Clinical trial results:
TRAnexamic Acid for Preventing postpartum hemorrhage following a Cesarean Delivery : a multicenter randomised, double blind placebo controlled trial (TRAAP2)

Summary

EudraCT number	2017-001144-36
Trial protocol	FR
Global end of trial date	08 April 2020

Results information

Result version number	v1 (current)
This version publication date	15 January 2022
First version publication date	15 January 2022

Trial information

Trial identification

Sponsor protocol code	CHUBX2015/41

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	CHU de Bordeaux
Sponsor organisation address	12 rue Dubernat , Talence cedex, France, 33404
Public contact	Pr Loïc Sentilhes, Pôle obstétrique, reproduction et gynécologie, Service de Gynécologie, +33 556 79 55 79, lois.sentilhes@chu-boreaux.fr
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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	08 April 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 June 2017
Global end of trial reached?	Yes
Global end of trial date	08 April 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To test the efficacy of a low dose of tranéxamic acid (1g) delivered within two minutes of the birth of a child by caesarean section versus placebo for the prevention of postpartum hemorrhage (PPH), defined by a Calculated blood loss of more than 1000mL (calculated blood loss = estimated blood volume x (preoperative Ht - preoperative Ht) / Ht preoperative (with estimated blood volume (in mL) = weight (in kg) x 85) A transfusion into globular concentrates before the second postpartum day (D2)

Protection of trial subjects:

The benefit/risk ratio was investigated in the study. TXA is a promising candidate as a preventive and morbidity-reducing treatment for PPH. In addition, it can be easily added to the delivery management protocol in all maternity hospitals worldwide.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 June 2017
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	France: 4551
Worldwide total number of subjects	4551
EEA total number of subjects	4551

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	4551
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The total duration of the trial is 27 months, 24 months of inclusion and 3 months of post-partum follow-up (looking for thromboembolic complications or other remote side effects of the treatment).
The total duration of the research project is 38 months
30 centres in France participated in the study.

Pre-assignment

Screening details:

Inclusion criteria:
- Patient ≥ 18 years
- Delivery by caesarean section
- Gestational age ≥ 34 weeks + 0 days
- Blood cell count within 3 days prior to caesarean delivery
- Haemoglobin level at last blood sample > 9g/dl
- Signed informed consent

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	TXA Group

Arm description:

Experimental drug 1 is tranexamic acid injection (EXACYL® 1g-10mL I.V., injectable solution)

Arm type	Experimental
Investigational medicinal product name	exacyl 1g-10mL
Investigational medicinal product code	SUB11214MIG
Other name	TRANEXAMIC ACID
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Il se présente sous forme de solution injectable conditionnée, pour une mise en aveugle, en flacon en verre de type 1 de 10 mL, à la concentration de 100mg /mL
La voie d'administration est la Voie intraveineuse lente stricte, durant la troisième phase du travail, dans les 3 minutes suivant la naissance d’un enfant par césarienne

Arm title	Placebo Group

Arm description:

Experimental drug 2 (placebo) is a 0.9%-10mL sodium chloride injection

Arm type	Placebo
Investigational medicinal product name	NaCL
Investigational medicinal product code	
Other name	Chlorure de sodium
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Il se présente sous forme de solution injectable conditionnée, pour une mise en aveugle, en flacon en verre
de type 1 de 10mL.
La voie d'administration est la Voie intraveineuse lente stricte

Number of subjects in period 1	TXA Group	Placebo Group
Started	2276	2275
Completed	2222	2209
Not completed	54	66
Consent withdrawn by subject	6	8
exclusion criteria	44	54
vaginal delivery	4	4

Baseline characteristics

Reporting groups	
Reporting group title	TXA Group
Reporting group description:	
Experimental drug 1 is tranexamic acid injection (EXACYL® 1g-10mL I.V., injectable solution)	
Reporting group title	Placebo Group
Reporting group description:	
Experimental drug 2 (placebo) is a 0.9%-10mL sodium chloride injection	

Reporting group values	TXA Group	Placebo Group	Total
Number of subjects	2276	2275	4551
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)	2276	2275	4551
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	2276	2275	4551
Male	0	0	0

Subject analysis sets	
Subject analysis set title	Modified ITT TXA
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
Population in underwent cesarean delivery analysed modifed intention to treat in the group TXA	
Subject analysis set title	Modified ITT Placebo
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
Population in underwent cesarean delivery analysed modifed intention to treat in the placebo group	

Reporting group values	Modified ITT TXA	Modified ITT Placebo	
Number of subjects	2222	2209	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	

Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	2222	2209	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	2222	2209	
Male	0	0	

End points

End points reporting groups

Reporting group title	TXA Group
Reporting group description:	
Experimental drug 1 is tranexamic acid injection (EXACYL® 1g-10mL I.V., injectable solution)	
Reporting group title	Placebo Group
Reporting group description:	
Experimental drug 2 (placebo) is a 0.9%-10mL sodium chloride injection	
Subject analysis set title	Modified ITT TXA
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
Population in underwent cesarean delivery analysed modifed intention to treat in the group TXA	
Subject analysis set title	Modified ITT Placebo
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
Population in underwent cesarean delivery analysed modifed intention to treat in the placebo group	

Primary: Occurrence of postpartum haemorrhage before day 2

End point title	Occurrence of postpartum haemorrhage before day 2
End point description:	
incidence of Post Partum Haemorrhage defined as calculated blood loss >1000mL [calculated blood loss = estimated blood volume x (preoperative Ht - postoperative Ht)/preoperative Ht; where estimated blood volume (mL) = weight (kg) x 85], or the need for transfusion of at least 1 packed red blood cell before D2	
End point type	Primary
End point timeframe:	
On the day of the cesarean delivery	

End point values	Modified ITT TXA	Modified ITT Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2086	2067		
Units: percent				
number (not applicable)				
Yes	26.7	31.6		
No	73.3	68.4		

Statistical analyses

Statistical analysis title	Effect of study treatment on primary endpoints

Statistical analysis description:

The incidence of PPH before D2 was compared between the two treatment groups using a mixed-effects Poisson regression model, with adjustment for the randomisation stratification factors of investigating centre and time of caesarean section (before or during labour).

Comparison groups	Modified ITT TXA v Modified ITT Placebo
Number of subjects included in analysis	4153
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0032
Method	Multiple imputation
Parameter estimate	Risk ratio (RR)
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	0.94

Secondary: Calculated blood loss > 500 millilitres

End point title	Calculated blood loss > 500 millilitres

End point description:

Incidence of calculated blood loss > 500 mL

End point type	Secondary

End point timeframe:

Delivered in the immediate aftermath of caesarean birth versus placebo, on other markers of postpartum blood loss.

End point values	Modified ITT TXA	Modified ITT Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2084	2066		
Units: percent				
number (not applicable)				
Yes	58.2	64.2		
No	41.8	35.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Calculated blood loss > 1000 millilitres

End point title	Calculated blood loss > 1000 millilitres

End point description:

Incidence of calculated blood loss > 1000 mL

End point type	Secondary

End point timeframe:

Delivered in the immediate aftermath of a caesarean birth versus placebo, on other markers of postpartum blood

End point values	Modified ITT TXA	Modified ITT Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2084	2066		
Units: percent				
number (not applicable)				
Yes	26.4	31.5		
No	73.6	68.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Calculated blood loss > 1500 millilitres

End point title	Calculated blood loss > 1500 millilitres

End point description:

Incidence of severe PPH, defined as calculated blood loss greater than 1500 mL

End point type	Secondary

End point timeframe:

Delivered in the immediate aftermath of a caesarean birth versus placebo, on other markers of postpartum blood loss.

End point values	Modified ITT TXA	Modified ITT Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2084	2066		
Units: percent				
number (not applicable)				
Yes	10.3	12.7		
No	89.7	87.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Use of an additional uterotonic

End point title	Use of an additional uterotonic

End point description:

Proportion of women requiring additional uterotonic treatment, including sulprostone.

End point type	Secondary

End point timeframe:

Delivered in the immediate aftermath of a caesarean birth versus placebo, on other markers of postpartum blood loss.

End point values	Modified ITT TXA	Modified ITT Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2217	2206		
Units: percent				
number (not applicable)				
Yes	5.9	7.2		
No	94.1	92.8		

Statistical analyses

Statistical analysis title	Effect of study treatment on secondary endpoints
Comparison groups	Modified ITT TXA v Modified ITT Placebo
Number of subjects included in analysis	4423
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.15
Method	Regression, Linear
Parameter estimate	Risk ratio (RR)
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	1.03

Secondary: Arterial embolization

End point title	Arterial embolization

End point description:

Incidence of arterial embolisation and haemostasis surgery for PPH

End point type	Secondary

End point timeframe:

Delivered in the immediate aftermath of a caesarean birth versus placebo, on other markers of postpartum blood loss.

End point values	Modified ITT TXA	Modified ITT Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2216	2206		
Units: percent				
number (not applicable)				
Yes	0.6	0.3		
No	99.4	99.7		

Statistical analyses

Statistical analysis title	Effect of study treatment on secondary endpoints
Comparison groups	Modified ITT TXA v Modified ITT Placebo
Number of subjects included in analysis	4422
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1933
Method	Regression, Linear
Parameter estimate	Risk ratio (RR)
Point estimate	2.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	5.66

Secondary: Transfusion during hospitalisation

End point title	Transfusion during hospitalisation

End point description:

Incidence of postpartum transfusion

End point type	Secondary

End point timeframe:

Delivered in the immediate aftermath of a caesarean birth versus placebo, on other markers of postpartum blood loss.

End point values	Modified ITT TXA	Modified ITT Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2221	2208		
Units: percent				
number (not applicable)				
Yes	1.9	1.8		
No	98.1	98.2		

Statistical analyses

Statistical analysis title	Effect of study treatment on secondary endpoints
Comparison groups	Modified ITT Placebo v Modified ITT TXA
Number of subjects included in analysis	4429
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7568
Method	Mixed models analysis
Parameter estimate	Risk ratio (RR)
Point estimate	1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.66

Secondary: Total number of red blood cell transfused

End point title	Total number of red blood cell transfused

End point description:

Number of red blood cell units transfused

End point type	Secondary

End point timeframe:

Delivered in the immediate aftermath of a caesarean birth versus placebo, on other markers of postpartum blood loss.

End point values	Modified ITT TXA	Modified ITT Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	39		
Units: millilitre(s)				
arithmetic mean (standard deviation)	3.1 (± 1.9)	3.2 (± 2.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Delta haemoglobin between day 2 and day 0

End point title	Delta haemoglobin between day 2 and day 0

End point description:

Mean change in haemoglobin levels (difference between the most recent haemoglobin measured in the 7 days prior to the caesarean section and that at day 2)

End point type	Secondary

End point timeframe:

Delivered in the immediate aftermath of a caesarean birth versus placebo, on other markers of postpartum blood loss.

End point values	Modified ITT TXA	Modified ITT Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2088	2071		
Units: g/dL				
arithmetic mean (standard deviation)	-1.2 (± 1.2)	-1.4 (± 1.2)		

Statistical analyses

Statistical analysis title	Effect of study treatment on secondary endpoints
Comparison groups	Modified ITT TXA v Modified ITT Placebo
Number of subjects included in analysis	4159
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Regression, Linear
Parameter estimate	Risk ratio (RR)
Point estimate	0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.11
upper limit	0.25

Secondary: Delta haematocrit between day 2 and day 0

End point title	Delta haematocrit between day 2 and day 0

End point description:

Mean change in haematocrit levels (difference between the most recent haematocrit measured in the 7 days prior to caesarean section and that at day 2)

End point type	Secondary

End point timeframe:

Delivered in the immediate aftermath of a caesarean birth versus placebo, on other markers of

postpartum blood loss.

End point values	Modified ITT TXA	Modified ITT Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2086	2071		
Units: g/dl				
arithmetic mean (standard deviation)	-3.5 (± 3.7)	-4.0 (± 3.7)		

Statistical analyses

Statistical analysis title	Effect of study treatment on secondary endpoints
Comparison groups	Modified ITT TXA v Modified ITT Placebo
Number of subjects included in analysis	4157
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Regression, Linear
Parameter estimate	Risk ratio (RR)
Point estimate	0.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.31
upper limit	0.75

Secondary: Gravimetrically estimated blood loss

End point title	Gravimetrically estimated blood loss
End point description:	
Gravimetrically estimated blood loss is described only in patients who delivered after 07 August 2018	
End point type	Secondary
End point timeframe:	
Delivered in the immediate aftermath of caesarean birth versus placebo, on other markers of postpartum blood loss	

End point values	Modified ITT TXA	Modified ITT Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1774	1754		
Units: millilitre(s)				
arithmetic mean (standard deviation)	688.7 (± 886.5)	719.3 (± 919.6)		

Statistical analyses

Statistical analysis title	Effect of study treatment on secondary endpoints
Comparison groups	Modified ITT TXA v Modified ITT Placebo
Number of subjects included in analysis	3528
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.214
Method	Regression, Linear
Parameter estimate	Risk ratio (RR)
Point estimate	-33.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-77.48
upper limit	11.37

Secondary: Total gravimetrically estimated blood loss > 500mL

End point title	Total gravimetrically estimated blood loss > 500mL

End point description:

Gravimetrically estimated blood loss is described only in patients who delivered after 07 August 2018.

End point type	Secondary

End point timeframe:

Delivered in the immediate aftermath of caesarean birth versus placebo, on other markers of postpartum blood loss

End point values	Modified ITT TXA	Modified ITT Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1774	1754		
Units: percent				
number (not applicable)				
Yes	63.9	63.3		
No	36.1	36.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Total gravimetrically estimated blood loss > 1000 mL

End point title	Total gravimetrically estimated blood loss > 1000 mL

End point description:

Gravimetrically estimated blood loss is described only in patients who delivered after 07 August 2018.

End point type	Secondary

End point timeframe:

Delivered in the immediate aftermath of caesarean birth versus placebo, on other markers of postpartum blood loss

End point values	Modified ITT TXA	Modified ITT Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1774	1754		
Units: percent				
number (not applicable)				
Yes	30.7	29.7		
No	69.3	70.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Calculated blood loss

End point title	Calculated blood loss

End point description:

Mean estimated blood loss at the end of caesarean section

End point type	Secondary

End point timeframe:

Delivered in the immediate aftermath of caesarean birth versus placebo, on other markers of postpartum blood loss

End point values	Modified ITT TXA	Modified ITT Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2084	2066		
Units: millilitre(s)				
arithmetic mean (standard deviation)	680.4 (± 748.3)	787.2 (± 750.0)		

Statistical analyses

Statistical analysis title	Effect of study treatment on secondary endpoints
Comparison groups	Modified ITT TXA v Modified ITT Placebo
Number of subjects included in analysis	4150
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Regression, Linear
Parameter estimate	Risk ratio (RR)
Point estimate	-107.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-151.53
upper limit	-63.11

Secondary: Clinically significant postpartum haemorrhage

End point title	Clinically significant postpartum haemorrhage

End point description:

Incidence of clinically significant postpartum haemorrhage (physician's clinical judgment)

End point type	Secondary

End point timeframe:

Delivered in the immediate aftermath of a caesarean birth versus placebo, on other markers of postpartum blood loss

End point values	Modified ITT TXA	Modified ITT Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2220	2208		
Units: percent				
number (not applicable)				
Yes	13.6	14.8		
No	86.4	85.2		

Statistical analyses

Statistical analysis title	Effect of study treatment on secondary endpoints
Comparison groups	Modified ITT TXA v Modified ITT Placebo

Number of subjects included in analysis	4428
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.372
Method	Regression, Linear
Parameter estimate	Risk ratio (RR)
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.08

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Within 12 months after the delivery	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups	
Reporting group title	Placebo Group
Reporting group description: -	
Reporting group title	TXA Group
Reporting group description: -	

Serious adverse events	Placebo Group	TXA Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	345 / 2209 (15.62%)	342 / 2222 (15.39%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Oncocytoma (10048757)	Additional description: Oncocytoma (10048757)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian neoplasm (10061535)	Additional description: Ovarian neoplasm (10061535)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma (10046798)	Additional description: Uterine leiomyoma (10046798)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Vascular disorders			
Bleeding varicose vein (10005144)	Additional description: Bleeding varicose vein (10005144)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis (10051055)	Additional description: Deep vein thrombosis (10051055)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemodynamic instability (10052076)	Additional description: Haemodynamic instability (10052076)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage (10055798)	Additional description: Haemorrhage (10055798)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension (10020772)	Additional description: Hypertension (10020772)		
alternative assessment type: Non-systematic			
subjects affected / exposed	6 / 2209 (0.27%)	3 / 2222 (0.14%)	
occurrences causally related to treatment / all	0 / 6	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension (10021097)	Additional description: Hypotension (10021097)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	2 / 2222 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jugular vein thrombosis (10023237)	Additional description: Jugular vein thrombosis (10023237)		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic venous thrombosis (10034272)	Additional description: Pelvic venous thrombosis (10034272)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis superficial (10043595)	Additional description: Thrombophlebitis superficial (10043595)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Breast conserving surgery (10076783)	Additional description: Breast conserving surgery (10076783)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Caecectomy (10062859)	Additional description: Caecectomy (10062859)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystectomy (10008611)	Additional description: Cholecystectomy (10008611)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eventration repair (10072804)	Additional description: Eventration repair (10072804)		
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hysterectomy (10021151)	Additional description: Hysterectomy (10021151)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal anastomosis (10057146)	Additional description: Intestinal anastomosis (10057146)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myomectomy (10028634)	Additional description: Myomectomy (10028634)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrectomy (10029116)	Additional description: Nephrectomy (10029116)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Proctectomy (10077252)	Additional description: Proctectomy (10077252)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retained placenta operation (10078243)	Additional description: Retained placenta operation (10078243)		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2209 (0.00%)	3 / 2222 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salpingo-oophorectomy (10039464)	Additional description: Salpingo-oophorectomy (10039464)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scar excision (10039583)	Additional description: Scar excision (10039583)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	3 / 2222 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suture insertion (10052665)	Additional description: Suture insertion (10052665)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transfusion (10066152)	Additional description: Transfusion (10066152)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine dilation and curettage (10057304)	Additional description: Uterine dilation and curettage (10057304)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wedge resection toenail (10047884)	Additional description: Wedge resection toenail (10047884)		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Anaphylactoid syndrome of pregnancy (10067010)	Additional description: Anaphylactoid syndrome of pregnancy (10067010)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eclampsia (10014129)	Additional description: Eclampsia (10014129)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gestational hypertension (10070538)	Additional description: Gestational hypertension (10070538)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice neonatal (10023138)	Additional description: Jaundice neonatal (10023138)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Low birth weight baby (10067508)	Additional description: Low birth weight baby (10067508)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripartum cardiomyopathy (10049430)	Additional description: Peripartum cardiomyopathy (10049430)		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postpartum haemorrhage (10036417)	Additional description: Postpartum haemorrhage (10036417)		
alternative assessment type: Non-systematic			
subjects affected / exposed	246 / 2209 (11.14%)	233 / 2222 (10.49%)	
occurrences causally related to treatment / all	3 / 246	4 / 233	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retained placenta or membranes (10038758)	Additional description: Retained placenta or membranes (10038758)		
alternative assessment type: Non-systematic			
subjects affected / exposed	6 / 2209 (0.27%)	4 / 2222 (0.18%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic delivery (10044520)	Additional description: Traumatic delivery (10044520)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine atony (10046763)	Additional description: Uterine atony (10046763)		
alternative assessment type: Non-systematic			
subjects affected / exposed	11 / 2209 (0.50%)	8 / 2222 (0.36%)	
occurrences causally related to treatment / all	1 / 11	1 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight decrease neonatal (10047894)	Additional description: Weight decrease neonatal (10047894)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest discomfort (10008469)	Additional description: Chest discomfort (10008469)		
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain (10008479)	Additional description: Chest pain (10008479)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthermia (10020843)	Additional description: Hyperthermia (10020843)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	2 / 2222 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise (10025482)	Additional description: Malaise (10025482)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral (10030124)	Additional description: Oedema peripheral (10030124)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia (10037660)	Additional description: Pyrexia (10037660)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic reaction (10002198)	Additional description: Anaphylactic reaction (10002198)		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2209 (0.00%)	2 / 2222 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic shock (10002199)	Additional description: Anaphylactic shock (10002199)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity (10020751)	Additional description: Hypersensitivity (10020751)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Endometriosis (10014778)	Additional description: Endometriosis (10014778)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibrocystic breast disease (10016621)	Additional description: Fibrocystic breast disease (10016621)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metrorrhagia (10027514)	Additional description: Metrorrhagia (10027514)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian vein thrombosis (10072059)	Additional description: Ovarian vein thrombosis (10072059)		
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 2209 (0.05%)	6 / 2222 (0.27%)	
occurrences causally related to treatment / all	0 / 1	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fluid collection (10065388)	Additional description: Pelvic fluid collection (10065388)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine haematoma (10063875)	Additional description: Uterine haematoma (10063875)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine haemorrhage (10046788)	Additional description: Uterine haemorrhage (10046788)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	3 / 2222 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine pain (10046809)	Additional description: Uterine pain (10046809)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulvovaginal discomfort (10047786)	Additional description: Vulvovaginal discomfort (10047786)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema (10001029)	Additional description: Acute pulmonary oedema (10001029)		
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea (10013968)	Additional description: Dyspnoea (10013968)		
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 2209 (0.14%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion (10035598)	Additional description: Pleural effusion (10035598)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	2 / 2222 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration (10035669)	Additional description: Pneumonia aspiration (10035669)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism (10037377)	Additional description: Pulmonary embolism (10037377)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema (10037423)	Additional description: Pulmonary oedema (10037423)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress (10038687)	Additional description: Respiratory distress (10038687)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	2 / 2222 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Psychiatric disorders			
Brief psychotic disorder, with postpartum onset (10006362)	Additional description: Brief psychotic disorder, with postpartum onset (10006362)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression (10012378)	Additional description: Depression (10012378)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perinatal depression (10078366)	Additional description: Perinatal depression (10078366)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post-traumatic stress disorder (10036316)	Additional description: Post-traumatic stress disorder (10036316)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Schizoaffective disorder (10039621)	Additional description: Schizoaffective disorder (10039621)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile duct stone (10004637)	Additional description: Bile duct stone (10004637)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic (10004663)	Additional description: Biliary colic (10004663)		

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	2 / 2222 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis (10008604)	Additional description: Cholangitis (10008604)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis (10008629)	Additional description: Cholelithiasis (10008629)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	2 / 2222 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis migration (10068884)	Additional description: Cholelithiasis migration (10068884)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatocellular injury (10019837)	Additional description: Hepatocellular injury (10019837)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood glucose increased (10005557)	Additional description: Blood glucose increased (10005557)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hysteroscopy (10050125)	Additional description: Hysteroscopy (10050125)		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammatory marker increased (10069826)	Additional description: Inflammatory marker increased (10069826)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Arterial injury (10003162)	Additional description: Arterial injury (10003162)		
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 2209 (0.14%)	3 / 2222 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder injury (10061698)	Additional description: Bladder injury (10061698)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dural tear (10063395)	Additional description: Dural tear (10063395)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign body (10070245)	Additional description: Foreign body (10070245)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incision site haemorrhage (10051100)	Additional description: Incision site haemorrhage (10051100)		
alternative assessment type: Non-systematic			

subjects affected / exposed	11 / 2209 (0.50%)	5 / 2222 (0.23%)	
occurrences causally related to treatment / all	0 / 11	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury (10061225)	Additional description: Limb injury (10061225)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medication error (10027091)	Additional description: Medication error (10027091)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage (10051077)	Additional description: Post procedural haemorrhage (10051077)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound complication (10061468)	Additional description: Postoperative wound complication (10061468)		
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 2209 (0.18%)	2 / 2222 (0.09%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural haemorrhage (10071229)	Additional description: Procedural haemorrhage (10071229)		
alternative assessment type: Non-systematic			
subjects affected / exposed	27 / 2209 (1.22%)	27 / 2222 (1.22%)	
occurrences causally related to treatment / all	0 / 27	1 / 27	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scar (10039580)	Additional description: Scar (10039580)		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous haematoma (10042345)	Additional description: Subcutaneous haematoma (10042345)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical procedure repeated (10042618)	Additional description: Surgical procedure repeated (10042618)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric injury (10046405)	Additional description: Ureteric injury (10046405)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine perforation (10046810)	Additional description: Uterine perforation (10046810)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine rupture (10046820)	Additional description: Uterine rupture (10046820)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	3 / 2222 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular injury (10047080)	Additional description: Vascular injury (10047080)		
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular procedure complication (10057462)	Additional description: Vascular procedure complication (10057462)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound evisceration (10054108)	Additional description: Wound evisceration (10054108)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	2 / 2222 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Urachal abnormality (10066125)	Additional description: Urachal abnormality (10066125)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiac failure (10007554)	Additional description: Cardiac failure (10007554)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-respiratory arrest (10007617)	Additional description: Cardio-respiratory arrest (10007617)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congestive cardiomyopathy (10056370)	Additional description: Congestive cardiomyopathy (10056370)		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palpitations (10033557)	Additional description: Palpitations (10033557)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Altered state of consciousness (10001854)	Additional description: Altered state of consciousness (10001854)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amnesia (10001949)	Additional description: Amnesia (10001949)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haematoma (10053942)	Additional description: Cerebral haematoma (10053942)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy (10015037)	Additional description: Epilepsy (10015037)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile convulsion (10016284)	Additional description: Febrile convulsion (10016284)		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised tonic-clonic seizure (10018100)	Additional description: Generalised tonic-clonic seizure (10018100)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache (10019211)	Additional description: Headache (10019211)		
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 2209 (0.23%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	2 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of consciousness (10024855)	Additional description: Loss of consciousness (10024855)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine with aura (10027607)	Additional description: Migraine with aura (10027607)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Motor dysfunction (10061296)	Additional description: Motor dysfunction (10061296)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia (10033775)	Additional description: Paraesthesia (10033775)		
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Posterior reversible encephalopathy syndrome (10071066)	Additional description: Posterior reversible encephalopathy syndrome (10071066)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reversible cerebral vasoconstriction syndrome (10073240)	Additional description: Reversible cerebral vasoconstriction syndrome (10073240)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure (10039906)	Additional description: Seizure (10039906)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	2 / 2222 (0.09%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia (10002034)	Additional description: Anaemia (10002034)		
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 2209 (0.18%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia of pregnancy (10066468)	Additional description: Anaemia of pregnancy (10066468)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Tinnitus (10043882)	Additional description: Tinnitus (10043882)		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo (10047340)	Additional description: Vertigo (10047340)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Photopsia (10034962)	Additional description: Photopsia (10034962)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment (10038848)	Additional description: Retinal detachment (10038848)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual impairment (10047571)	Additional description: Visual impairment (10047571)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain (10000081)	Additional description: Abdominal pain (10000081)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	2 / 2222 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain lower (10000084)	Additional description: Abdominal pain lower (10000084)		
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall haematoma (10067383)	Additional description: Abdominal wall haematoma (10067383)		
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 2209 (0.18%)	6 / 2222 (0.27%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fissure (10002153)	Additional description: Anal fissure (10002153)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendiceal mucocoele (10057986)	Additional description: Appendiceal mucocoele (10057986)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites (10003445)	Additional description: Ascites (10003445)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ulcerative (10009900)	Additional description: Colitis ulcerative (10009900)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea (10012735)	Additional description: Diarrhoea (10012735)		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis (10017853)	Additional description: Gastritis (10017853)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis (10018830)	Additional description: Haematemesis (10018830)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernial eventration (10057391)	Additional description: Hernial eventration (10057391)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus (10021328)	Additional description: Ileus (10021328)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction (10022687)	Additional description: Intestinal obstruction (10022687)		
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 2209 (0.14%)	4 / 2222 (0.18%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal obstruction (10062062)	Additional description: Large intestinal obstruction (10062062)		
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea (10028813)	Additional description: Nausea (10028813)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute (10033647)	Additional description: Pancreatitis acute (10033647)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneal disorder (10061343)	Additional description: Peritoneal disorder (10061343)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	2 / 2222 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneal haemorrhage (10034666)	Additional description: Peritoneal haemorrhage (10034666)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction (10041101)	Additional description: Small intestinal obstruction (10041101)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Strangulated umbilical hernia (10076931)	Additional description: Strangulated umbilical hernia (10076931)		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia (10045458)	Additional description: Umbilical hernia (10045458)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting (10047700)	Additional description: Vomiting (10047700)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema (10002424)	Additional description: Angioedema (10002424)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised erythema (10051576)	Additional description: Generalised erythema (10051576)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pruritus (10037087)	Additional description: Pruritus (10037087)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash (10037844)	Additional description: Rash (10037844)		
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury (10069339)	Additional description: Acute kidney injury (10069339)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anuria (10002847)	Additional description: Anuria (10002847)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria (10018867)	Additional description: Haematuria (10018867)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic (10038419)	Additional description: Renal colic (10038419)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	2 / 2222 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal vein thrombosis (10038548)	Additional description: Renal vein thrombosis (10038548)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder rupture (10046530)	Additional description: Urinary bladder rupture (10046530)		
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinoma (10050091)	Additional description: Urinoma (10050091)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Hyperparathyroidism primary (10020707)	Additional description: Hyperparathyroidism primary (10020707)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion (10050296)	Additional description: Intervertebral disc protrusion (10050296)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck pain (10028836)	Additional description: Neck pain (10028836)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal wall abscess (10000099)	Additional description: Abdominal wall abscess (10000099)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	4 / 2222 (0.18%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall infection (10051254)	Additional description: Abdominal wall infection (10051254)		
alternative assessment type: Non-			

systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast abscess (10006171)	Additional description: Breast abscess (10006171)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometritis (10014791)	Additional description: Endometritis (10014791)		
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 2209 (0.18%)	6 / 2222 (0.27%)	
occurrences causally related to treatment / all	0 / 4	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometritis decidual (10014792)	Additional description: Endometritis decidual (10014792)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	5 / 2222 (0.23%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia infection (10061126)	Additional description: Escherichia infection (10061126)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital infection (10048461)	Additional description: Genital infection (10048461)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incision site abscess (10049660)	Additional description: Incision site abscess (10049660)		
alternative assessment type: Non-systematic			

subjects affected / exposed	3 / 2209 (0.14%)	2 / 2222 (0.09%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected cyst (10058015)	Additional description: Infected cyst (10058015)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infection (10061229)	Additional description: Lung infection (10061229)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphangitis (10025226)	Additional description: Lymphangitis (10025226)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle abscess (10049206)	Additional description: Muscle abscess (10049206)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paronychia (10034016)	Additional description: Paronychia (10034016)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic abscess (10034236)	Additional description: Pelvic abscess (10034236)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Perineal abscess (10052457)	Additional description: Perineal abscess (10052457)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Peritonitis (10034674)	Additional description: Peritonitis (10034674)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pneumonia (10035664)	Additional description: Pneumonia (10035664)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Postpartum sepsis (10036422)	Additional description: Postpartum sepsis (10036422)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Puerperal pyrexia (10037294)	Additional description: Puerperal pyrexia (10037294)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pyelonephritis (10037596)	Additional description: Pyelonephritis (10037596)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pyelonephritis acute (10037597)	Additional description: Pyelonephritis acute (10037597)		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2209 (0.00%)	2 / 2222 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis (10040047)	Additional description: Sepsis (10040047)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock (10040070)	Additional description: Septic shock (10040070)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin infection (10040872)	Additional description: Skin infection (10040872)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	2 / 2222 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection (10046571)	Additional description: Urinary tract infection (10046571)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Diabetes mellitus (10012601)	Additional description: Diabetes mellitus (10012601)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia (10020583)	Additional description: Hypercalcaemia (10020583)		
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia (10020646)	Additional description: Hyperkalaemia (10020646)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia (10020993)	Additional description: Hypoglycaemia (10020993)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia neonatal (10020994)	Additional description: Hypoglycaemia neonatal (10020994)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo Group	TXA Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1206 / 2209 (54.59%)	1213 / 2222 (54.59%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Borderline mucinous tumour of ovary (10073266)	Additional description: Borderline mucinous tumour of ovary (10073266)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Haemangioma of liver (10018821)	Additional description: Haemangioma of liver (10018821)		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Uterine leiomyoma (10046798)	Additional description: Uterine leiomyoma (10046798)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Vascular disorders			
Bleeding varicose vein (10005144)	Additional description: Bleeding varicose vein (10005144)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Flushing (10016825)	Additional description: Flushing (10016825)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	0 / 2222 (0.00%)	
occurrences (all)	2	0	
Haematoma (10018852)	Additional description: Haematoma (10018852)		
alternative assessment type: Non-systematic			
subjects affected / exposed	8 / 2209 (0.36%)	2 / 2222 (0.09%)	
occurrences (all)	8	2	
Haemodynamic instability (10052076)	Additional description: Haemodynamic instability (10052076)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Haemorrhage (10055798)	Additional description: Haemorrhage (10055798)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Hot flush (10060800)	Additional description: Hot flush (10060800)		
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 2209 (0.18%)	7 / 2222 (0.32%)	
occurrences (all)	4	7	
Hypertension (10020772)	Additional description: Hypertension (10020772)		
alternative assessment type: Non-systematic			

subjects affected / exposed	44 / 2209 (1.99%)	49 / 2222 (2.21%)	
occurrences (all)	46	49	
Hypotension (10021097)	Additional description: Hypotension (10021097)		
alternative assessment type: Non-systematic			
subjects affected / exposed	29 / 2209 (1.31%)	22 / 2222 (0.99%)	
occurrences (all)	29	22	
Labile blood pressure (10023533)	Additional description: Labile blood pressure (10023533)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences (all)	1	1	
Labile hypertension (10049079)	Additional description: Labile hypertension (10049079)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Orthostatic hypotension (10031127)	Additional description: Orthostatic hypotension (10031127)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	1 / 2222 (0.05%)	
occurrences (all)	2	1	
Pallor (10033546)	Additional description: Pallor (10033546)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences (all)	1	1	
Shock (10040560)	Additional description: Shock (10040560)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Thrombophlebitis superficial (10043595)	Additional description: Thrombophlebitis superficial (10043595)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	3 / 2222 (0.14%)	
occurrences (all)	0	4	
Thrombosis (10043607)	Additional description: Thrombosis (10043607)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	1 / 2222 (0.05%)	
occurrences (all)	2	1	

Varicose vein (10046996)	Additional description: Varicose vein (10046996)		
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 2209 (0.14%)	3 / 2222 (0.14%)	
occurrences (all)	3	3	
Surgical and medical procedures			
Caesarean section (10006924)	Additional description: Caesarean section (10006924)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
General anaesthesia (10018060)	Additional description: General anaesthesia (10018060)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Haemostasis (10067439)	Additional description: Haemostasis (10067439)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Salpingectomy (10039449)	Additional description: Salpingectomy (10039449)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Pregnancy, puerperium and perinatal conditions			
Amniorrhexis (10051641)	Additional description: Amniorrhexis (10051641)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Foetal macrosomia (10053700)	Additional description: Foetal macrosomia (10053700)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Gestational diabetes (10018209)	Additional description: Gestational diabetes (10018209)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Gestational hypertension	Additional description: Gestational hypertension (10070538)		

(10070538)			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Postpartum haemorrhage (10036417)	Additional description: Postpartum haemorrhage (10036417)		
alternative assessment type: Non-systematic			
subjects affected / exposed	40 / 2209 (1.81%)	36 / 2222 (1.62%)	
occurrences (all)	40	36	
Pre-eclampsia (10036485)	Additional description: Pre-eclampsia (10036485)		
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 2209 (0.23%)	6 / 2222 (0.27%)	
occurrences (all)	5	6	
Retained placenta or membranes (10038758)	Additional description: Retained placenta or membranes (10038758)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	2 / 2222 (0.09%)	
occurrences (all)	2	2	
Uterine atony (10046763)	Additional description: Uterine atony (10046763)		
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 2209 (0.18%)	2 / 2222 (0.09%)	
occurrences (all)	4	2	
Uterine inversion (10046796)	Additional description: Uterine inversion (10046796)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Asthenia (10003549)	Additional description: Asthenia (10003549)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	2 / 2222 (0.09%)	
occurrences (all)	0	2	
Chest discomfort (10008469)	Additional description: Chest discomfort (10008469)		
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 2209 (0.14%)	1 / 2222 (0.05%)	
occurrences (all)	3	1	
Chest pain (10008479)	Additional description: Chest pain (10008479)		

alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 2209 (0.14%)	7 / 2222 (0.32%)	
occurrences (all)	3	7	
Chills (10008531)	Additional description: Chills (10008531)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	6 / 2222 (0.27%)	
occurrences (all)	1	6	
Crepitations (10011376)	Additional description: Crepitations (10011376)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Drug intolerance (10061822)	Additional description: Drug intolerance (10061822)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Face oedema (10016029)	Additional description: Face oedema (10016029)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Fatigue (10016256)	Additional description: Fatigue (10016256)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences (all)	1	1	
Feeling abnormal (10016322)	Additional description: Feeling abnormal (10016322)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Generalised oedema (10018092)	Additional description: Generalised oedema (10018092)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Hernia (10019909)	Additional description: Hernia (10019909)		
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Hyperthermia (10020843)	Additional description: Hyperthermia (10020843)		
alternative assessment type: Non-systematic			
subjects affected / exposed	10 / 2209 (0.45%)	9 / 2222 (0.41%)	
occurrences (all)	10	9	
Hypothermia (10021113)	Additional description: Hypothermia (10021113)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Inflammation (10061218)	Additional description: Inflammation (10061218)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Injection site haematoma (10022066)	Additional description: Injection site haematoma (10022066)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Injection site pain (10022086)	Additional description: Injection site pain (10022086)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Injection site paraesthesia (10022088)	Additional description: Injection site paraesthesia (10022088)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Localised oedema (10048961)	Additional description: Localised oedema (10048961)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Malaise (10025482)	Additional description: Malaise (10025482)		
alternative assessment type: Non-systematic			

subjects affected / exposed	21 / 2209 (0.95%)	13 / 2222 (0.59%)	
occurrences (all)	21	13	
Oedema (10030095)	Additional description: Oedema (10030095)		
alternative assessment type: Non-systematic			
subjects affected / exposed	11 / 2209 (0.50%)	16 / 2222 (0.72%)	
occurrences (all)	11	16	
Oedema peripheral (10030124)	Additional description: Oedema peripheral (10030124)		
alternative assessment type: Non-systematic			
subjects affected / exposed	129 / 2209 (5.84%)	133 / 2222 (5.99%)	
occurrences (all)	131	135	
Pain (10033371)	Additional description: Pain (10033371)		
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 2209 (0.18%)	4 / 2222 (0.18%)	
occurrences (all)	4	4	
Pyrexia (10037660)	Additional description: Pyrexia (10037660)		
alternative assessment type: Non-systematic			
subjects affected / exposed	7 / 2209 (0.32%)	18 / 2222 (0.81%)	
occurrences (all)	7	19	
Sense of oppression (10040007)	Additional description: Sense of oppression (10040007)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences (all)	1	1	
Swelling (10042674)	Additional description: Swelling (10042674)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Immune system disorders			
Hypersensitivity (10020751)	Additional description: Hypersensitivity (10020751)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	2 / 2222 (0.09%)	
occurrences (all)	2	2	
Reproductive system and breast disorders			
Breast cyst (10006220)	Additional description: Breast cyst (10006220)		
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Breast engorgement (10006240)	Additional description: Breast engorgement (10006240)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Breast mass (10006272)	Additional description: Breast mass (10006272)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	0 / 2222 (0.00%)	
occurrences (all)	2	0	
Dyspareunia (10013941)	Additional description: Dyspareunia (10013941)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Female genital tract fistula (10061149)	Additional description: Female genital tract fistula (10061149)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Galactocele (10017590)	Additional description: Galactocele (10017590)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Lactation disorder (10061261)	Additional description: Lactation disorder (10061261)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	2 / 2222 (0.09%)	
occurrences (all)	2	2	
Metrorrhagia (10027514)	Additional description: Metrorrhagia (10027514)		
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 2209 (0.18%)	1 / 2222 (0.05%)	
occurrences (all)	4	1	
Nipple disorder (10029417)	Additional description: Nipple disorder (10029417)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences (all)	1	1	

Ovarian cyst (10033132)	Additional description: Ovarian cyst (10033132)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Pelvic pain (10034263)	Additional description: Pelvic pain (10034263)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	2 / 2222 (0.09%)	
occurrences (all)	1	2	
Threatened uterine rupture (10080427)	Additional description: Threatened uterine rupture (10080427)		
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 2209 (0.14%)	2 / 2222 (0.09%)	
occurrences (all)	3	2	
Uterine haemorrhage (10046788)	Additional description: Uterine haemorrhage (10046788)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	4 / 2222 (0.18%)	
occurrences (all)	2	4	
Uterine pain (10046809)	Additional description: Uterine pain (10046809)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	0 / 2222 (0.00%)	
occurrences (all)	2	0	
Uterine spasm (10046823)	Additional description: Uterine spasm (10046823)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Vaginal discharge (10046901)	Additional description: Vaginal discharge (10046901)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Vulvovaginal pruritus (10056530)	Additional description: Vulvovaginal pruritus (10056530)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			

Asthma (10003553)	Additional description: Asthma (10003553)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Choking sensation (10008590)	Additional description: Choking sensation (10008590)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Cough (10011224)	Additional description: Cough (10011224)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	2 / 2222 (0.09%)	
occurrences (all)	1	3	
Dyspnoea (10013968)	Additional description: Dyspnoea (10013968)		
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 2209 (0.23%)	4 / 2222 (0.18%)	
occurrences (all)	5	4	
Emphysema (10014561)	Additional description: Emphysema (10014561)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Oropharyngeal pain (10068319)	Additional description: Oropharyngeal pain (10068319)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Productive cough (10036790)	Additional description: Productive cough (10036790)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Rales (10037833)	Additional description: Rales (10037833)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Respiratory distress (10038687)	Additional description: Respiratory distress (10038687)		
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Rhinorrhoea (10039101)	Additional description: Rhinorrhoea (10039101)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Throat irritation (10043521)	Additional description: Throat irritation (10043521)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Wheezing (10047924)	Additional description: Wheezing (10047924)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Psychiatric disorders			
Anxiety (10002855)	Additional description: Anxiety (10002855)		
alternative assessment type: Non-systematic			
subjects affected / exposed	7 / 2209 (0.32%)	4 / 2222 (0.18%)	
occurrences (all)	7	4	
Depressed mood (10012374)	Additional description: Depressed mood (10012374)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Depression (10012378)	Additional description: Depression (10012378)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	1 / 2222 (0.05%)	
occurrences (all)	2	1	
Dissociation (10013457)	Additional description: Dissociation (10013457)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Emotional distress (10049119)	Additional description: Emotional distress (10049119)		
alternative assessment type: Non-systematic			

subjects affected / exposed	9 / 2209 (0.41%)	8 / 2222 (0.36%)	
occurrences (all)	9	8	
Hallucination (10019063)	Additional description: Hallucination (10019063)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Hallucination, visual (10019075)	Additional description: Hallucination, visual (10019075)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Insomnia (10022437)	Additional description: Insomnia (10022437)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Mental disorder (10061284)	Additional description: Mental disorder (10061284)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Perinatal depression (10078366)	Additional description: Perinatal depression (10078366)		
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 2209 (0.18%)	6 / 2222 (0.27%)	
occurrences (all)	4	6	
Sleep disorder (10040984)	Additional description: Sleep disorder (10040984)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Hepatobiliary disorders			
Cholelithiasis (10008629)	Additional description: Cholelithiasis (10008629)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	2 / 2222 (0.09%)	
occurrences (all)	2	2	
Hepatocellular injury (10019837)	Additional description: Hepatocellular injury (10019837)		
alternative assessment type: Non-systematic			

subjects affected / exposed	6 / 2209 (0.27%)	10 / 2222 (0.45%)	
occurrences (all)	6	10	
Investigations			
Activated partial thromboplastin time prolonged (10000636)	Additional description: Activated partial thromboplastin time prolonged (10000636)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	0 / 2222 (0.00%)	
occurrences (all)	2	0	
Antinuclear antibody (10002807)	Additional description: Antinuclear antibody (10002807)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Blood alkaline phosphatase increased (10059570)	Additional description: Blood alkaline phosphatase increased (10059570)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Blood creatinine increased (10005483)	Additional description: Blood creatinine increased (10005483)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	1 / 2222 (0.05%)	
occurrences (all)	2	1	
Blood culture positive (10005488)	Additional description: Blood culture positive (10005488)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Blood glucose fluctuation (10049803)	Additional description: Blood glucose fluctuation (10049803)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Blood uric acid increased (10005861)	Additional description: Blood uric acid increased (10005861)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
C-reactive protein increased (10006825)	Additional description: C-reactive protein increased (10006825)		
alternative assessment type: Non-			

systematic			
subjects affected / exposed	2 / 2209 (0.09%)	1 / 2222 (0.05%)	
occurrences (all)	2	1	
Citrobacter test positive (10069963)	Additional description: Citrobacter test positive (10069963)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Electrocardiogram abnormal (10014363)	Additional description: Electrocardiogram abnormal (10014363)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Haemoglobin decreased (10018884)	Additional description: Haemoglobin decreased (10018884)		
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 2209 (0.23%)	2 / 2222 (0.09%)	
occurrences (all)	5	2	
Homans' sign positive (10051031)	Additional description: Homans' sign positive (10051031)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Liver function test abnormal (10024690)	Additional description: Liver function test abnormal (10024690)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences (all)	1	2	
Oxygen saturation decreased (10033318)	Additional description: Oxygen saturation decreased (10033318)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	2 / 2222 (0.09%)	
occurrences (all)	1	2	
Proteus test positive (10070134)	Additional description: Proteus test positive (10070134)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Renal function test abnormal (10061480)	Additional description: Renal function test abnormal (10061480)		
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Smear cervix abnormal (10041206)	Additional description: Smear cervix abnormal (10041206)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Transaminases increased (10054889)	Additional description: Transaminases increased (10054889)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences (all)	1	1	
Injury, poisoning and procedural complications			
Anaesthetic complication (10060938)	Additional description: Anaesthetic complication (10060938)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Arterial injury (10003162)	Additional description: Arterial injury (10003162)		
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 2209 (0.14%)	3 / 2222 (0.14%)	
occurrences (all)	3	3	
Bladder injury (10061698)	Additional description: Bladder injury (10061698)		
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 2209 (0.14%)	4 / 2222 (0.18%)	
occurrences (all)	3	4	
Dural tear (10063395)	Additional description: Dural tear (10063395)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	2 / 2222 (0.09%)	
occurrences (all)	1	2	
Fall (10016173)	Additional description: Fall (10016173)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	0 / 2222 (0.00%)	
occurrences (all)	2	0	
Head injury (10019196)	Additional description: Head injury (10019196)		
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Incision site discharge (10082296)	Additional description: Incision site discharge (10082296)		
alternative assessment type: Non-systematic			
subjects affected / exposed	11 / 2209 (0.50%)	6 / 2222 (0.27%)	
occurrences (all)	11	6	
Incision site haematoma (10059241)	Additional description: Incision site haematoma (10059241)		
alternative assessment type: Non-systematic			
subjects affected / exposed	24 / 2209 (1.09%)	12 / 2222 (0.54%)	
occurrences (all)	24	12	
Incision site haemorrhage (10051100)	Additional description: Incision site haemorrhage (10051100)		
alternative assessment type: Non-systematic			
subjects affected / exposed	10 / 2209 (0.45%)	6 / 2222 (0.27%)	
occurrences (all)	10	6	
Incision site hypoaesthesia (10069386)	Additional description: Incision site hypoaesthesia (10069386)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Incision site oedema (10065614)	Additional description: Incision site oedema (10065614)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	3 / 2222 (0.14%)	
occurrences (all)	1	3	
Incision site pain (10058043)	Additional description: Incision site pain (10058043)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Joint dislocation (10023204)	Additional description: Joint dislocation (10023204)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Ligament sprain (10024453)	Additional description: Ligament sprain (10024453)		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Meniscus injury (10072970)	Additional description: Meniscus injury (10072970)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Post lumbar puncture syndrome (10060854)	Additional description: Post lumbar puncture syndrome (10060854)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	4 / 2222 (0.18%)	
occurrences (all)	2	4	
Post procedural urine leak (10057587)	Additional description: Post procedural urine leak (10057587)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Postoperative wound complication (10061468)	Additional description: Postoperative wound complication (10061468)		
alternative assessment type: Non-systematic			
subjects affected / exposed	36 / 2209 (1.63%)	28 / 2222 (1.26%)	
occurrences (all)	36	28	
Procedural haemorrhage (10071229)	Additional description: Procedural haemorrhage (10071229)		
alternative assessment type: Non-systematic			
subjects affected / exposed	8 / 2209 (0.36%)	7 / 2222 (0.32%)	
occurrences (all)	8	7	
Procedural hypotension (10062300)	Additional description: Procedural hypotension (10062300)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	2 / 2222 (0.09%)	
occurrences (all)	2	2	
Procedural pain (10064882)	Additional description: Procedural pain (10064882)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Reproductive tract procedural complication (10081324)	Additional description: Reproductive tract procedural complication (10081324)		
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 2209 (0.05%)	3 / 2222 (0.14%)	
occurrences (all)	1	3	
Scar (10039580)	Additional description: Scar (10039580)		
alternative assessment type: Non-systematic			
subjects affected / exposed	8 / 2209 (0.36%)	7 / 2222 (0.32%)	
occurrences (all)	8	7	
Surgical procedure repeated (10042618)	Additional description: Surgical procedure repeated (10042618)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Transfusion-associated dyspnoea (10072266)	Additional description: Transfusion-associated dyspnoea (10072266)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Uterine rupture (10046820)	Additional description: Uterine rupture (10046820)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	4 / 2222 (0.18%)	
occurrences (all)	1	4	
Wound (10052428)	Additional description: Wound (10052428)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Wound secretion (10048629)	Additional description: Wound secretion (10048629)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Wrong technique in product usage process (10076573)	Additional description: Wrong technique in product usage process (10076573)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Congenital, familial and genetic disorders			

Thalassaemia (10043388)	Additional description: Thalassaemia (10043388)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			
Atrioventricular block (10003671)	Additional description: Atrioventricular block (10003671)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Bradycardia (10006093)	Additional description: Bradycardia (10006093)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	4 / 2222 (0.18%)	
occurrences (all)	2	4	
Extrasystoles (10015856)	Additional description: Extrasystoles (10015856)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Palpitations (10033557)	Additional description: Palpitations (10033557)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	3 / 2222 (0.14%)	
occurrences (all)	1	3	
Sinus tachycardia (10040752)	Additional description: Sinus tachycardia (10040752)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Tachycardia (10043071)	Additional description: Tachycardia (10043071)		
alternative assessment type: Non-systematic			
subjects affected / exposed	7 / 2209 (0.32%)	8 / 2222 (0.36%)	
occurrences (all)	7	8	
Nervous system disorders			
Carpal tunnel syndrome (10007697)	Additional description: Carpal tunnel syndrome (10007697)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	1 / 2222 (0.05%)	
occurrences (all)	2	1	
Cervical radiculopathy (10050217)	Additional description: Cervical radiculopathy (10050217)		

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Dizziness postural (10013578)	Additional description: Dizziness postural (10013578)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Dysarthria (10013887)	Additional description: Dysarthria (10013887)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Headache (10019211)	Additional description: Headache (10019211)		
alternative assessment type: Non-systematic			
subjects affected / exposed	46 / 2209 (2.08%)	44 / 2222 (1.98%)	
occurrences (all)	47	45	
Loss of consciousness (10024855)	Additional description: Loss of consciousness (10024855)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Migraine (10027599)	Additional description: Migraine (10027599)		
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 2209 (0.23%)	0 / 2222 (0.00%)	
occurrences (all)	5	0	
Migraine with aura (10027607)	Additional description: Migraine with aura (10027607)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Motor dysfunction (10061296)	Additional description: Motor dysfunction (10061296)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Paraesthesia (10033775)	Additional description: Paraesthesia (10033775)		
alternative assessment type: Non-systematic			

subjects affected / exposed	5 / 2209 (0.23%)	3 / 2222 (0.14%)	
occurrences (all)	5	3	
Presyncope (10036653)	Additional description: Presyncope (10036653)		
alternative assessment type: Non-systematic			
subjects affected / exposed	9 / 2209 (0.41%)	6 / 2222 (0.27%)	
occurrences (all)	9	6	
Sciatica (10039674)	Additional description: Sciatica (10039674)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Sensory disturbance (10040026)	Additional description: Sensory disturbance (10040026)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Syncope (10042772)	Additional description: Syncope (10042772)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Tremor (10044565)	Additional description: Tremor (10044565)		
alternative assessment type: Non-systematic			
subjects affected / exposed	8 / 2209 (0.36%)	5 / 2222 (0.23%)	
occurrences (all)	8	5	
Blood and lymphatic system disorders			
Anaemia (10002034)	Additional description: Anaemia (10002034)		
alternative assessment type: Non-systematic			
subjects affected / exposed	242 / 2209 (10.96%)	212 / 2222 (9.54%)	
occurrences (all)	242	212	
Anaemia of pregnancy (10066468)	Additional description: Anaemia of pregnancy (10066468)		
alternative assessment type: Non-systematic			
subjects affected / exposed	69 / 2209 (3.12%)	48 / 2222 (2.16%)	
occurrences (all)	70	48	
Coagulopathy (10009802)	Additional description: Coagulopathy (10009802)		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Hyperfibrinogenaemia (10051124)	Additional description: Hyperfibrinogenaemia (10051124)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Normocytic anaemia (10029784)	Additional description: Normocytic anaemia (10029784)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Pancytopenia (10033661)	Additional description: Pancytopenia (10033661)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Thrombocytopenia (10043554)	Additional description: Thrombocytopenia (10043554)		
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 2209 (0.14%)	7 / 2222 (0.32%)	
occurrences (all)	3	7	
Thrombocytosis (10043563)	Additional description: Thrombocytosis (10043563)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Ear and labyrinth disorders			
Tinnitus (10043882)	Additional description: Tinnitus (10043882)		
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 2209 (0.18%)	6 / 2222 (0.27%)	
occurrences (all)	4	6	
Tympanic membrane perforation (10045210)	Additional description: Tympanic membrane perforation (10045210)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Vertigo (10047340)	Additional description: Vertigo (10047340)		
alternative assessment type: Non-systematic			

subjects affected / exposed	102 / 2209 (4.62%)	112 / 2222 (5.04%)	
occurrences (all)	104	113	
Eye disorders			
Chalazion (10008388)	Additional description: Chalazion (10008388)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Eyelid oedema (10015993)	Additional description: Eyelid oedema (10015993)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Photophobia (10034960)	Additional description: Photophobia (10034960)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	2 / 2222 (0.09%)	
occurrences (all)	0	2	
Photopsia (10034962)	Additional description: Photopsia (10034962)		
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 2209 (0.14%)	8 / 2222 (0.36%)	
occurrences (all)	3	8	
Vision blurred (10047513)	Additional description: Vision blurred (10047513)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	1 / 2222 (0.05%)	
occurrences (all)	2	1	
Visual impairment (10047571)	Additional description: Visual impairment (10047571)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Abdominal distension (10000060)	Additional description: Abdominal distension (10000060)		
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 2209 (0.23%)	4 / 2222 (0.18%)	
occurrences (all)	5	4	
Abdominal pain (10000081)	Additional description: Abdominal pain (10000081)		
alternative assessment type: Non-systematic			

subjects affected / exposed	5 / 2209 (0.23%)	8 / 2222 (0.36%)	
occurrences (all)	5	8	
Abdominal pain lower (10000084)	Additional description: Abdominal pain lower (10000084)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	1 / 2222 (0.05%)	
occurrences (all)	2	1	
Abdominal pain upper (10000087)	Additional description: Abdominal pain upper (10000087)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	6 / 2222 (0.27%)	
occurrences (all)	0	6	
Abdominal wall haematoma (10067383)	Additional description: Abdominal wall haematoma (10067383)		
alternative assessment type: Non-systematic			
subjects affected / exposed	46 / 2209 (2.08%)	33 / 2222 (1.49%)	
occurrences (all)	46	33	
Constipation (10010774)	Additional description: Constipation (10010774)		
alternative assessment type: Non-systematic			
subjects affected / exposed	105 / 2209 (4.75%)	115 / 2222 (5.18%)	
occurrences (all)	106	115	
Diarrhoea (10012735)	Additional description: Diarrhoea (10012735)		
alternative assessment type: Non-systematic			
subjects affected / exposed	13 / 2209 (0.59%)	8 / 2222 (0.36%)	
occurrences (all)	13	8	
Dyspepsia (10013946)	Additional description: Dyspepsia (10013946)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Flatulence (10016766)	Additional description: Flatulence (10016766)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	1 / 2222 (0.05%)	
occurrences (all)	2	1	
Gastrointestinal pain (10017999)	Additional description: Gastrointestinal pain (10017999)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	

Gastrooesophageal reflux disease (10017885)	Additional description: Gastrooesophageal reflux disease (10017885)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	2 / 2222 (0.09%)	
occurrences (all)	1	2	
Haemorrhoids (10019022)	Additional description: Haemorrhoids (10019022)		
alternative assessment type: Non-systematic			
subjects affected / exposed	9 / 2209 (0.41%)	5 / 2222 (0.23%)	
occurrences (all)	9	5	
Haemorrhoids thrombosed (10019023)	Additional description: Haemorrhoids thrombosed (10019023)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Hypoaesthesia oral (10057371)	Additional description: Hypoaesthesia oral (10057371)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Intestinal mass (10059017)	Additional description: Intestinal mass (10059017)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Nausea (10028813)	Additional description: Nausea (10028813)		
alternative assessment type: Non-systematic			
subjects affected / exposed	475 / 2209 (21.50%)	529 / 2222 (23.81%)	
occurrences (all)	502	545	
Obstruction gastric (10029957)	Additional description: Obstruction gastric (10029957)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Toothache (10044055)	Additional description: Toothache (10044055)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Umbilical hernia (10045458)	Additional description: Umbilical hernia (10045458)		
alternative assessment type: Non-			

systematic			
subjects affected / exposed	2 / 2209 (0.09%)	0 / 2222 (0.00%)	
occurrences (all)	2	0	
Vomiting (10047700)	Additional description: Vomiting (10047700)		
alternative assessment type: Non-systematic			
subjects affected / exposed	254 / 2209 (11.50%)	299 / 2222 (13.46%)	
occurrences (all)	264	316	
Skin and subcutaneous tissue disorders			
Acne (10000496)	Additional description: Acne (10000496)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Blister (10005191)	Additional description: Blister (10005191)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Dermatitis (10012431)	Additional description: Dermatitis (10012431)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	0 / 2222 (0.00%)	
occurrences (all)	2	0	
Dermatitis allergic (10012434)	Additional description: Dermatitis allergic (10012434)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Dermatitis contact (10012442)	Additional description: Dermatitis contact (10012442)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences (all)	1	1	
Ecchymosis (10014080)	Additional description: Ecchymosis (10014080)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	2 / 2222 (0.09%)	
occurrences (all)	1	2	
Eczema (10014184)	Additional description: Eczema (10014184)		
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Erythema (10015150)	Additional description: Erythema (10015150)		
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 2209 (0.18%)	5 / 2222 (0.23%)	
occurrences (all)	4	5	
Hyperhidrosis (10020642)	Additional description: Hyperhidrosis (10020642)		
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 2209 (0.23%)	4 / 2222 (0.18%)	
occurrences (all)	5	4	
Pruritus (10037087)	Additional description: Pruritus (10037087)		
alternative assessment type: Non-systematic			
subjects affected / exposed	17 / 2209 (0.77%)	17 / 2222 (0.77%)	
occurrences (all)	17	17	
Pruritus generalised (10052576)	Additional description: Pruritus generalised (10052576)		
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 2209 (0.18%)	2 / 2222 (0.09%)	
occurrences (all)	4	2	
Rash (10037844)	Additional description: Rash (10037844)		
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 2209 (0.14%)	6 / 2222 (0.27%)	
occurrences (all)	3	6	
Rash erythematous (10037855)	Additional description: Rash erythematous (10037855)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Rash pruritic (10037884)	Additional description: Rash pruritic (10037884)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Scar pain (10049002)	Additional description: Scar pain (10049002)		
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 2209 (0.23%)	10 / 2222 (0.45%)	
occurrences (all)	5	10	

Skin maceration (10048625)	Additional description: Skin maceration (10048625)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences (all)	1	1	
Subcutaneous emphysema (10042344)	Additional description: Subcutaneous emphysema (10042344)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Urticaria (10046735)	Additional description: Urticaria (10046735)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	1 / 2222 (0.05%)	
occurrences (all)	2	1	
Renal and urinary disorders			
Acute kidney injury (10069339)	Additional description: Acute kidney injury (10069339)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Dysuria (10013990)	Additional description: Dysuria (10013990)		
alternative assessment type: Non-systematic			
subjects affected / exposed	9 / 2209 (0.41%)	9 / 2222 (0.41%)	
occurrences (all)	9	10	
Haematuria (10018867)	Additional description: Haematuria (10018867)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	1 / 2222 (0.05%)	
occurrences (all)	2	1	
Hypotonic urinary bladder (10058914)	Additional description: Hypotonic urinary bladder (10058914)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Nephrolithiasis (10029148)	Additional description: Nephrolithiasis (10029148)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Prerenal failure (10072370)	Additional description: Prerenal failure (10072370)		

alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Proteinuria (10037032)	Additional description: Proteinuria (10037032)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	2 / 2222 (0.09%)	
occurrences (all)	1	2	
Renal colic (10038419)	Additional description: Renal colic (10038419)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Renal failure (10038435)	Additional description: Renal failure (10038435)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Stress urinary incontinence (10066218)	Additional description: Stress urinary incontinence (10066218)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Tubulointerstitial nephritis (10048302)	Additional description: Tubulointerstitial nephritis (10048302)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Urinary bladder rupture (10046530)	Additional description: Urinary bladder rupture (10046530)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Urinary retention (10046555)	Additional description: Urinary retention (10046555)		
alternative assessment type: Non-systematic			
subjects affected / exposed	170 / 2209 (7.70%)	161 / 2222 (7.25%)	
occurrences (all)	170	161	
Endocrine disorders			

Hyperthyroidism (10020850)	Additional description: Hyperthyroidism (10020850)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Arthralgia (10003239)	Additional description: Arthralgia (10003239)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	2 / 2222 (0.09%)	
occurrences (all)	1	2	
Axillary mass (10049021)	Additional description: Axillary mass (10049021)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Back pain (10003988)	Additional description: Back pain (10003988)		
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 2209 (0.23%)	12 / 2222 (0.54%)	
occurrences (all)	5	12	
Coccydynia (10009829)	Additional description: Coccydynia (10009829)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences (all)	1	1	
Diastasis recti abdominis (10073169)	Additional description: Diastasis recti abdominis (10073169)		
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 2209 (0.14%)	0 / 2222 (0.00%)	
occurrences (all)	3	0	
Fistula (10016717)	Additional description: Fistula (10016717)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Flank pain (10016750)	Additional description: Flank pain (10016750)		
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 2209 (0.14%)	1 / 2222 (0.05%)	
occurrences (all)	3	1	
Intervertebral disc protrusion (10050296)	Additional description: Intervertebral disc protrusion (10050296)		

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Muscle spasms (10028334)	Additional description: Muscle spasms (10028334)		
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 2209 (0.14%)	0 / 2222 (0.00%)	
occurrences (all)	3	0	
Musculoskeletal chest pain (10050819)	Additional description: Musculoskeletal chest pain (10050819)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	2 / 2222 (0.09%)	
occurrences (all)	1	2	
Musculoskeletal pain (10028391)	Additional description: Musculoskeletal pain (10028391)		
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 2209 (0.18%)	3 / 2222 (0.14%)	
occurrences (all)	4	3	
Myositis (10028653)	Additional description: Myositis (10028653)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Neck pain (10028836)	Additional description: Neck pain (10028836)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	4 / 2222 (0.18%)	
occurrences (all)	1	4	
Pain in extremity (10033425)	Additional description: Pain in extremity (10033425)		
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 2209 (0.23%)	5 / 2222 (0.23%)	
occurrences (all)	6	5	
Polyarthritis (10036030)	Additional description: Polyarthritis (10036030)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Infections and infestations			
Abdominal wall abscess (10000099)	Additional description: Abdominal wall abscess (10000099)		
alternative assessment type: Non-systematic			

subjects affected / exposed	2 / 2209 (0.09%)	0 / 2222 (0.00%)	
occurrences (all)	2	0	
Acarodermatitis (10063409)	Additional description: Acarodermatitis (10063409)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Bacterial disease carrier (10004017)	Additional description: Bacterial disease carrier (10004017)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Bacterial vaginosis (10004055)	Additional description: Bacterial vaginosis (10004055)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	0 / 2222 (0.00%)	
occurrences (all)	2	0	
Bronchitis (10006451)	Additional description: Bronchitis (10006451)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Cystitis (10011781)	Additional description: Cystitis (10011781)		
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 2209 (0.14%)	1 / 2222 (0.05%)	
occurrences (all)	3	1	
Cystitis bacterial (10065198)	Additional description: Cystitis bacterial (10065198)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences (all)	1	1	
Cystitis escherichia (10011790)	Additional description: Cystitis escherichia (10011790)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	0 / 2222 (0.00%)	
occurrences (all)	2	0	
Dermatophytosis (10012504)	Additional description: Dermatophytosis (10012504)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	

Dermatophytosis of nail (10012511)	Additional description: Dermatophytosis of nail (10012511)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Ear infection (10014011)	Additional description: Ear infection (10014011)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Endometritis (10014791)	Additional description: Endometritis (10014791)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	8 / 2222 (0.36%)	
occurrences (all)	2	8	
Endometritis decidual (10014792)	Additional description: Endometritis decidual (10014792)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	2 / 2222 (0.09%)	
occurrences (all)	1	2	
Fungal infection (10017533)	Additional description: Fungal infection (10017533)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Incision site abscess (10049660)	Additional description: Incision site abscess (10049660)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	2 / 2222 (0.09%)	
occurrences (all)	2	2	
Influenza (10022000)	Additional description: Influenza (10022000)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Lung infection (10061229)	Additional description: Lung infection (10061229)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Lymphangitis (10025226)	Additional description: Lymphangitis (10025226)		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Mastitis (10026883)	Additional description: Mastitis (10026883)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	3 / 2222 (0.14%)	
occurrences (all)	2	3	
Nasal herpes (10074936)	Additional description: Nasal herpes (10074936)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	2 / 2222 (0.09%)	
occurrences (all)	0	2	
Nasopharyngitis (10028810)	Additional description: Nasopharyngitis (10028810)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Oral herpes (10067152)	Additional description: Oral herpes (10067152)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	3 / 2222 (0.14%)	
occurrences (all)	0	3	
Pilonidal cyst (10035043)	Additional description: Pilonidal cyst (10035043)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	0 / 2222 (0.00%)	
occurrences (all)	2	0	
Pneumonia (10035664)	Additional description: Pneumonia (10035664)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Puerperal pyrexia (10037294)	Additional description: Puerperal pyrexia (10037294)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Purulent discharge (10037569)	Additional description: Purulent discharge (10037569)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	1 / 2222 (0.05%)	
occurrences (all)	2	1	

Pyelonephritis (10037596)	Additional description: Pyelonephritis (10037596)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	2 / 2222 (0.09%)	
occurrences (all)	1	2	
Sinusitis (10040753)	Additional description: Sinusitis (10040753)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Skin infection (10040872)	Additional description: Skin infection (10040872)		
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 2209 (0.14%)	4 / 2222 (0.18%)	
occurrences (all)	3	4	
Tonsillitis (10044008)	Additional description: Tonsillitis (10044008)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Urinary tract infection (10046571)	Additional description: Urinary tract infection (10046571)		
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 2209 (0.18%)	10 / 2222 (0.45%)	
occurrences (all)	4	10	
Vaginal infection (10046914)	Additional description: Vaginal infection (10046914)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences (all)	1	1	
Vaginitis gardnerella (10046957)	Additional description: Vaginitis gardnerella (10046957)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	1 / 2222 (0.05%)	
occurrences (all)	1	1	
Vulvovaginal mycotic infection (10064899)	Additional description: Vulvovaginal mycotic infection (10064899)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			

Hyperinsulinaemic hypoglycaemia (10077216)	Additional description: Hyperinsulinaemic hypoglycaemia (10077216)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Hyperkalaemia (10020646)	Additional description: Hyperkalaemia (10020646)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Hypoglycaemia (10020993)	Additional description: Hypoglycaemia (10020993)		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2209 (0.09%)	2 / 2222 (0.09%)	
occurrences (all)	2	2	
Hypokalaemia (10021015)	Additional description: Hypokalaemia (10021015)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	2 / 2222 (0.09%)	
occurrences (all)	0	2	
Hypovitaminosis (10021135)	Additional description: Hypovitaminosis (10021135)		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2209 (0.05%)	0 / 2222 (0.00%)	
occurrences (all)	1	0	
Hypovolaemia (10021137)	Additional description: Hypovolaemia (10021137)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	
Obesity (10029883)	Additional description: Obesity (10029883)		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2209 (0.00%)	1 / 2222 (0.05%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 December 2017	1. Additional information in participant information letter upon request of CNIL (French Data Protection Authority) 2. Modification of the circuit of centralization of the nominative data 3. Addition of a investigating site (CHU de Caen)
15 February 2018	1. The 4-hour delay after the injection before the start of breastfeeding is removed 2. Comprehensive safety of all serious adverse events is reduced to the 1st month of participation. Only serious adverse events will then be reported. 3. A secondary medico-economic objective is added: calculation of the incremental cost/effectiveness ratio of TXA versus placebo from the point of view of health insurance 4. The inclusion criterion 'CBC within 3 days prior to caesarean section' becomes '...within 7 days prior to caesarean section'. 5. Change of the principal investigator of Sites CHU de Rennes and CHU de Toulouse 6. Addition of two investigating sites : CHI de Créteil and CH de Pau
18 June 2018	1. Changing the way centralized data is transmitted 2. The addition of a TRAAP 2 presentation poster for waiting rooms. 3. Addition of two investigating sites : CHU de Poitiers et CHU de Strasbourg (second site) 4. Modification of the possibility of participating in another study for TRAPP 2 participant
09 January 2019	1. Midwife role clarification. 2. Addition of a list of adverse events not to be reported (provided that they are not serious) 3. Updating the protocol and the information note in accordance with General Data Protection Regulation (GDPR) 4. Update of the SPC of Exacyl (Annex 2 of the protocol) 5. Update of the coordinating correspondents 6. Various typo corrections
31 May 2019	1. Increase in the number of expected patients 2. Punctual corrections in the protocol 3. Timing of study treatment 4. Modification of principal investigator for 2 sites : CHU de Besançon and CHU de Strasbourg

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/33913639

http://www.ncbi.nlm.nih.gov/pubmed/32005192