



## 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:

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**Subjects enrolled per age group**

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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

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## Subject disposition

### Recruitment

Recruitment details:

We enrolled adults ( $\geq 18$  years of age) who had early AF (defined as atrial fibrillation diagnosed  $\leq 12$  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  $\leq 1$  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
<b>Arm title</b>	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.

<b>Arm title</b>	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	

<b>Number of subjects in period 1</b>	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

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

### Statistical analyses

<b>Statistical analysis title</b>	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	

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

### Statistical analyses

<b>Statistical analysis title</b>	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

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### 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

<b>Statistical analysis title</b>	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

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### Primary: Acute Coronary Syndrome

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

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

### Statistical analyses

<b>Statistical analysis title</b>	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<sup>[1]</sup>

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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
Thromboembolctomy			
Additional description: Thromboembolctomy			

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	
<b>General disorders and administration site conditions</b>			
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	
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	
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	
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	
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	
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	
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	
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	
<b>Immune system disorders</b>			
<b>Amyloidosis</b>	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	
<b>Drug hypersensitivity</b>	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	
<b>Hypersensitivity</b>	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	
<b>Reproductive system and breast disorders</b>			
<b>Benign prostatic hyperplasia</b>	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	
<b>Female genital tract fistula</b>	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	
<b>Pelvic pain</b>	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	
<b>Prostatitis</b>	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 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Device lead issue	
	0 / 1395 (0.00%)	1 / 1394 (0.07%)
	0 / 0	0 / 1
	0 / 0	0 / 0
Device occlusion subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Device occlusion	
	0 / 1395 (0.00%)	1 / 1394 (0.07%)
	0 / 0	0 / 1
	0 / 0	0 / 0
Device power source issue subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Device power source issue	
	3 / 1395 (0.22%)	4 / 1394 (0.29%)
	0 / 3	0 / 4
	0 / 0	0 / 0
Lead dislodgement subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Lead dislodgement	
	1 / 1395 (0.07%)	1 / 1394 (0.07%)
	0 / 1	0 / 1
	0 / 0	0 / 0
Hepatobiliary disorders Acute hepatic failure subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Acute hepatic failure	
	1 / 1395 (0.07%)	0 / 1394 (0.00%)
	0 / 1	0 / 0
	0 / 1	0 / 0
Autoimmune hepatitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Autoimmune hepatitis	
	1 / 1395 (0.07%)	0 / 1394 (0.00%)
	0 / 1	0 / 0
	0 / 0	0 / 0
Bile duct stone subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Bile duct stone	
	3 / 1395 (0.22%)	6 / 1394 (0.43%)
	0 / 3	0 / 6
	0 / 0	0 / 0
Cholangitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Cholangitis	
	0 / 1395 (0.00%)	3 / 1394 (0.22%)
	0 / 0	0 / 3
	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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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Congenital, familial and genetic disorders			
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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	
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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	
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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	
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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	
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Cardiac disorders	Additional description: Acute coronary syndrome		
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	
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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	
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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	
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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	
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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	
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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	
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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	
Embolitic 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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
<b>Eye disorders</b>			
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	
Additional description: Angle closure glaucoma			
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	
Additional description: Entropion			
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	
Additional description: Eye haemorrhage			
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	
Additional description: Glaucoma			
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	
Additional description: Retinal artery embolism			
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	
Additional description: Retinal artery occlusion			
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	
Additional description: Retinal detachment			
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	Additional description: Abdominal discomfort		
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	
<b>Renal and urinary disorders</b>			
Additional description: Acute kidney injury			
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	
Additional description: Calculus bladder			
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	
Additional description: Calculus urinary			
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	
Additional description: Chronic kidney disease			
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	
Additional description: Cystitis haemorrhagic			
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	
Additional description: Haematuria			
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	
Additional description: Hydronephrosis			
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	
Additional description: Incontinence			
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	
<b>Hypothyroidism</b>			
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	
<b>Inappropriate antidiuretic hormone secretion</b>			
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	
<b>Pituitary-dependent Cushing's syndrome</b>			
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	
<b>Musculoskeletal and connective tissue disorders</b>			
<b>Arthralgia</b>			
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	
<b>Arthritis</b>			
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	
<b>Back pain</b>			
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	
<b>Bursitis</b>			
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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
<b>Infections and infestations</b>			
<b>Abdominal abscess</b>	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	
<b>Abscess</b>	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	
<b>Abscess bacterial</b>	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	
<b>Anal abscess</b>	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	
<b>Appendicitis</b>	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	
<b>Arthritis bacterial</b>	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	
<b>Bacterial infection</b>	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	
<b>Bronchitis</b>	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	
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Empyema	Additional description: Empyema		
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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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	
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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 %

<b>Non-serious adverse events</b>	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:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported