



Clinical trial results:

Intraoperative wound irrigation to prevent surgical site infection after laparotomy

Summary

EudraCT number	2017-000152-26
Trial protocol	DE
Global end of trial date	03 January 2022

Results information

Result version number	v1 (current)
This version publication date	19 January 2023
First version publication date	19 January 2023

Trial information

Trial identification

Sponsor protocol code	IOW-1755-REI-0540-I
-----------------------	---------------------

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Technische Universität München, Fakultät für Medizin
Sponsor organisation address	Ismaninger Str. 22, München, Germany, 81675
Public contact	Prof. Dr. Daniel Reim, Klinikum rechts der Isar der Technischen Universität München Department of Surgery, 0049 (0)8941405019, daniel.reim@tum.de
Scientific contact	Prof. Dr. Daniel Reim, Klinikum rechts der Isar der Technischen Universität München Department of Surgery, 0049 (0)8941405019, daniel.reim@tum.de

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	03 January 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	03 January 2022
Global end of trial reached?	Yes
Global end of trial date	03 January 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate whether the use of intraoperative, epifascial wound irrigation with polyhexanide (PHX) solution can reduce surgical site infections after laparotomy for visceral surgery compared to saline irrigation or no irrigation.

Protection of trial subjects:

The conduct of this clinical study met all local legal and regulatory requirements. The study was conducted in accordance the ethical principles of Good Clinical Practice (GCP). Participating subjects signed informed consent form and could withdraw from the study at any time without any disadvantage and without having to provide a reason for this decision. The study was regularly monitored by the Sponsor and all investigators connected to the study were GCP trained.

Background therapy:

Standard of care.

Evidence for comparator:

No intraoperative wound irrigation.

Actual start date of recruitment	19 September 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	Germany: 689
Worldwide total number of subjects	689
EEA total number of subjects	689

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)	332
From 65 to 84 years	347
85 years and over	10

Subject disposition

Recruitment

Recruitment details:

The study was conducted multicentric (10 study sites) in Germany. The recruitment took place between September 21, 2017 (first patient recruited) and January 3, 2022 (last patient completed).

Pre-assignment

Screening details:

All patients that underwent visceral surgery by laparotomy within the recruitment period were screened for the trial.

The patients must be thoroughly informed about all aspects of the study. Only patients who meet all inclusion criteria and who do not have any exclusion criteria were included in the clinical study (screening).

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind ^[1]
Roles blinded	Subject, Data analyst, Assessor

Blinding implementation details:

The blinding procedure is restricted to participating patients, outcome assessors and the trial statistician. Blinding of the surgical team that performs the intervention is impossible because the control arm does not receive any wound irrigation. A member of the local study team, who will not take part in postoperative patient visits, performs randomization after confirmed closure of the abdominal fascia. A central online randomization tool of the MSZ (RANDOBASE) will effectuate randomization.

Arms

Are arms mutually exclusive?	Yes
Arm title	Intervention I: PHX

Arm description:

- Intervention 1: Irrigation of the subcutaneous tissue after closure of the abdominal fascia with 1000ml PHX solution (0.04%)

Treatment Arm: To investigate whether the use of intraoperative, epifascial wound irrigation with polyhexanide (PHX) solution can reduce surgical site infections after laparotomy for visceral surgery compared to saline irrigation or no irrigation.

Arm type	Experimental
Investigational medicinal product name	POLIHAXANIDE
Investigational medicinal product code	SUB09970MIG
Other name	CAS number 32289-58-0,
Pharmaceutical forms	Irrigation solution
Routes of administration	Other use

Dosage and administration details:

1000 ml total

Arm title	Intervention 2: Saline
------------------	------------------------

Arm description:

- Intervention 2: Irrigation of the subcutaneous tissue after closure of the abdominal fascia with 1000ml saline solution (NaCl 0.9%)

Arm type	comparator
No investigational medicinal product assigned in this arm	

Arm title	No Irrigation -control arm
------------------	----------------------------

Arm description:

No Intervention - control arm (Standard of care)

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

Notes:

[1] - The roles blinded appear to be inconsistent with a double blind trial.

Justification: This is an observer and patient blinded study.

Number of subjects in period 1	Intervention 1: PHX	Intervention 2: Saline	No Irrigation - control arm
Started	292	295	102
Completed	242	238	77
Not completed	50	57	25
Adverse event, serious fatal	2	7	2
Consent withdrawn by subject	4	5	2
Adverse event, non-fatal	30	36	16
Not specified	5	-	3
Lost to follow-up	9	9	2

Baseline characteristics

Reporting groups

Reporting group title	Intervention I: PHX
Reporting group description:	
<ul style="list-style-type: none"> Intervention 1: Irrigation of the subcutaneous tissue after closure of the abdominal fascia with 1000ml PHX solution (0.04%) 	
Treatment Arm: To investigate whether the use of intraoperative, epifascial wound irrigation with polyhexanide (PHX) solution can reduce surgical site infections after laparotomy for visceral surgery compared to saline irrigation or no irrigation.	
Reporting group title	Intervention 2: Saline
Reporting group description:	
<ul style="list-style-type: none"> Intervention 2: Irrigation of the subcutaneous tissue after closure of the abdominal fascia with 1000ml saline solution (NaCl 0.9%) 	
Reporting group title	No Irrigation -control arm
Reporting group description:	
No Intervention - control arm (Standard of care)	

Reporting group values	Intervention I: PHX	Intervention 2: Saline	No Irrigation - control arm
Number of subjects	292	295	102
Age categorical			
Units: Subjects			
Adults (18-64 years)	138	137	57
From 65-84 years	151	153	43
85 years and over	3	5	2
Gender categorical			
Units: Subjects			
Female	126	124	37
Male	166	171	65
ASA			
Units: Subjects			
ASA=1	19	17	5
ASA=2	122	126	44
ASA=3	151	152	53
BMI			
Body mass index			
Units: Subjects			
BMI < 18.5	3	8	8
18.5 <= BMI < 25	145	125	39
25 <= BMI < 30	94	110	39
30 <= BMI	50	52	16
Diabetes			
Diabetes as an ongoing comorbidity			
Units: Subjects			
yes	54	59	21
no	238	236	81
Smoker			
Units: Subjects			
no	192	205	63

yes, current	45	47	18
yes, previously	55	43	21
Alcohol			
Alcohol consume			
Units: Subjects			
no	214	218	74
yes, currently	69	61	25
yes, previously	9	16	3
Previous abdominal surgeries			
Units: Subjects			
yes	175	200	65
no	117	95	37
History of SSI			
Units: Subjects			
yes	17	11	9
no	275	284	93
History of radiotherapy			
Units: Subjects			
yes	31	39	12
no	261	256	90
History of chemotherapy			
Units: Subjects			
yes	83	99	33
no	209	196	69
Main surgery type			
Units: Subjects			
Colorectal	56	52	21
HBP	174	177	60
Upper-GI	54	55	18
Other	8	9	3
Not specified	0	2	0
Level of contamination			
Units: Subjects			
Class I (clean)	1	1	0
Class II (clean-contaminated)	271	272	94
Class III (contaminated)	18	22	8
Class IV (dirty-infected)	2	0	0

Reporting group values	Total		
Number of subjects	689		
Age categorical			
Units: Subjects			
Adults (18-64 years)	332		
From 65-84 years	347		
85 years and over	10		
Gender categorical			
Units: Subjects			
Female	287		
Male	402		

ASA			
Units: Subjects			
ASA=1	41		
ASA=2	292		
ASA=3	356		
BMI			
Body mass index			
Units: Subjects			
BMI < 18.5	19		
18.5 <= BMI < 25	309		
25 <= BMI < 30	243		
30 <= BMI	118		
Diabetes			
Diabetes as an ongoing comorbidity			
Units: Subjects			
yes	134		
no	555		
Smoker			
Units: Subjects			
no	460		
yes, current	110		
yes, previously	119		
Alcohol			
Alcohol consume			
Units: Subjects			
no	506		
yes, currently	155		
yes, previously	28		
Previous abdominal surgeries			
Units: Subjects			
yes	440		
no	249		
History of SSI			
Units: Subjects			
yes	37		
no	652		
History of radiotherapy			
Units: Subjects			
yes	82		
no	607		
History of chemotherapy			
Units: Subjects			
yes	215		
no	474		
Main surgery type			
Units: Subjects			
Colorectal	129		
HBP	411		
Upper-GI	127		
Other	20		
Not specified	2		

Level of contamination			
Units: Subjects			
Class I (clean)	2		
Class II (clean-contaminated)	637		
Class III (contaminated)	48		
Class IV (dirty-infected)	2		

Subject analysis sets

Subject analysis set title	Intention to treat
Subject analysis set type	Intention-to-treat

Subject analysis set description:

The ITT set contains all randomized patients with results attributed to the treatment group they were randomized to.

Reporting group values	Intention to treat		
Number of subjects	689		
Age categorical			
Units: Subjects			
Adults (18-64 years)	332		
From 65-84 years	347		
85 years and over	10		
Gender categorical			
Units: Subjects			
Female	287		
Male	402		
ASA			
Units: Subjects			
ASA=1	41		
ASA=2	292		
ASA=3	356		
BMI			
Body mass index			
Units: Subjects			
BMI < 18.5	19		
18.5 <= BMI < 25	309		
25 <= BMI < 30	243		
30 <= BMI	118		
Diabetes			
Diabetes as an ongoing comorbidity			
Units: Subjects			
yes	134		
no	555		
Smoker			
Units: Subjects			
no	460		
yes, current	110		
yes, previously	119		
Alcohol			
Alcohol consume			
Units: Subjects			

no	506		
yes, currently	155		
yes, previously	28		
Previous abdominal surgeries Units: Subjects			
yes	440		
no	249		
History of SSI Units: Subjects			
yes	37		
no	652		
History of radiotherapy Units: Subjects			
yes	82		
no	607		
History of chemotherapy Units: Subjects			
yes	215		
no	474		
Main surgery type Units: Subjects			
Colorectal	129		
HBP	411		
Upper-GI	127		
Other	20		
Not specified	2		
Level of contamination Units: Subjects			
Class I (clean)	2		
Class II (clean-contaminated)	637		
Class III (contaminated)	48		
Class IV (dirty-infected)	2		

End points

End points reporting groups

Reporting group title	Intervention I: PHX
Reporting group description:	
<ul style="list-style-type: none">Intervention 1: Irrigation of the subcutaneous tissue after closure of the abdominal fascia with 1000ml PHX solution (0.04%)	
Treatment Arm: To investigate whether the use of intraoperative, epifascial wound irrigation with polyhexanide (PHX) solution can reduce surgical site infections after laparotomy for visceral surgery compared to saline irrigation or no irrigation.	
Reporting group title	Intervention 2: Saline
Reporting group description:	
<ul style="list-style-type: none">Intervention 2: Irrigation of the subcutaneous tissue after closure of the abdominal fascia with 1000ml saline solution (NaCl 0.9%)	
Reporting group title	No Irrigation -control arm
Reporting group description:	
No Intervention - control arm (Standard of care)	
Subject analysis set title	Intention to treat
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
The ITT set contains all randomized patients with results attributed to the treatment group they were randomized to.	

Primary: SSI

End point title	SSI
End point description:	
Frequency of SSI within 30 days of surgery	
End point type	Primary
End point timeframe:	
within 30 days of surgery	

End point values	Intervention I: PHX	Intervention 2: Saline	No Irrigation - control arm	Intention to treat
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	292	295	102	689
Units: patients				
yes	31	37	13	81
no	261	258	89	608

Statistical analyses

Statistical analysis title	Competing risks I
Statistical analysis description:	
Subdistributional hazard model of Fine and Gray with SSI as main event, re-laparotomy and death as competing risks, treatment group, level of contamination, and BMI class as covariates.	
Comparison groups	Intervention I: PHX v No Irrigation -control arm

Number of subjects included in analysis	394
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.544 ^[1]
Method	Fine and Gray subdistributional hazard
Parameter estimate	Hazard ratio (HR)
Point estimate	1.226
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.636
upper limit	2.364

Notes:

[1] - Not statistically significant

Statistical analysis title	Competing risks II
-----------------------------------	--------------------

Statistical analysis description:

Subdistributional hazard model of Fine and Gray with SSI as main event, re-laparotomy and death as competing risks, treatment group, level of contamination, and BMI class as covariates.

Comparison groups	Intervention I: PHX v Intervention 2: Saline
Number of subjects included in analysis	587
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.471 ^[2]
Method	Fine and Gray subdistributional hazard
Parameter estimate	Hazard ratio (HR)
Point estimate	1.194
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.737
upper limit	1.937

Notes:

[2] - Not statistically significant

Secondary: Type of SSI

End point title	Type of SSI
-----------------	-------------

End point description:

End point type	Secondary
----------------	-----------

End point timeframe:

Within 30 days of surgery

End point values	Intervention 1: PHX	Intervention 2: Saline	No Irrigation - control arm	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	292	295	102	
Units: patients				
No SSI	254	248	85	
Superficial incisional SSI	15	22	9	
Deep incisional SSI	7	6	1	
Organ space SSI	9	9	3	
Missing	7	10	4	

Statistical analyses

Statistical analysis title	Type of SSI I
Statistical analysis description:	
Difference in type of SSI between PHX and no irrigation	
Comparison groups	Intervention I: PHX v No Irrigation -control arm
Number of subjects included in analysis	394
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.507
Method	Fisher exact

Statistical analysis title	Type of SSI II
Statistical analysis description:	
Difference in type of SSI between PHX and saline solution	
Comparison groups	Intervention I: PHX v Intervention 2: Saline
Number of subjects included in analysis	587
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.699
Method	Fisher exact

Secondary: Re-laparotomy

End point title	Re-laparotomy
End point description:	
End point type	Secondary
End point timeframe:	
Within 30 days of surgery	

End point values	Intervention 1: PHX	Intervention 2: Saline	No Irrigation - control arm	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	292	295	102	
Units: patients				
yes	27	31	15	
no	265	264	87	

Statistical analyses

Statistical analysis title	Re-laparotomy I
Statistical analysis description: Differences in the frequency of re-laparotomy between PHX and no irrigation	
Comparison groups	Intervention 1: PHX v No Irrigation -control arm
Number of subjects included in analysis	394
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.124
Method	Chi-squared

Statistical analysis title	Re-laparotomy II
Statistical analysis description: Differences in the frequency of re-laparotomy between PHX and saline solution	
Comparison groups	Intervention 1: PHX v Intervention 2: Saline
Number of subjects included in analysis	587
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.609
Method	Chi-squared

Secondary: 30-day mortality

End point title	30-day mortality
End point description:	
End point type	Secondary
End point timeframe: within 30 days of surgery	

End point values	Intervention 1: PHX	Intervention 2: Saline	No Irrigation - control arm	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	292	295	102	
Units: patients				
died within 30 days of surgery	2	6	2	
alive within 30 days of surgery	290	289	100	

Statistical analyses

Statistical analysis title	30 day mortality I
Statistical analysis description: Differences in 30-day mortality between PHX and no irrigation	
Comparison groups	Intervention 1: PHX v No Irrigation -control arm
Number of subjects included in analysis	394
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.276
Method	Fisher exact

Statistical analysis title	30 day mortality II
Statistical analysis description: Differences in 30-day mortality between PHX and saline solution	
Comparison groups	Intervention 1: PHX v Intervention 2: Saline
Number of subjects included in analysis	587
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.286
Method	Fisher exact

Secondary: Any non-infectious wound complications

End point title	Any non-infectious wound complications
End point description:	
End point type	Secondary
End point timeframe: within 30 days of surgery	

End point values	Intervention 1: PHX	Intervention 2: Saline	No Irrigation - control arm	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	292	295	102	
Units: patients				
yes	53	51	21	
no	232	234	77	
missing	7	10	4	

Statistical analyses

Statistical analysis title	Any non-infectious wound complications I
Statistical analysis description:	
Difference in the frequency of any non-infectious wound complications between PHX and no irrigation	
Comparison groups	No Irrigation -control arm v Intervention I: PHX
Number of subjects included in analysis	394
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.54
Method	Chi-squared

Statistical analysis title	Any non-infectious wound complications II
Statistical analysis description:	
Difference in the frequency of any non-infectious wound complications between PHX and saline solution	
Comparison groups	Intervention I: PHX v Intervention 2: Saline
Number of subjects included in analysis	587
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.828
Method	Chi-squared

Secondary: Duration of hospital stay

End point title	Duration of hospital stay
End point description:	
End point type	Secondary
End point timeframe: entire study	

End point values	Intervention 1: PHX	Intervention 2: Saline	No Irrigation - control arm	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	292	295	102	
Units: day				
median (full range (min-max))	14.5 (4 to 45)	15 (5 to 41)	13 (5 to 46)	

Statistical analyses

Statistical analysis title	Duration of hospital stay I
Statistical analysis description: Difference in duration of hospital stay between PHX and no irrigation	
Comparison groups	Intervention I: PHX v No Irrigation -control arm
Number of subjects included in analysis	394
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.563
Method	Wilcoxon (Mann-Whitney)

Statistical analysis title	Duration of hospital stay II
Statistical analysis description: Difference in duration of hospital stay between PHX and saline solution	
Comparison groups	Intervention I: PHX v Intervention 2: Saline
Number of subjects included in analysis	587
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.234
Method	Wilcoxon (Mann-Whitney)

Secondary: Number of AEs per patient

End point title	Number of AEs per patient
End point description:	
End point type	Secondary
End point timeframe: entire study	

End point values	Intervention 1: PHX	Intervention 2: Saline	No Irrigation - control arm	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	292	295	102	
Units: number				
median (full range (min-max))	2 (0 to 18)	2 (0 to 15)	1 (1 to 20)	

Statistical analyses

Statistical analysis title	Number of AEs per patient I
Statistical analysis description:	
Differences in the number of AEs per patient in PHX and no irrigation	
Comparison groups	Intervention I: PHX v No Irrigation -control arm
Number of subjects included in analysis	394
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.823
Method	Wilcoxon (Mann-Whitney)

Statistical analysis title	Number of AEs per patient II
Statistical analysis description:	
Differences in the number of AEs per patient in PHX and saline solution	
Comparison groups	Intervention I: PHX v Intervention 2: Saline
Number of subjects included in analysis	587
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.128
Method	Wilcoxon (Mann-Whitney)

Secondary: Number of SAEs per patient

End point title	Number of SAEs per patient
End point description:	
End point type	Secondary
End point timeframe:	
entire study	

End point values	Intervention 1: PHX	Intervention 2: Saline	No Irrigation - control arm	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	292	295	102	
Units: number				
median (full range (min-max))	0 (0 to 8)	0 (0 to 5)	0 (0 to 7)	

Statistical analyses

Statistical analysis title	Number of SAEs per patient I
Statistical analysis description:	
Differences in the number of SAEs per patient between PHX and no irrigation	
Comparison groups	Intervention I: PHX v No Irrigation -control arm
Number of subjects included in analysis	394
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.288
Method	Wilcoxon (Mann-Whitney)

Statistical analysis title	Number of SAEs per patient II
Statistical analysis description:	
Differences in the number of SAEs per patient between PHX and saline solution	
Comparison groups	Intervention I: PHX v Intervention 2: Saline
Number of subjects included in analysis	587
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.515
Method	Wilcoxon (Mann-Whitney)

Adverse events

Adverse events information

Timeframe for reporting adverse events:

The obligation to document any AE in the study, starts with the randomization and ends with completion of the last study visit.

Adverse event reporting additional description:

AE/SAEs are documented according to the standard grading on the AE/SAE reporting forms. Surgical site infections (primary endpoint) and all other local wound complications (secondary endpoint) will be documented as AE/SAE. In addition, their severity and the consequent treatment will be documented according to the Clavien Dindo classification.

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	MedDRA
Dictionary version	20

Reporting groups

Reporting group title	Intervention I: PHX
-----------------------	---------------------

Reporting group description:

Patients treated with PHX irrigation

Reporting group title	Saline solution
-----------------------	-----------------

Reporting group description:

Irrigation with saline solution

Reporting group title	No irrigation
-----------------------	---------------

Reporting group description: -

Serious adverse events	Intervention I: PHX	Saline solution	No irrigation
Total subjects affected by serious adverse events			
subjects affected / exposed	95 / 291 (32.65%)	104 / 295 (35.25%)	63 / 103 (61.17%)
number of deaths (all causes)	17	25	8
number of deaths resulting from adverse events	17	25	8
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Gastric cancer			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to lung			

subjects affected / exposed	0 / 291 (0.00%)	0 / 295 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Arterial haemorrhage			
subjects affected / exposed	1 / 291 (0.34%)	5 / 295 (1.69%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 0
Circulatory collapse			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	3 / 291 (1.03%)	3 / 295 (1.02%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hypotension			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemia			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Lymphatic fistula			
subjects affected / exposed	1 / 291 (0.34%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock haemorrhagic			

subjects affected / exposed	0 / 291 (0.00%)	2 / 295 (0.68%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Superior mesenteric artery syndrome			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Surgical and medical procedures			
Hepatectomy			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical device battery replacement			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatectomy			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreaticojejunostomy			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Resuscitation			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheostomy			

subjects affected / exposed	0 / 291 (0.00%)	0 / 295 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary cystectomy			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	0 / 291 (0.00%)	0 / 295 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	4 / 291 (1.37%)	2 / 295 (0.68%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernia			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired healing			
subjects affected / exposed	1 / 291 (0.34%)	2 / 295 (0.68%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			

subjects affected / exposed	2 / 291 (0.69%)	2 / 295 (0.68%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 0
Pain			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	3 / 291 (1.03%)	3 / 295 (1.02%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asphyxia			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspiration			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	3 / 291 (1.03%)	5 / 295 (1.69%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonia aspiration			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pulmonary embolism			
subjects affected / exposed	4 / 291 (1.37%)	2 / 295 (0.68%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	3 / 291 (1.03%)	2 / 295 (0.68%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Thoracic haemorrhage			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			

Delirium			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device dislocation			
subjects affected / exposed	3 / 291 (1.03%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Biopsy pancreas			
subjects affected / exposed	0 / 291 (0.00%)	0 / 295 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood electrolytes abnormal			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
C-reactive protein increased			
subjects affected / exposed	1 / 291 (0.34%)	3 / 295 (1.02%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decreased			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory marker increased			
subjects affected / exposed	4 / 291 (1.37%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Oxygen saturation decreased subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcus test positive subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count increased subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Abdominal wound dehiscence subjects affected / exposed	2 / 291 (0.69%)	5 / 295 (1.69%)	3 / 103 (2.91%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Anastomotic complication			
subjects affected / exposed	7 / 291 (2.41%)	9 / 295 (3.05%)	5 / 103 (4.85%)
occurrences causally related to treatment / all	0 / 7	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 1
Anastomotic leak			
subjects affected / exposed	4 / 291 (1.37%)	6 / 295 (2.03%)	3 / 103 (2.91%)
occurrences causally related to treatment / all	0 / 4	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pancreatic leak			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anastomotic haemorrhage			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural bile leak			
subjects affected / exposed	3 / 291 (1.03%)	2 / 295 (0.68%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary anastomosis complication			
subjects affected / exposed	0 / 291 (0.00%)	0 / 295 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brachial plexus injury			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal anastomotic leak			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal anastomosis complication			

subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative delirium			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative respiratory distress			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seroma			
subjects affected / exposed	3 / 291 (1.03%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suture related complication			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal injury			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			
subjects affected / exposed	4 / 291 (1.37%)	2 / 295 (0.68%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound haemorrhage			

subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound secretion			
subjects affected / exposed	1 / 291 (0.34%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 291 (0.00%)	2 / 295 (0.68%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Arrhythmia			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	1 / 291 (0.34%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac failure			
subjects affected / exposed	1 / 291 (0.34%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiopulmonary failure			

subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiovascular disorder			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Nervous system disorders			
Carotid artery stenosis			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	1 / 291 (0.34%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Monoparesis			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurological symptom			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord paresis			

subjects affected / exposed	1 / 291 (0.34%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulopathy			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic infarction			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Intra-abdominal haemorrhage			
subjects affected / exposed	1 / 291 (0.34%)	1 / 295 (0.34%)	3 / 103 (2.91%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Abdominal compartment syndrome			
subjects affected / exposed	1 / 291 (0.34%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Abdominal pain			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			

subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute abdomen			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Ascites			
subjects affected / exposed	1 / 291 (0.34%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric perforation			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 291 (0.34%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal ischaemia			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal motility disorder			
subjects affected / exposed	3 / 291 (1.03%)	1 / 295 (0.34%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal necrosis			

subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus paralytic			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	2 / 291 (0.69%)	2 / 295 (0.68%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal dilatation			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal fistula			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	1 / 291 (0.34%)	2 / 295 (0.68%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal fluid collection			

subjects affected / exposed	2 / 291 (0.69%)	2 / 295 (0.68%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 291 (0.34%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic fistula			
subjects affected / exposed	3 / 291 (1.03%)	6 / 295 (2.03%)	2 / 103 (1.94%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pancreatitis acute			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal haematoma			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 291 (0.00%)	0 / 295 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 291 (0.34%)	1 / 295 (0.34%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary ascites			

subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 291 (0.00%)	3 / 295 (1.02%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal haematoma			
subjects affected / exposed	3 / 291 (1.03%)	2 / 295 (0.68%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct necrosis			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract disorder			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biloma			
subjects affected / exposed	2 / 291 (0.69%)	3 / 295 (1.02%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	2 / 291 (0.69%)	6 / 295 (2.03%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder fistula			

subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder rupture			
subjects affected / exposed	2 / 291 (0.69%)	0 / 295 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hepatic artery occlusion			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 291 (0.00%)	2 / 295 (0.68%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Hepatic infarction			
subjects affected / exposed	0 / 291 (0.00%)	0 / 295 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein occlusion			
subjects affected / exposed	0 / 291 (0.00%)	0 / 295 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein stenosis			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			

subjects affected / exposed	1 / 291 (0.34%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	3 / 291 (1.03%)	0 / 295 (0.00%)	2 / 103 (1.94%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Urethral disorder			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula			
subjects affected / exposed	2 / 291 (0.69%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	2 / 291 (0.69%)	2 / 295 (0.68%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal infection			
subjects affected / exposed	0 / 291 (0.00%)	0 / 295 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Abscess			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder abscess			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma infection			
subjects affected / exposed	0 / 291 (0.00%)	2 / 295 (0.68%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal gangrene			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Liver abscess			

subjects affected / exposed	2 / 291 (0.69%)	0 / 295 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric abscess			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perihepatic abscess			
subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 291 (0.00%)	3 / 295 (1.02%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	6 / 291 (2.06%)	3 / 295 (1.02%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	2 / 291 (0.69%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	3 / 291 (1.03%)	2 / 295 (0.68%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 0
Septic shock			
subjects affected / exposed	1 / 291 (0.34%)	2 / 295 (0.68%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superinfection			

subjects affected / exposed	0 / 291 (0.00%)	1 / 295 (0.34%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 291 (0.00%)	0 / 295 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	4 / 291 (1.37%)	4 / 295 (1.36%)	2 / 103 (1.94%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus inadequate control			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid retention			
subjects affected / exposed	2 / 291 (0.69%)	6 / 295 (2.03%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hyperglycaemia			
subjects affected / exposed	2 / 291 (0.69%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 291 (0.00%)	0 / 295 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			

subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 291 (0.00%)	0 / 295 (0.00%)	2 / 103 (1.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 3 diabetes mellitus			
subjects affected / exposed	1 / 291 (0.34%)	0 / 295 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Intervention I: PHX	Saline solution	No irrigation
Total subjects affected by non-serious adverse events			
subjects affected / exposed	179 / 291 (61.51%)	198 / 295 (67.12%)	40 / 103 (38.83%)
Investigations			
C-reactive protein increased			
subjects affected / exposed	12 / 291 (4.12%)	17 / 295 (5.76%)	3 / 103 (2.91%)
occurrences (all)	12	18	3
Inflammatory marker increased			
subjects affected / exposed	9 / 291 (3.09%)	14 / 295 (4.75%)	2 / 103 (1.94%)
occurrences (all)	9	16	2
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	8 / 291 (2.75%)	7 / 295 (2.37%)	6 / 103 (5.83%)
occurrences (all)	8	7	6
Seroma			
subjects affected / exposed	16 / 291 (5.50%)	13 / 295 (4.41%)	3 / 103 (2.91%)
occurrences (all)	16	13	3
Wound dehiscence			
subjects affected / exposed	13 / 291 (4.47%)	6 / 295 (2.03%)	3 / 103 (2.91%)
occurrences (all)	13	6	3
General disorders and administration			

site conditions			
Impaired healing			
subjects affected / exposed	21 / 291 (7.22%)	15 / 295 (5.08%)	3 / 103 (2.91%)
occurrences (all)	21	16	3
Pyrexia			
subjects affected / exposed	12 / 291 (4.12%)	15 / 295 (5.08%)	3 / 103 (2.91%)
occurrences (all)	12	16	3
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	30 / 291 (10.31%)	29 / 295 (9.83%)	5 / 103 (4.85%)
occurrences (all)	30	29	5
Vomiting			
subjects affected / exposed	20 / 291 (6.87%)	24 / 295 (8.14%)	6 / 103 (5.83%)
occurrences (all)	20	25	6
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	9 / 291 (3.09%)	19 / 295 (6.44%)	0 / 103 (0.00%)
occurrences (all)	9	21	0
Wound infection			
subjects affected / exposed	12 / 291 (4.12%)	11 / 295 (3.73%)	7 / 103 (6.80%)
occurrences (all)	12	12	7
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	19 / 291 (6.53%)	30 / 295 (10.17%)	8 / 103 (7.77%)
occurrences (all)	19	33	8

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 May 2019	Addition of two further trial sites
08 March 2021	Major changes: <ul style="list-style-type: none">- Extension of study duration- Changes in statistical analysis plan because of an unexpected high number of drop-outs due to relaparotomy- to maintain statistical power, the sample size had to be increased

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported