjects affected / exposed	0 / 1395 (0.00%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage	Additional description: Haemorrhage		
subjects affected / exposed	73 / 1395 (5.23%)	83 / 1394 (5.95%)	
occurrences causally related to treatment / all	1 / 81	1 / 97	
deaths causally related to treatment / all	0 / 0	0 / 10	
Hypertension	Additional description: Hypertension		

subjects affected / exposed	34 / 1395 (2.44%)	41 / 1394 (2.94%)	
occurrences causally related to treatment / all	1 / 36	0 / 49	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive crisis	Additional description: Hypertensive crisis		
subjects affected / exposed	11 / 1395 (0.79%)	11 / 1394 (0.79%)	
occurrences causally related to treatment / all	0 / 11	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension	Additional description: Hypotension		
subjects affected / exposed	4 / 1395 (0.29%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iliac artery stenosis	Additional description: Iliac artery stenosis		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease	Additional description: Peripheral arterial occlusive disease		
subjects affected / exposed	3 / 1395 (0.22%)	6 / 1394 (0.43%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral embolism	Additional description: Peripheral embolism		
subjects affected / exposed	0 / 1395 (0.00%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Peripheral ischaemia	Additional description: Peripheral ischaemia		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post thrombotic syndrome	Additional description: Post thrombotic syndrome		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renovascular hypertension	Additional description: Renovascular hypertension		

subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Temporal arteritis	Additional description: Temporal arteritis		
subjects affected / exposed	0 / 1395 (0.00%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis	Additional description: Thrombophlebitis		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis	Additional description: Vasculitis		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Abdominal operation	Additional description: Abdominal operation		
subjects affected / exposed	5 / 1395 (0.36%)	7 / 1394 (0.50%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenalectomy	Additional description: Adrenalectomy		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol detoxification	Additional description: Alcohol detoxification		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol rehabilitation	Additional description: Alcohol rehabilitation		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Allogenic bone marrow transplantation therapy	Additional description: Allogenic bone marrow transplantation therapy		

subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angioplasty	Additional description: Angioplasty		
subjects affected / exposed	3 / 1395 (0.22%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle operation	Additional description: Ankle operation		
subjects affected / exposed	5 / 1395 (0.36%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anorectal operation	Additional description: Anorectal operation		
subjects affected / exposed	5 / 1395 (0.36%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm repair	Additional description: Aortic aneurysm repair		
subjects affected / exposed	4 / 1395 (0.29%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve replacement	Additional description: Aortic valve replacement		
subjects affected / exposed	4 / 1395 (0.29%)	5 / 1394 (0.36%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicectomy	Additional description: Appendicectomy		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial repair	Additional description: Arterial repair		
subjects affected / exposed	3 / 1395 (0.22%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula operation	Additional description: Arteriovenous fistula operation		

subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthrodesis	Additional description: Arthrodesis		
subjects affected / exposed	0 / 1395 (0.00%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthroscopic surgery	Additional description: Arthroscopic surgery		
subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Artificial urinary sphincter implant	Additional description: Artificial urinary sphincter implant		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atherectomy	Additional description: Atherectomy		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial septal defect repair	Additional description: Atrial septal defect repair		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Baker's cyst excision	Additional description: Baker's cyst excision		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stent removal	Additional description: Bile duct stent removal		
subjects affected / exposed	0 / 1395 (0.00%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neoplasm surgery	Additional description: Bladder neoplasm surgery		

subjects affected / exposed	2 / 1395 (0.14%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder operation	Additional description: Bladder operation		
subjects affected / exposed	2 / 1395 (0.14%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Caesarean section	Additional description: Caesarean section		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac ablation	Additional description: Cardiac ablation		
subjects affected / exposed	27 / 1395 (1.94%)	20 / 1394 (1.43%)	
occurrences causally related to treatment / all	4 / 27	1 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac operation	Additional description: Cardiac operation		
subjects affected / exposed	15 / 1395 (1.08%)	14 / 1394 (1.00%)	
occurrences causally related to treatment / all	0 / 15	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pacemaker insertion	Additional description: Cardiac pacemaker insertion		
subjects affected / exposed	88 / 1395 (6.31%)	83 / 1394 (5.95%)	
occurrences causally related to treatment / all	11 / 90	4 / 88	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac pacemaker replacement	Additional description: Cardiac pacemaker replacement		
subjects affected / exposed	6 / 1395 (0.43%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac resynchronisation therapy	Additional description: Cardiac resynchronisation therapy		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardioversion	Additional description: Cardioversion		

subjects affected / exposed	225 / 1395 (16.13%)	223 / 1394 (16.00%)	
occurrences causally related to treatment / all	4 / 357	5 / 390	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid endarterectomy	Additional description: Carotid endarterectomy		
subjects affected / exposed	6 / 1395 (0.43%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 7	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract operation	Additional description: Cataract operation		
subjects affected / exposed	11 / 1395 (0.79%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 15	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Central venous catheterisation	Additional description: Central venous catheterisation		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical polypectomy	Additional description: Cervical polypectomy		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chemotherapy	Additional description: Chemotherapy		
subjects affected / exposed	2 / 1395 (0.14%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 12	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystectomy	Additional description: Cholecystectomy		
subjects affected / exposed	16 / 1395 (1.15%)	17 / 1394 (1.22%)	
occurrences causally related to treatment / all	0 / 17	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Circumcision	Additional description: Circumcision		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colectomy	Additional description: Colectomy		

subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon operation	Additional description: Colon operation		
subjects affected / exposed	3 / 1395 (0.22%)	5 / 1394 (0.36%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colostomy	Additional description: Colostomy		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary angioplasty	Additional description: Coronary angioplasty		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery bypass	Additional description: Coronary artery bypass		
subjects affected / exposed	14 / 1395 (1.00%)	13 / 1394 (0.93%)	
occurrences causally related to treatment / all	0 / 14	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cox-Maze procedure	Additional description: Cox-Maze procedure		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dacryocystorhinostomy	Additional description: Dacryocystorhinostomy		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Debridement	Additional description: Debridement		
subjects affected / exposed	0 / 1395 (0.00%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Elbow operation	Additional description: Elbow operation		

subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endarterectomy	Additional description: Endarterectomy		
subjects affected / exposed	2 / 1395 (0.14%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterostomy	Additional description: Enterostomy		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye operation	Additional description: Eye operation		
subjects affected / exposed	8 / 1395 (0.57%)	12 / 1394 (0.86%)	
occurrences causally related to treatment / all	0 / 8	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eyelid operation	Additional description: Eyelid operation		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot operation	Additional description: Foot operation		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foraminotomy	Additional description: Foraminotomy		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric operation	Additional description: Gastric operation		
subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal surgery	Additional description: Gastrointestinal surgery		

subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrostomy	Additional description: Gastrostomy		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma surgery	Additional description: Glaucoma surgery		
subjects affected / exposed	3 / 1395 (0.22%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoid operation	Additional description: Haemorrhoid operation		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart valve operation	Additional description: Heart valve operation		
subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart valve replacement	Additional description: Heart valve replacement		
subjects affected / exposed	11 / 1395 (0.79%)	11 / 1394 (0.79%)	
occurrences causally related to treatment / all	0 / 11	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia repair	Additional description: Hernia repair		
subjects affected / exposed	13 / 1395 (0.93%)	11 / 1394 (0.79%)	
occurrences causally related to treatment / all	0 / 13	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip arthroplasty	Additional description: Hip arthroplasty		
subjects affected / exposed	42 / 1395 (3.01%)	43 / 1394 (3.08%)	
occurrences causally related to treatment / all	0 / 48	0 / 47	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip surgery	Additional description: Hip surgery		

subjects affected / exposed	9 / 1395 (0.65%)	12 / 1394 (0.86%)	
occurrences causally related to treatment / all	0 / 11	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocele operation	Additional description: Hydrocele operation		
subjects affected / exposed	3 / 1395 (0.22%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hysterectomy	Additional description: Hysterectomy		
subjects affected / exposed	2 / 1395 (0.14%)	5 / 1394 (0.36%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ileostomy	Additional description: Ileostomy		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implantable defibrillator insertion	Additional description: Implantable defibrillator insertion		
subjects affected / exposed	1 / 1395 (0.07%)	5 / 1394 (0.36%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implantable defibrillator replacement	Additional description: Implantable defibrillator replacement		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia repair	Additional description: Inguinal hernia repair		
subjects affected / exposed	7 / 1395 (0.50%)	6 / 1394 (0.43%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc operation	Additional description: Intervertebral disc operation		
subjects affected / exposed	3 / 1395 (0.22%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal operation	Additional description: Intestinal operation		

subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intra-cerebral aneurysm operation	Additional description: Intra-cerebral aneurysm operation		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint arthroplasty	Additional description: Joint arthroplasty		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint resurfacing surgery	Additional description: Joint resurfacing surgery		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Keratomileusis	Additional description: Keratomileusis		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Knee arthroplasty	Additional description: Knee arthroplasty		
subjects affected / exposed	36 / 1395 (2.58%)	39 / 1394 (2.80%)	
occurrences causally related to treatment / all	0 / 39	0 / 46	
deaths causally related to treatment / all	0 / 0	0 / 0	
Knee operation	Additional description: Knee operation		
subjects affected / exposed	19 / 1395 (1.36%)	26 / 1394 (1.87%)	
occurrences causally related to treatment / all	0 / 19	0 / 27	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laparotomy	Additional description: Laparotomy		
subjects affected / exposed	2 / 1395 (0.14%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal polypectomy	Additional description: Large intestinal polypectomy		

subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal operation	Additional description: Laryngeal operation		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb operation	Additional description: Limb operation		
subjects affected / exposed	6 / 1395 (0.43%)	5 / 1394 (0.36%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lithotripsy	Additional description: Lithotripsy		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung neoplasm surgery	Additional description: Lung neoplasm surgery		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenectomy	Additional description: Lymphadenectomy		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mammoplasty	Additional description: Mammoplasty		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mastectomy	Additional description: Mastectomy		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device removal	Additional description: Medical device removal		

subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma surgery	Additional description: Meningioma surgery		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus operation	Additional description: Meniscus operation		
subjects affected / exposed	0 / 1395 (0.00%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus removal	Additional description: Meniscus removal		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic surgery	Additional description: Metabolic surgery		
subjects affected / exposed	2 / 1395 (0.14%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve repair	Additional description: Mitral valve repair		
subjects affected / exposed	5 / 1395 (0.36%)	6 / 1394 (0.43%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve replacement	Additional description: Mitral valve replacement		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal operation	Additional description: Nasal operation		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrectomy	Additional description: Nephrectomy		

subjects affected / exposed	2 / 1395 (0.14%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthopaedic procedure	Additional description: Orthopaedic procedure		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otorhinolaryngological surgery	Additional description: Otorhinolaryngological surgery		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatectomy	Additional description: Pancreatectomy		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parathyroidectomy	Additional description: Parathyroidectomy		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parotidectomy	Additional description: Parotidectomy		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic floor repair	Additional description: Pelvic floor repair		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Percutaneous coronary intervention	Additional description: Percutaneous coronary intervention		
subjects affected / exposed	65 / 1395 (4.66%)	57 / 1394 (4.09%)	
occurrences causally related to treatment / all	0 / 77	0 / 69	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery angioplasty	Additional description: Peripheral artery angioplasty		

subjects affected / exposed	18 / 1395 (1.29%)	23 / 1394 (1.65%)	
occurrences causally related to treatment / all	0 / 27	0 / 31	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery bypass	Additional description: Peripheral artery bypass		
subjects affected / exposed	1 / 1395 (0.07%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral endarterectomy	Additional description: Peripheral endarterectomy		
subjects affected / exposed	3 / 1395 (0.22%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phlebectomy	Additional description: Phlebectomy		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pituitary tumour removal	Additional description: Pituitary tumour removal		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plastic surgery	Additional description: Plastic surgery		
subjects affected / exposed	0 / 1395 (0.00%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleurectomy	Additional description: Pleurectomy		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polypectomy	Additional description: Polypectomy		
subjects affected / exposed	7 / 1395 (0.50%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 8	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatectomy	Additional description: Prostatectomy		

subjects affected / exposed	5 / 1395 (0.36%)	14 / 1394 (1.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic operation	Additional description: Prostatic operation		
subjects affected / exposed	2 / 1395 (0.14%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radioactive iodine therapy	Additional description: Radioactive iodine therapy		
subjects affected / exposed	5 / 1395 (0.36%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiotherapy	Additional description: Radiotherapy		
subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal prolapse repair	Additional description: Rectal prolapse repair		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal stone removal	Additional description: Renal stone removal		
subjects affected / exposed	3 / 1395 (0.22%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal surgery	Additional description: Renal surgery		
subjects affected / exposed	3 / 1395 (0.22%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Resuscitation	Additional description: Resuscitation		
subjects affected / exposed	3 / 1395 (0.22%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinoplasty	Additional description: Rhinoplasty		

subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland operation	Additional description: Salivary gland operation		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salpingo-oophorectomy	Additional description: Salpingo-oophorectomy		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shoulder arthroplasty	Additional description: Shoulder arthroplasty		
subjects affected / exposed	4 / 1395 (0.29%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shoulder operation	Additional description: Shoulder operation		
subjects affected / exposed	6 / 1395 (0.43%)	12 / 1394 (0.86%)	
occurrences causally related to treatment / all	0 / 7	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus operation	Additional description: Sinus operation		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin cosmetic procedure	Additional description: Skin cosmetic procedure		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin graft	Additional description: Skin graft		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin neoplasm excision	Additional description: Skin neoplasm excision		

subjects affected / exposed	5 / 1395 (0.36%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin operation	Additional description: Skin operation		
subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal laminectomy	Additional description: Spinal laminectomy		
subjects affected / exposed	4 / 1395 (0.29%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal operation	Additional description: Spinal operation		
subjects affected / exposed	18 / 1395 (1.29%)	23 / 1394 (1.65%)	
occurrences causally related to treatment / all	0 / 19	0 / 27	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgery	Additional description: Surgery		
subjects affected / exposed	2 / 1395 (0.14%)	6 / 1394 (0.43%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon operation	Additional description: Tendon operation		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Therapeutic embolisation	Additional description: Therapeutic embolisation		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombectomy	Additional description: Thrombectomy		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thromboembolectomy	Additional description: Thromboembolectomy		

subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroidectomy	Additional description: Thyroidectomy		
subjects affected / exposed	4 / 1395 (0.29%)	6 / 1394 (0.43%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toe amputation	Additional description: Toe amputation		
subjects affected / exposed	3 / 1395 (0.22%)	5 / 1394 (0.36%)	
occurrences causally related to treatment / all	0 / 3	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toe operation	Additional description: Toe operation		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillectomy	Additional description: Tonsillectomy		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth extraction	Additional description: Tooth extraction		
subjects affected / exposed	4 / 1395 (0.29%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheostomy tube removal	Additional description: Tracheostomy tube removal		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transurethral bladder resection	Additional description: Transurethral bladder resection		
subjects affected / exposed	2 / 1395 (0.14%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transurethral prostatectomy	Additional description: Transurethral prostatectomy		

subjects affected / exposed	3 / 1395 (0.22%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tricuspid valve repair	Additional description: Tricuspid valve repair		
subjects affected / exposed	2 / 1395 (0.14%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tympanoplasty	Additional description: Tympanoplasty		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia repair	Additional description: Umbilical hernia repair		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral caruncle removal	Additional description: Urethral caruncle removal		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral operation	Additional description: Urethral operation		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethrotomy	Additional description: Urethrotomy		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract operation	Additional description: Urinary tract operation		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine operation	Additional description: Uterine operation		

subjects affected / exposed	1 / 1395 (0.07%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal operation	Additional description: Vaginal operation		
subjects affected / exposed	0 / 1395 (0.00%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose vein operation	Additional description: Varicose vein operation		
subjects affected / exposed	11 / 1395 (0.79%)	9 / 1394 (0.65%)	
occurrences causally related to treatment / all	0 / 12	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular septal defect repair	Additional description: Ventricular septal defect repair		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebroplasty	Additional description: Vertebroplasty		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitrectomy	Additional description: Vitrectomy		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord nodule removal	Additional description: Vocal cord nodule removal		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound treatment	Additional description: Wound treatment		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist surgery	Additional description: Wrist surgery		

subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
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			
Asthenia	Additional description: Asthenia		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac death	Additional description: Cardiac death		
subjects affected / exposed	19 / 1395 (1.36%)	22 / 1394 (1.58%)	
occurrences causally related to treatment / all	0 / 19	0 / 22	
deaths causally related to treatment / all	0 / 19	0 / 21	
Catheter site haemorrhage	Additional description: Catheter site haemorrhage		
subjects affected / exposed	8 / 1395 (0.57%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	5 / 8	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain	Additional description: Chest pain		
subjects affected / exposed	25 / 1395 (1.79%)	12 / 1394 (0.86%)	
occurrences causally related to treatment / all	0 / 28	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death	Additional description: Death		
subjects affected / exposed	109 / 1395 (7.81%)	131 / 1394 (9.40%)	
occurrences causally related to treatment / all	0 / 109	1 / 131	
deaths causally related to treatment / all	0 / 109	1 / 131	
Discomfort	Additional description: Discomfort		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extravasation	Additional description: Extravasation		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait disturbance	Additional description: Gait disturbance		

subjects affected / exposed	2 / 1395 (0.14%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration	Additional description: General physical health deterioration		
subjects affected / exposed	1 / 1395 (0.07%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia	Additional description: Hernia		
subjects affected / exposed	7 / 1395 (0.50%)	7 / 1394 (0.50%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothermia	Additional description: Hypothermia		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Impaired healing	Additional description: Impaired healing		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome	Additional description: Multiple organ dysfunction syndrome		
subjects affected / exposed	2 / 1395 (0.14%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Necrosis	Additional description: Necrosis		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema	Additional description: Oedema		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral	Additional description: Oedema peripheral		

subjects affected / exposed	3 / 1395 (0.22%)	5 / 1394 (0.36%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pacemaker generated arrhythmia	Additional description: Pacemaker generated arrhythmia		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain	Additional description: Pain		
subjects affected / exposed	1 / 1395 (0.07%)	5 / 1394 (0.36%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stent-graft endoleak	Additional description: Stent-graft endoleak		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Strangulated hernia	Additional description: Strangulated hernia		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden cardiac death	Additional description: Sudden cardiac death		
subjects affected / exposed	8 / 1395 (0.57%)	11 / 1394 (0.79%)	
occurrences causally related to treatment / all	0 / 8	0 / 11	
deaths causally related to treatment / all	0 / 8	0 / 11	
Sudden death	Additional description: Sudden death		
subjects affected / exposed	2 / 1395 (0.14%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 2	
Vascular stent thrombosis	Additional description: Vascular stent thrombosis		

subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Immune system disorders			
Amyloidosis	Additional description: Amyloidosis		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity	Additional description: Drug hypersensitivity		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity	Additional description: Hypersensitivity		
subjects affected / exposed	3 / 1395 (0.22%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Benign prostatic hyperplasia	Additional description: Benign prostatic hyperplasia		
subjects affected / exposed	4 / 1395 (0.29%)	5 / 1394 (0.36%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Female genital tract fistula	Additional description: Female genital tract fistula		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis	Additional description: Prostatitis		
subjects affected / exposed	2 / 1395 (0.14%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure	Additional description: Acute respiratory failure		
subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma	Additional description: Asthma		
subjects affected / exposed	5 / 1395 (0.36%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 9	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atelectasis	Additional description: Atelectasis		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopulmonary disease	Additional description: Bronchopulmonary disease		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	24 / 1395 (1.72%)	28 / 1394 (2.01%)	
occurrences causally related to treatment / all	0 / 41	0 / 41	
deaths causally related to treatment / all	0 / 0	0 / 2	
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	15 / 1395 (1.08%)	12 / 1394 (0.86%)	
occurrences causally related to treatment / all	1 / 15	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea exertional	Additional description: Dyspnoea exertional		
subjects affected / exposed	4 / 1395 (0.29%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	5 / 1395 (0.36%)	9 / 1394 (0.65%)	
occurrences causally related to treatment / all	0 / 5	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	

Haemoptysis	Additional description: Haemoptysis		
subjects affected / exposed	2 / 1395 (0.14%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemothorax	Additional description: Haemothorax		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiccups	Additional description: Hiccups		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperventilation	Additional description: Hyperventilation		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease	Additional description: Interstitial lung disease		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infiltration	Additional description: Lung infiltration		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	4 / 1395 (0.29%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 1395 (0.00%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pneumothorax	Additional description: Pneumothorax		

subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism	Additional description: Pulmonary embolism		
subjects affected / exposed	11 / 1395 (0.79%)	8 / 1394 (0.57%)	
occurrences causally related to treatment / all	0 / 13	0 / 8	
deaths causally related to treatment / all	0 / 4	0 / 2	
Pulmonary fibrosis	Additional description: Pulmonary fibrosis		
subjects affected / exposed	2 / 1395 (0.14%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	1 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary hypertension	Additional description: Pulmonary hypertension		
subjects affected / exposed	4 / 1395 (0.29%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema	Additional description: Pulmonary oedema		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary sarcoidosis	Additional description: Pulmonary sarcoidosis		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure	Additional description: Respiratory failure		
subjects affected / exposed	2 / 1395 (0.14%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Sleep apnoea syndrome	Additional description: Sleep apnoea syndrome		
subjects affected / exposed	0 / 1395 (0.00%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord disorder	Additional description: Vocal cord disorder		

subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Alcohol withdrawal syndrome	Additional description: Alcohol withdrawal syndrome		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholism	Additional description: Alcoholism		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety disorder	Additional description: Anxiety disorder		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide	Additional description: Completed suicide		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Delirium	Additional description: Delirium		
subjects affected / exposed	3 / 1395 (0.22%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression	Additional description: Depression		
subjects affected / exposed	3 / 1395 (0.22%)	6 / 1394 (0.43%)	
occurrences causally related to treatment / all	0 / 3	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Panic attack	Additional description: Panic attack		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			

Device lead issue	Additional description: Device lead issue		
	subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)
	occurrences causally related to treatment / all	0 / 0	0 / 1
	deaths causally related to treatment / all	0 / 0	0 / 0
Device occlusion	Additional description: Device occlusion		
	subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)
	occurrences causally related to treatment / all	0 / 0	0 / 1
	deaths causally related to treatment / all	0 / 0	0 / 0
Device power source issue	Additional description: Device power source issue		
	subjects affected / exposed	3 / 1395 (0.22%)	4 / 1394 (0.29%)
	occurrences causally related to treatment / all	0 / 3	0 / 4
	deaths causally related to treatment / all	0 / 0	0 / 0
Lead dislodgement	Additional description: Lead dislodgement		
	subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)
	occurrences causally related to treatment / all	0 / 1	0 / 1
	deaths causally related to treatment / all	0 / 0	0 / 0
Hepatobiliary disorders			
	Additional description: Acute hepatic failure		
	subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)
	occurrences causally related to treatment / all	0 / 1	0 / 0
Autoimmune hepatitis	Additional description: Autoimmune hepatitis		
	subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)
	occurrences causally related to treatment / all	0 / 1	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0
Bile duct stone	Additional description: Bile duct stone		
	subjects affected / exposed	3 / 1395 (0.22%)	6 / 1394 (0.43%)
	occurrences causally related to treatment / all	0 / 3	0 / 6
	deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis	Additional description: Cholangitis		
	subjects affected / exposed	0 / 1395 (0.00%)	3 / 1394 (0.22%)
	occurrences causally related to treatment / all	0 / 0	0 / 3
	deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis	Additional description: Cholecystitis		

subjects affected / exposed	7 / 1395 (0.50%)	5 / 1394 (0.36%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute	Additional description: Cholecystitis acute		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis	Additional description: Cholelithiasis		
subjects affected / exposed	4 / 1395 (0.29%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis	Additional description: Hepatic cirrhosis		
subjects affected / exposed	2 / 1395 (0.14%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cyst	Additional description: Hepatic cyst		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis	Additional description: Hepatitis		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis toxic	Additional description: Hepatitis toxic		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal vein thrombosis	Additional description: Portal vein thrombosis		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Angiogram	Additional description: Angiogram		

subjects affected / exposed	31 / 1395 (2.22%)	16 / 1394 (1.15%)	
occurrences causally related to treatment / all	0 / 32	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthroscopy	Additional description: Arthroscopy		
subjects affected / exposed	4 / 1395 (0.29%)	5 / 1394 (0.36%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biopsy bone	Additional description: Biopsy bone		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biopsy breast	Additional description: Biopsy breast		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biopsy lung normal	Additional description: Biopsy lung normal		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biopsy lymph gland	Additional description: Biopsy lymph gland		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biopsy prostate	Additional description: Biopsy prostate		
subjects affected / exposed	0 / 1395 (0.00%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood thyroid stimulating hormone increased	Additional description: Blood thyroid stimulating hormone increased		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchoscopy	Additional description: Bronchoscopy		

subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac monitoring	Additional description: Cardiac monitoring		
subjects affected / exposed	3 / 1395 (0.22%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pacemaker evaluation	Additional description: Cardiac pacemaker evaluation		
subjects affected / exposed	2 / 1395 (0.14%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pharmacologic stress test	Additional description: Cardiac pharmacologic stress test		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac stress test	Additional description: Cardiac stress test		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiovascular evaluation	Additional description: Cardiovascular evaluation		
subjects affected / exposed	0 / 1395 (0.00%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colonoscopy	Additional description: Colonoscopy		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diagnostic procedure	Additional description: Diagnostic procedure		

subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Echocardiogram	Additional description: Echocardiogram		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram QT prolonged	Additional description: Electrocardiogram QT prolonged		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gynaecological examination	Additional description: Gynaecological examination		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoglobin decreased	Additional description: Haemoglobin decreased		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased	Additional description: Hepatic enzyme increased		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hysteroscopy	Additional description: Hysteroscopy		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Magnetic resonance imaging	Additional description: Magnetic resonance imaging		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress echocardiogram	Additional description: Stress echocardiogram		

subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin increased	Additional description: Troponin increased		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour marker increased	Additional description: Tumour marker increased		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral test negative	Additional description: Viral test negative		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight decreased	Additional description: Weight decreased		
subjects affected / exposed	0 / 1395 (0.00%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Alcohol poisoning	Additional description: Alcohol poisoning		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia postoperative	Additional description: Anaemia postoperative		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Animal bite	Additional description: Animal bite		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture	Additional description: Ankle fracture		

subjects affected / exposed	6 / 1395 (0.43%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropod bite	Additional description: Arthropod bite		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Buttock injury	Additional description: Buttock injury		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical vertebral fracture	Additional description: Cervical vertebral fracture		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle fracture	Additional description: Clavicle fracture		
subjects affected / exposed	0 / 1395 (0.00%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral injury	Additional description: Craniocerebral injury		
subjects affected / exposed	9 / 1395 (0.65%)	13 / 1394 (0.93%)	
occurrences causally related to treatment / all	0 / 10	0 / 14	
deaths causally related to treatment / all	0 / 1	0 / 1	
Endotracheal intubation complication	Additional description: Endotracheal intubation complication		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial bones fracture	Additional description: Facial bones fracture		
subjects affected / exposed	5 / 1395 (0.36%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall	Additional description: Fall		

subjects affected / exposed	14 / 1395 (1.00%)	10 / 1394 (0.72%)	
occurrences causally related to treatment / all	0 / 14	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture	Additional description: Femur fracture		
subjects affected / exposed	11 / 1395 (0.79%)	8 / 1394 (0.57%)	
occurrences causally related to treatment / all	0 / 14	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 2	
Fibula fracture	Additional description: Fibula fracture		
subjects affected / exposed	3 / 1395 (0.22%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture	Additional description: Foot fracture		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fractured sacrum	Additional description: Fractured sacrum		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal stoma complication	Additional description: Gastrointestinal stoma complication		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hand fracture	Additional description: Hand fracture		
subjects affected / exposed	2 / 1395 (0.14%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury	Additional description: Head injury		
subjects affected / exposed	4 / 1395 (0.29%)	11 / 1394 (0.79%)	
occurrences causally related to treatment / all	0 / 4	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture	Additional description: Hip fracture		

subjects affected / exposed	0 / 1395 (0.00%)	12 / 1394 (0.86%)	
occurrences causally related to treatment / all	0 / 0	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 1	
Humerus fracture	Additional description: Humerus fracture		
subjects affected / exposed	4 / 1395 (0.29%)	15 / 1394 (1.08%)	
occurrences causally related to treatment / all	0 / 5	1 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury	Additional description: Injury		
subjects affected / exposed	2 / 1395 (0.14%)	7 / 1394 (0.50%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint dislocation	Additional description: Joint dislocation		
subjects affected / exposed	4 / 1395 (0.29%)	5 / 1394 (0.36%)	
occurrences causally related to treatment / all	0 / 9	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal injury	Additional description: Laryngeal injury		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb crushing injury	Additional description: Limb crushing injury		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury	Additional description: Limb injury		
subjects affected / exposed	0 / 1395 (0.00%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture	Additional description: Lower limb fracture		
subjects affected / exposed	1 / 1395 (0.07%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture	Additional description: Lumbar vertebral fracture		

subjects affected / exposed	1 / 1395 (0.07%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple injuries	Additional description: Multiple injuries		
subjects affected / exposed	7 / 1395 (0.50%)	5 / 1394 (0.36%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 1	
Nerve injury	Additional description: Nerve injury		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose	Additional description: Overdose		
subjects affected / exposed	3 / 1395 (0.22%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patella fracture	Additional description: Patella fracture		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture	Additional description: Pelvic fracture		
subjects affected / exposed	5 / 1395 (0.36%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post-traumatic neck syndrome	Additional description: Post-traumatic neck syndrome		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural complication	Additional description: Post procedural complication		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematoma	Additional description: Post procedural haematoma		

subjects affected / exposed	0 / 1395 (0.00%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage	Additional description: Post procedural haemorrhage		
subjects affected / exposed	26 / 1395 (1.86%)	26 / 1394 (1.87%)	
occurrences causally related to treatment / all	1 / 26	0 / 26	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative thoracic procedure complication	Additional description: Postoperative thoracic procedure complication		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural intestinal perforation	Additional description: Procedural intestinal perforation		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture	Additional description: Radius fracture		
subjects affected / exposed	9 / 1395 (0.65%)	12 / 1394 (0.86%)	
occurrences causally related to treatment / all	0 / 10	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	4 / 1395 (0.29%)	8 / 1394 (0.57%)	
occurrences causally related to treatment / all	0 / 4	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident	Additional description: Road traffic accident		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fracture	Additional description: Spinal fracture		
subjects affected / exposed	9 / 1395 (0.65%)	11 / 1394 (0.79%)	
occurrences causally related to treatment / all	0 / 9	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sternal fracture	Additional description: Sternal fracture		

subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma	Additional description: Subdural haematoma		
subjects affected / exposed	8 / 1395 (0.57%)	6 / 1394 (0.43%)	
occurrences causally related to treatment / all	0 / 10	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Tendon rupture	Additional description: Tendon rupture		
subjects affected / exposed	1 / 1395 (0.07%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic vertebral fracture	Additional description: Thoracic vertebral fracture		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture	Additional description: Tibia fracture		
subjects affected / exposed	2 / 1395 (0.14%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents	Additional description: Toxicity to various agents		
subjects affected / exposed	83 / 1395 (5.95%)	70 / 1394 (5.02%)	
occurrences causally related to treatment / all	26 / 88	8 / 78	
deaths causally related to treatment / all	0 / 0	0 / 1	
Traumatic fracture	Additional description: Traumatic fracture		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haematoma	Additional description: Traumatic haematoma		
subjects affected / exposed	4 / 1395 (0.29%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haemorrhage	Additional description: Traumatic haemorrhage		

subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulna fracture	Additional description: Ulna fracture		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture	Additional description: Upper limb fracture		
subjects affected / exposed	3 / 1395 (0.22%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine rupture	Additional description: Uterine rupture		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular pseudoaneurysm	Additional description: Vascular pseudoaneurysm		
subjects affected / exposed	3 / 1395 (0.22%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture	Additional description: Wrist fracture		
subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Atrial septal defect	Additional description: Atrial septal defect		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocele	Additional description: Hydrocele		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phimosis	Additional description: Phimosis		

subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syringomyelia	Additional description: Syringomyelia		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome	Additional description: Acute coronary syndrome		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction	Additional description: Acute myocardial infarction		
subjects affected / exposed	37 / 1395 (2.65%)	52 / 1394 (3.73%)	
occurrences causally related to treatment / all	0 / 46	0 / 63	
deaths causally related to treatment / all	0 / 2	0 / 3	
Angina pectoris	Additional description: Angina pectoris		
subjects affected / exposed	49 / 1395 (3.51%)	37 / 1394 (2.65%)	
occurrences causally related to treatment / all	0 / 58	0 / 42	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable	Additional description: Angina unstable		
subjects affected / exposed	17 / 1395 (1.22%)	15 / 1394 (1.08%)	
occurrences causally related to treatment / all	0 / 19	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis	Additional description: Aortic valve stenosis		
subjects affected / exposed	7 / 1395 (0.50%)	5 / 1394 (0.36%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia	Additional description: Arrhythmia		
subjects affected / exposed	2 / 1395 (0.14%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	1 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation	Additional description: Atrial fibrillation		

subjects affected / exposed	314 / 1395 (22.51%)	308 / 1394 (22.09%)	
occurrences causally related to treatment / all	10 / 526	6 / 559	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter	Additional description: Atrial flutter		
subjects affected / exposed	35 / 1395 (2.51%)	25 / 1394 (1.79%)	
occurrences causally related to treatment / all	3 / 46	1 / 30	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial tachycardia	Additional description: Atrial tachycardia		
subjects affected / exposed	7 / 1395 (0.50%)	6 / 1394 (0.43%)	
occurrences causally related to treatment / all	1 / 9	1 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block	Additional description: Atrioventricular block		
subjects affected / exposed	15 / 1395 (1.08%)	10 / 1394 (0.72%)	
occurrences causally related to treatment / all	3 / 16	1 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block complete	Additional description: Atrioventricular block complete		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia	Additional description: Bradycardia		
subjects affected / exposed	49 / 1395 (3.51%)	37 / 1394 (2.65%)	
occurrences causally related to treatment / all	18 / 52	9 / 40	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bundle branch block left	Additional description: Bundle branch block left		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest	Additional description: Cardiac arrest		
subjects affected / exposed	7 / 1395 (0.50%)	6 / 1394 (0.43%)	
occurrences causally related to treatment / all	1 / 7	1 / 6	
deaths causally related to treatment / all	0 / 1	0 / 2	
Cardiac failure	Additional description: Cardiac failure		

subjects affected / exposed	140 / 1395 (10.04%)	170 / 1394 (12.20%)	
occurrences causally related to treatment / all	3 / 222	0 / 297	
deaths causally related to treatment / all	0 / 15	0 / 9	
Cardiac failure congestive	Additional description: Cardiac failure congestive		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac tamponade	Additional description: Cardiac tamponade		
subjects affected / exposed	7 / 1395 (0.50%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	3 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiogenic shock	Additional description: Cardiogenic shock		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiomyopathy	Additional description: Cardiomyopathy		
subjects affected / exposed	4 / 1395 (0.29%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 2	
Cardiovascular disorder	Additional description: Cardiovascular disorder		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congestive cardiomyopathy	Additional description: Congestive cardiomyopathy		
subjects affected / exposed	3 / 1395 (0.22%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Coronary artery disease	Additional description: Coronary artery disease		
subjects affected / exposed	2 / 1395 (0.14%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracardiac thrombus	Additional description: Intracardiac thrombus		

subjects affected / exposed	3 / 1395 (0.22%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cardiomyopathy	Additional description: Ischaemic cardiomyopathy		
subjects affected / exposed	5 / 1395 (0.36%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular failure	Additional description: Left ventricular failure		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve disease	Additional description: Mitral valve disease		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve incompetence	Additional description: Mitral valve incompetence		
subjects affected / exposed	3 / 1395 (0.22%)	7 / 1394 (0.50%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial ischaemia	Additional description: Myocardial ischaemia		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palpitations	Additional description: Palpitations		
subjects affected / exposed	5 / 1395 (0.36%)	11 / 1394 (0.79%)	
occurrences causally related to treatment / all	0 / 5	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion	Additional description: Pericardial effusion		
subjects affected / exposed	3 / 1395 (0.22%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	1 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinoatrial block	Additional description: Sinoatrial block		

subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus node dysfunction	Additional description: Sinus node dysfunction		
subjects affected / exposed	37 / 1395 (2.65%)	35 / 1394 (2.51%)	
occurrences causally related to treatment / all	5 / 41	1 / 37	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus tachycardia	Additional description: Sinus tachycardia		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress cardiomyopathy	Additional description: Stress cardiomyopathy		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Supraventricular tachyarrhythmia	Additional description: Supraventricular tachyarrhythmia		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia	Additional description: Supraventricular tachycardia		
subjects affected / exposed	2 / 1395 (0.14%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Torsade de pointes	Additional description: Torsade de pointes		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular extrasystoles	Additional description: Ventricular extrasystoles		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation	Additional description: Ventricular fibrillation		

subjects affected / exposed	4 / 1395 (0.29%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Ventricular tachycardia	Additional description: Ventricular tachycardia		
subjects affected / exposed	3 / 1395 (0.22%)	6 / 1394 (0.43%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Amnesia	Additional description: Amnesia		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal ganglia haemorrhage	Additional description: Basal ganglia haemorrhage		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain injury	Additional description: Brain injury		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Carotid artery stenosis	Additional description: Carotid artery stenosis		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carpal tunnel syndrome	Additional description: Carpal tunnel syndrome		
subjects affected / exposed	2 / 1395 (0.14%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haemorrhage	Additional description: Cerebral haemorrhage		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral infarction	Additional description: Cerebral infarction		

subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cerebral small vessel ischaemic disease	Additional description: Cerebral small vessel ischaemic disease		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrospinal fluid leakage	Additional description: Cerebrospinal fluid leakage		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervicobrachial syndrome	Additional description: Cervicobrachial syndrome		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic inflammatory demyelinating polyradiculoneuropathy	Additional description: Chronic inflammatory demyelinating polyradiculoneuropathy		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia	Additional description: Dementia		
subjects affected / exposed	3 / 1395 (0.22%)	5 / 1394 (0.36%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia with Lewy bodies	Additional description: Dementia with Lewy bodies		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic hyperosmolar coma	Additional description: Diabetic hyperosmolar coma		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness	Additional description: Dizziness		

subjects affected / exposed	6 / 1395 (0.43%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug withdrawal headache	Additional description: Drug withdrawal headache		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic cerebral infarction	Additional description: Embolic cerebral infarction		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy	Additional description: Encephalopathy		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy	Additional description: Epilepsy		
subjects affected / exposed	8 / 1395 (0.57%)	9 / 1394 (0.65%)	
occurrences causally related to treatment / all	0 / 9	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Guillain-Barre syndrome	Additional description: Guillain-Barre syndrome		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial	Additional description: Haemorrhage intracranial		
subjects affected / exposed	0 / 1395 (0.00%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic stroke	Additional description: Haemorrhagic stroke		
subjects affected / exposed	7 / 1395 (0.50%)	13 / 1394 (0.93%)	
occurrences causally related to treatment / all	0 / 7	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 4	
Headache	Additional description: Headache		

subjects affected / exposed	4 / 1395 (0.29%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocephalus	Additional description: Hydrocephalus		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intercostal neuralgia	Additional description: Intercostal neuralgia		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial aneurysm	Additional description: Intracranial aneurysm		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke	Additional description: Ischaemic stroke		
subjects affected / exposed	32 / 1395 (2.29%)	48 / 1394 (3.44%)	
occurrences causally related to treatment / all	0 / 35	0 / 51	
deaths causally related to treatment / all	0 / 1	0 / 4	
Migraine	Additional description: Migraine		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple sclerosis	Additional description: Multiple sclerosis		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple system atrophy	Additional description: Multiple system atrophy		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myasthenia gravis	Additional description: Myasthenia gravis		

subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuralgia	Additional description: Neuralgia		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuritis	Additional description: Neuritis		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurodegenerative disorder	Additional description: Neurodegenerative disorder		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurological symptom	Additional description: Neurological symptom		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normal pressure hydrocephalus	Additional description: Normal pressure hydrocephalus		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic neuritis	Additional description: Optic neuritis		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia	Additional description: Paraesthesia		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parkinson's disease	Additional description: Parkinson's disease		

subjects affected / exposed	6 / 1395 (0.43%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 9	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial seizures	Additional description: Partial seizures		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral nerve lesion	Additional description: Peripheral nerve lesion		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Piriformis syndrome	Additional description: Piriformis syndrome		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyneuropathy	Additional description: Polyneuropathy		
subjects affected / exposed	4 / 1395 (0.29%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyneuropathy alcoholic	Additional description: Polyneuropathy alcoholic		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope	Additional description: Presyncope		
subjects affected / exposed	1 / 1395 (0.07%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica	Additional description: Sciatica		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord compression	Additional description: Spinal cord compression		

subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord ischaemia	Additional description: Spinal cord ischaemia		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal epidural haematoma	Additional description: Spinal epidural haematoma		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subarachnoid haemorrhage	Additional description: Subarachnoid haemorrhage		
subjects affected / exposed	2 / 1395 (0.14%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Syncope	Additional description: Syncope		
subjects affected / exposed	62 / 1395 (4.44%)	46 / 1394 (3.30%)	
occurrences causally related to treatment / all	5 / 71	2 / 57	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack	Additional description: Transient ischaemic attack		
subjects affected / exposed	25 / 1395 (1.79%)	25 / 1394 (1.79%)	
occurrences causally related to treatment / all	0 / 25	0 / 28	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tremor	Additional description: Tremor		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIIIth nerve lesion	Additional description: VIIIth nerve lesion		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIth nerve disorder	Additional description: VIth nerve disorder		

subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

VIth nerve paralysis	Additional description: VIth nerve paralysis		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Blood and lymphatic system disorders			
Agranulocytosis	Additional description: Agranulocytosis		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Anaemia	Additional description: Anaemia		
subjects affected / exposed	15 / 1395 (1.08%)	19 / 1394 (1.36%)	
occurrences causally related to treatment / all	0 / 16	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	

Anaemia of malignant disease	Additional description: Anaemia of malignant disease		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Iron deficiency anaemia	Additional description: Iron deficiency anaemia		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Lymphadenopathy	Additional description: Lymphadenopathy		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Nephrogenic anaemia	Additional description: Nephrogenic anaemia		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pancytopenia	Additional description: Pancytopenia		

subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia	Additional description: Thrombocytopenia		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Acute vestibular syndrome	Additional description: Acute vestibular syndrome		
subjects affected / exposed	2 / 1395 (0.14%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness	Additional description: Deafness		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exostosis of external ear canal	Additional description: Exostosis of external ear canal		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniere's disease	Additional description: Meniere's disease		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo	Additional description: Vertigo		
subjects affected / exposed	8 / 1395 (0.57%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional	Additional description: Vertigo positional		
subjects affected / exposed	5 / 1395 (0.36%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder	Additional description: Vestibular disorder		

subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders	Additional description: Age-related macular degeneration		
Age-related macular degeneration			
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angle closure glaucoma	Additional description: Angle closure glaucoma		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Entropion	Additional description: Entropion		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye haemorrhage	Additional description: Eye haemorrhage		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma	Additional description: Glaucoma		
subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery embolism	Additional description: Retinal artery embolism		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery occlusion	Additional description: Retinal artery occlusion		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment	Additional description: Retinal detachment		

subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vein occlusion	Additional description: Retinal vein occlusion		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual impairment	Additional description: Visual impairment		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal discomfort	Additional description: Abdominal discomfort		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia	Additional description: Abdominal hernia		
subjects affected / exposed	2 / 1395 (0.14%)	5 / 1394 (0.36%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	21 / 1395 (1.51%)	12 / 1394 (0.86%)	
occurrences causally related to treatment / all	0 / 21	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute abdomen	Additional description: Acute abdomen		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cheilitis	Additional description: Cheilitis		

subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis	Additional description: Colitis		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic	Additional description: Colitis ischaemic		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation	Additional description: Constipation		
subjects affected / exposed	3 / 1395 (0.22%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Crohn's disease	Additional description: Crohn's disease		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diaphragmatic hernia	Additional description: Diaphragmatic hernia		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	3 / 1395 (0.22%)	6 / 1394 (0.43%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum	Additional description: Diverticulum		
subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenogastric reflux	Additional description: Duodenogastric reflux		

subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia	Additional description: Dysphagia		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis	Additional description: Enteritis		
subjects affected / exposed	3 / 1395 (0.22%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis	Additional description: Enterocolitis		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage	Additional description: Gastric haemorrhage		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis	Additional description: Gastritis		
subjects affected / exposed	12 / 1395 (0.86%)	10 / 1394 (0.72%)	
occurrences causally related to treatment / all	0 / 12	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage	Additional description: Gastrointestinal haemorrhage		
subjects affected / exposed	40 / 1395 (2.87%)	26 / 1394 (1.87%)	
occurrences causally related to treatment / all	0 / 46	0 / 28	
deaths causally related to treatment / all	0 / 1	0 / 1	
Gastrointestinal ischaemia	Additional description: Gastrointestinal ischaemia		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastrooesophageal reflux disease	Additional description: Gastrooesophageal reflux disease		

subjects affected / exposed	0 / 1395 (0.00%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoperitoneum	Additional description: Haemoperitoneum		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids	Additional description: Haemorrhoids		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiatus hernia	Additional description: Hiatus hernia		
subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus	Additional description: Ileus		
subjects affected / exposed	4 / 1395 (0.29%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Inguinal hernia	Additional description: Inguinal hernia		
subjects affected / exposed	4 / 1395 (0.29%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia strangulated	Additional description: Inguinal hernia strangulated		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal fistula	Additional description: Intestinal fistula		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction	Additional description: Intestinal obstruction		

subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation	Additional description: Large intestine perforation		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine polyp	Additional description: Large intestine polyp		
subjects affected / exposed	1 / 1395 (0.07%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mallory-Weiss syndrome	Additional description: Mallory-Weiss syndrome		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melaena	Additional description: Melaena		
subjects affected / exposed	0 / 1395 (0.00%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric arterial occlusion	Additional description: Mesenteric arterial occlusion		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Mesenteric artery embolism	Additional description: Mesenteric artery embolism		
subjects affected / exposed	1 / 1395 (0.07%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Mesenteric vein thrombosis	Additional description: Mesenteric vein thrombosis		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea	Additional description: Nausea		

subjects affected / exposed	2 / 1395 (0.14%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal stenosis	Additional description: Oesophageal stenosis		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis	Additional description: Oesophagitis		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis	Additional description: Pancreatitis		
subjects affected / exposed	1 / 1395 (0.07%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute	Additional description: Pancreatitis acute		
subjects affected / exposed	4 / 1395 (0.29%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis chronic	Additional description: Pancreatitis chronic		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer	Additional description: Peptic ulcer		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage	Additional description: Rectal haemorrhage		
subjects affected / exposed	2 / 1395 (0.14%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland enlargement	Additional description: Salivary gland enlargement		

subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Short-bowel syndrome	Additional description: Short-bowel syndrome		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus	Additional description: Subileus		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia	Additional description: Umbilical hernia		
subjects affected / exposed	2 / 1395 (0.14%)	5 / 1394 (0.36%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Volvulus	Additional description: Volvulus		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting	Additional description: Vomiting		
subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Decubitus ulcer	Additional description: Decubitus ulcer		
subjects affected / exposed	3 / 1395 (0.22%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis	Additional description: Dermatitis		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot	Additional description: Diabetic foot		

subjects affected / exposed	2 / 1395 (0.14%)	5 / 1394 (0.36%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema	Additional description: Eczema		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erythema	Additional description: Erythema		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Granuloma annulare	Additional description: Granuloma annulare		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pruritus	Additional description: Pruritus		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriasis	Additional description: Psoriasis		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin lesion	Additional description: Skin lesion		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer	Additional description: Skin ulcer		
subjects affected / exposed	3 / 1395 (0.22%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria	Additional description: Urticaria		

subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	6 / 1395 (0.43%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus bladder	Additional description: Calculus bladder		
subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urinary	Additional description: Calculus urinary		
subjects affected / exposed	5 / 1395 (0.36%)	5 / 1394 (0.36%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease	Additional description: Chronic kidney disease		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis haemorrhagic	Additional description: Cystitis haemorrhagic		
subjects affected / exposed	0 / 1395 (0.00%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria	Additional description: Haematuria		
subjects affected / exposed	0 / 1395 (0.00%)	5 / 1394 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis	Additional description: Hydronephrosis		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incontinence	Additional description: Incontinence		

subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
	Additional description: Nephrolithiasis		
subjects affected / exposed	3 / 1395 (0.22%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrotic syndrome			
	Additional description: Nephrotic syndrome		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (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			
	Additional description: Renal artery stenosis		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic			
	Additional description: Renal colic		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
	Additional description: Renal failure		
subjects affected / exposed	21 / 1395 (1.51%)	21 / 1394 (1.51%)	
occurrences causally related to treatment / all	0 / 25	0 / 23	
deaths causally related to treatment / all	0 / 2	0 / 2	
Renal haemorrhage			
	Additional description: Renal haemorrhage		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress urinary incontinence			
	Additional description: Stress urinary incontinence		
subjects affected / exposed	3 / 1395 (0.22%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral obstruction			
	Additional description: Urethral obstruction		

subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary incontinence	Additional description: Urinary incontinence		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	5 / 1395 (0.36%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 6	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urogenital haemorrhage	Additional description: Urogenital haemorrhage		
subjects affected / exposed	3 / 1395 (0.22%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal insufficiency	Additional description: Adrenal insufficiency		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenocortical insufficiency acute	Additional description: Adrenocortical insufficiency acute		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Goitre	Additional description: Goitre		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperadrenocorticism	Additional description: Hyperadrenocorticism		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism	Additional description: Hyperthyroidism		

subjects affected / exposed	6 / 1395 (0.43%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	3 / 6	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism	Additional description: Hypothyroidism		
subjects affected / exposed	3 / 1395 (0.22%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inappropriate antidiuretic hormone secretion	Additional description: Inappropriate antidiuretic hormone secretion		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pituitary-dependent Cushing's syndrome	Additional description: Pituitary-dependent Cushing's syndrome		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	6 / 1395 (0.43%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis	Additional description: Arthritis		
subjects affected / exposed	3 / 1395 (0.22%)	5 / 1394 (0.36%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain	Additional description: Back pain		
subjects affected / exposed	24 / 1395 (1.72%)	16 / 1394 (1.15%)	
occurrences causally related to treatment / all	0 / 31	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis	Additional description: Bursitis		
subjects affected / exposed	2 / 1395 (0.14%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cervical spinal stenosis	Additional description: Cervical spinal stenosis		
	subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)
	occurrences causally related to treatment / all	0 / 1	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0
Dupuytren's contracture	Additional description: Dupuytren's contracture		
	subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)
	occurrences causally related to treatment / all	0 / 1	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0
Exostosis	Additional description: Exostosis		
	subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)
	occurrences causally related to treatment / all	0 / 1	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0
Fistula	Additional description: Fistula		
	subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)
	occurrences causally related to treatment / all	0 / 0	0 / 1
	deaths causally related to treatment / all	0 / 0	0 / 0
Foot deformity	Additional description: Foot deformity		
	subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)
	occurrences causally related to treatment / all	0 / 1	0 / 2
	deaths causally related to treatment / all	0 / 0	0 / 0
Groin pain	Additional description: Groin pain		
	subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)
	occurrences causally related to treatment / all	0 / 1	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0
Haemarthrosis	Additional description: Haemarthrosis		
	subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)
	occurrences causally related to treatment / all	0 / 1	0 / 1
	deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc protrusion	Additional description: Intervertebral disc protrusion		
	subjects affected / exposed	5 / 1395 (0.36%)	7 / 1394 (0.50%)
	occurrences causally related to treatment / all	0 / 9	0 / 8
	deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar spinal stenosis	Additional description: Lumbar spinal stenosis		

subjects affected / exposed	4 / 1395 (0.29%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain	Additional description: Musculoskeletal chest pain		
subjects affected / exposed	2 / 1395 (0.14%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain	Additional description: Musculoskeletal pain		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myalgia	Additional description: Myalgia		
subjects affected / exposed	0 / 1395 (0.00%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis	Additional description: Osteoarthritis		
subjects affected / exposed	7 / 1395 (0.50%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteonecrosis	Additional description: Osteonecrosis		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoporotic fracture	Additional description: Osteoporotic fracture		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	3 / 1395 (0.22%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pathological fracture	Additional description: Pathological fracture		

subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyarthritis	Additional description: Polyarthritis		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis	Additional description: Rhabdomyolysis		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatoid arthritis	Additional description: Rheumatoid arthritis		
subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scleroderma	Additional description: Scleroderma		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal stenosis	Additional description: Spinal stenosis		
subjects affected / exposed	1 / 1395 (0.07%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylitis	Additional description: Spondylitis		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis	Additional description: Spondylolisthesis		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic lupus erythematosus	Additional description: Systemic lupus erythematosus		

subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal abscess	Additional description: Abdominal abscess		
subjects affected / exposed	2 / 1395 (0.14%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess	Additional description: Abscess		
subjects affected / exposed	3 / 1395 (0.22%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess bacterial	Additional description: Abscess bacterial		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess	Additional description: Anal abscess		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis	Additional description: Appendicitis		
subjects affected / exposed	3 / 1395 (0.22%)	7 / 1394 (0.50%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial	Additional description: Arthritis bacterial		
subjects affected / exposed	2 / 1395 (0.14%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial infection	Additional description: Bacterial infection		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis	Additional description: Bronchitis		

subjects affected / exposed	2 / 1395 (0.14%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac infection	Additional description: Cardiac infection		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis	Additional description: Cellulitis		
subjects affected / exposed	3 / 1395 (0.22%)	5 / 1394 (0.36%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic sinusitis	Additional description: Chronic sinusitis		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis	Additional description: Clostridium difficile colitis		
subjects affected / exposed	0 / 1395 (0.00%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Creutzfeldt-Jakob disease	Additional description: Creutzfeldt-Jakob disease		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Device related infection	Additional description: Device related infection		
subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis	Additional description: Diverticulitis		
subjects affected / exposed	15 / 1395 (1.08%)	13 / 1394 (0.93%)	
occurrences causally related to treatment / all	0 / 18	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear infection	Additional description: Ear infection		

subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emphyema	Additional description: Emphyema		
subjects affected / exposed	2 / 1395 (0.14%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis	Additional description: Encephalitis		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis	Additional description: Endocarditis		
subjects affected / exposed	4 / 1395 (0.29%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Epididymitis	Additional description: Epididymitis		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas	Additional description: Erysipelas		
subjects affected / exposed	15 / 1395 (1.08%)	11 / 1394 (0.79%)	
occurrences causally related to treatment / all	0 / 19	0 / 15	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastroenteritis	Additional description: Gastroenteritis		
subjects affected / exposed	9 / 1395 (0.65%)	13 / 1394 (0.93%)	
occurrences causally related to treatment / all	0 / 10	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal infection	Additional description: Gastrointestinal infection		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin abscess	Additional description: Groin abscess		

subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster	Additional description: Herpes zoster		
subjects affected / exposed	2 / 1395 (0.14%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection	Additional description: Infection		
subjects affected / exposed	14 / 1395 (1.00%)	11 / 1394 (0.79%)	
occurrences causally related to treatment / all	0 / 16	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 0	
Intervertebral discitis	Additional description: Intervertebral discitis		
subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised infection	Additional description: Localised infection		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinitis	Additional description: Mediastinitis		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle abscess	Additional description: Muscle abscess		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal candidiasis	Additional description: Oesophageal candidiasis		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ophthalmic herpes zoster	Additional description: Ophthalmic herpes zoster		

subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis	Additional description: Osteomyelitis		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media	Additional description: Otitis media		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paronychia	Additional description: Paronychia		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis	Additional description: Peritonitis		
subjects affected / exposed	3 / 1395 (0.22%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis	Additional description: Pharyngitis		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	69 / 1395 (4.95%)	81 / 1394 (5.81%)	
occurrences causally related to treatment / all	1 / 90	1 / 106	
deaths causally related to treatment / all	0 / 7	1 / 9	
Post procedural infection	Additional description: Post procedural infection		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis	Additional description: Pyelonephritis		

subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute	Additional description: Pyelonephritis acute		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (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	Additional description: Respiratory tract infection		
subjects affected / exposed	9 / 1395 (0.65%)	13 / 1394 (0.93%)	
occurrences causally related to treatment / all	0 / 9	0 / 14	
deaths causally related to treatment / all	0 / 1	0 / 0	
Rotavirus infection	Additional description: Rotavirus infection		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis	Additional description: Sepsis		
subjects affected / exposed	13 / 1395 (0.93%)	17 / 1394 (1.22%)	
occurrences causally related to treatment / all	0 / 14	0 / 17	
deaths causally related to treatment / all	0 / 7	0 / 7	
Septic encephalopathy	Additional description: Septic encephalopathy		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock	Additional description: Septic shock		
subjects affected / exposed	2 / 1395 (0.14%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 3	
Skin bacterial infection	Additional description: Skin bacterial infection		
subjects affected / exposed	6 / 1395 (0.43%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal sepsis	Additional description: Staphylococcal sepsis		

subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Tick-borne viral encephalitis	Additional description: Tick-borne viral encephalitis		
subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth abscess	Additional description: Tooth abscess		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculosis	Additional description: Tuberculosis		
subjects affected / exposed	0 / 1395 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	27 / 1395 (1.94%)	19 / 1394 (1.36%)	
occurrences causally related to treatment / all	0 / 35	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis	Additional description: Urosepsis		
subjects affected / exposed	6 / 1395 (0.43%)	9 / 1394 (0.65%)	
occurrences causally related to treatment / all	0 / 6	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 1	
Viral infection	Additional description: Viral infection		
subjects affected / exposed	1 / 1395 (0.07%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection	Additional description: Wound infection		
subjects affected / exposed	5 / 1395 (0.36%)	11 / 1394 (0.79%)	
occurrences causally related to treatment / all	0 / 6	0 / 12	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metabolism and nutrition disorders			
Dehydration	Additional description: Dehydration		

subjects affected / exposed	4 / 1395 (0.29%)	4 / 1394 (0.29%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus	Additional description: Diabetes mellitus		
subjects affected / exposed	0 / 1395 (0.00%)	7 / 1394 (0.50%)	
occurrences causally related to treatment / all	0 / 0	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyslipidaemia	Additional description: Dyslipidaemia		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrolyte imbalance	Additional description: Electrolyte imbalance		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gout	Additional description: Gout		
subjects affected / exposed	2 / 1395 (0.14%)	5 / 1394 (0.36%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	2 / 1395 (0.14%)	3 / 1394 (0.22%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia	Additional description: Hyperkalaemia		
subjects affected / exposed	2 / 1395 (0.14%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia	Additional description: Hypoglycaemia		
subjects affected / exposed	3 / 1395 (0.22%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia	Additional description: Hypokalaemia		

subjects affected / exposed	1 / 1395 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia	Additional description: Hyponatraemia		
subjects affected / exposed	2 / 1395 (0.14%)	6 / 1394 (0.43%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic acidosis	Additional description: Metabolic acidosis		
subjects affected / exposed	1 / 1395 (0.07%)	0 / 1394 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Early rhythm control	Usual care	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 1395 (0.00%)	0 / 1394 (0.00%)	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 December 2010	Essential changes in inclusion criteria
09 December 2011	essential changes and administrative changes
14 May 2015	essential changes and further administrative changes

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported