Clinical trial results:
A phase II randomized, placebo-controlled, double-blind, dose-escalation study to evaluate safety, pharmacokinetics and pharmacodynamic dose response relationship of IFX-1 in patients undergoing complex cardiac surgery (CARDIAC)

Summary

EudraCT number	2015-003036-12
Trial protocol	DE
Global end of trial date	24 January 2017

Results information

Result version number	v1 (current)
This version publication date	14 May 2021
First version publication date	14 May 2021

Trial information

Trial identification

Sponsor protocol code	IFX-1-P2.2

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	InflaRx GmbH
Sponsor organisation address	Winzerlaer Str.2, Jena, Germany, 07745
Public contact	InflaRx GmbH, InflaRx GmbH, +49 3641508 180, info@inflarx.de
Scientific contact	InflaRx GmbH, InflaRx GmbH, +49 3641508 180, info@inflarx.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	20 October 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	24 January 2017
Global end of trial reached?	Yes
Global end of trial date	24 January 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the effect of four different doses of IFX-1 on interleukin (IL)-6 peak levels in patients undergoing complex cardiac surgery compared to placebo.

Protection of trial subjects:

The study was conducted in accordance with the ethical principles of the Declaration of Helsinki (Version Fortaleza 2013), as well as all pertinent laws and the International Conference on Harmonization (ICH) guidelines for Good Clinical Practice (GCP) issued in June 1996 and CPMP/ICH/135/95 from September 1997. The study only started after obtaining a positive evaluation by the leading ethics committee and approval from the respective federal authority.
Only subjects that met all inclusion criteria and no exclusion criteria were to enter the study. All patients were free to discontinue their participation in the study at any time.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 June 2016
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: 115
Worldwide total number of subjects	115
EEA total number of subjects	115

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)	30
From 65 to 84 years	84

85 years and over	1

Subject disposition

Recruitment

Recruitment details:

The study included patients of 18 years or older with a planned cardiac surgical procedure with cardiopulmonary bypass. The study was conducted at 10 sites in Germany, 9 of which enrolled patients between 06 Jun 2016 and 24 Jan 2017. Due to missing age data, not the 120 patients enrolled but only the 115 patients randomized are presented above.

Pre-assignment

Screening details:

All 120 patients were screened for eligibility before participating in the active treatment phase of the study. Subjects were not to be entered to the trial treatment if any of the eligibility criteria were violated. Of the 120 patients, 115 patients were randomized and of these, 104 were treated.

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, Carer

Blinding implementation details:

To ensure adequate blinding after reconstitution, standard measures will be taken for the investigational medicinal product (IMP, e.g., same container/closure system, storage conditions, color, and foaming property). In addition, each reconstituted IMP that is transferred to the operating room is only labeled with blinded information. In general, access to study documents containing information on IFX-1 level and treatment groups will be restricted to unblinded personnel.

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects in this arm were administered a single intravenous administration of placebo with doses corresponding to the IFX-1 dose cohorts. The ratio between IFX-1 and placebo within one dose cohort was 4:1. All four placebo dose cohorts of 1, 2, 4 or 8 mg/kg body weight (bw) are presented combined. Dosing started after completion of anaesthesia and was finished prior to start of surgery.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administration of 1, 2, 4 or 8 mg/kg bw placebo as an intravenous infusion via infusomat over 30 minutes (min), and within 30 min after completion of successful anaesthesia.
Placebo matching the IFX-1 was supplied in 10 mL glass vials containing the equivalent colourless phosphat buffered saline solution with polysorbate 80 without the active pharmaceutical ingredient.
For patients with a body weight between 100 and 130 kg, the dose calculation was based on 100 kg body weight.

Arm title	1 mg/kg bw IFX-1

Arm description:

Subjects in this arm were administered a single intravenous administration of 1 mg/kg bw IFX-1. Dosing started after completion of anaesthesia and was finished prior to start of surgery.

Arm type	Experimental

Investigational medicinal product name	IFX-1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intracavernous use

Dosage and administration details:

Administration of 1 mg/kg bw IFX-1 as an intravenous infusion via infusomat over 30 min, and within 30 min after completion of successful anaesthesia.
IFX-1 was formulated in a phosphate buffered saline and polysorbate 80 and was supplied in 10 mL glass vials in strength of 10 mg/mL.
For patients with a body weight between 100 and 130 kg, the dose calculation was based on 100 kg body weight.

Arm title	2 mg/kg bw IFX-1

Arm description:

Subjects in this arm were administered a single intravenous administration of 2 mg/kg bw IFX-1. Dosing started after completion of anaesthesia and was finished prior to start of surgery.

Arm type	Experimental
Investigational medicinal product name	IFX-1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intracavernous use

Dosage and administration details:

Administration of 2 mg/kg bw IFX-1 as an intravenous infusion via infusomat over 30 min, and within 30 min after completion of successful anaesthesia.
IFX-1 was formulated in a phosphate buffered saline and polysorbate 80 and was supplied in 10 mL glass vials in strength of 10 mg/mL.
For patients with a body weight between 100 and 130 kg, the dose calculation was based on 100 kg body weight.

Arm title	4 mg/kg bw IFX-1

Arm description:

Subjects in this arm were administered a single intravenous administration of 4 mg/kg bw IFX-1. Dosing started after completion of anaesthesia and was finished prior to start of surgery.

Arm type	Experimental
Investigational medicinal product name	IFX-1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intracavernous use

Dosage and administration details:

Administration of 4 mg/kg bw IFX-1 as an intravenous infusion via infusomat over 30 min, and within 30 min after completion of successful anaesthesia.
IFX-1 was formulated in a phosphate buffered saline and polysorbate 80 and was supplied in 10 mL glass vials in strength of 10 mg/mL.
For patients with a body weight between 100 and 130 kg, the dose calculation was based on 100 kg body weight.

Arm title	8 mg/kg bw IFX-1

Arm description:

Subjects in this arm were administered a single intravenous administration of 8 mg/kg bw IFX-1. Dosing started after completion of anaesthesia and was finished prior to start of surgery.

Arm type	Experimental
Investigational medicinal product name	IFX-1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intracavernous use

Dosage and administration details:

Administration of 8 mg/kg bw IFX-1 as an intravenous infusion via infusomat over 30 min, and within 30 min after completion of successful anaesthesia.
IFX-1 was formulated in a phosphate buffered saline and polysorbate 80 and was supplied in 10 mL glass vials in strength of 10 mg/mL.
For patients with a body weight between 100 and 130 kg, the dose calculation was based on 100 kg body weight.

Number of subjects in period 1[1]	Placebo	1 mg/kg bw IFX-1	2 mg/kg bw IFX-1
Started	23	21	19
Completed	23	19	19
Not completed	0	2	0
Adverse event, serious fatal	-	2	-

Number of subjects in period 1[1]	4 mg/kg bw IFX-1	8 mg/kg bw IFX-1
Started	21	20
Completed	21	20
Not completed	0	0
Adverse event, serious fatal	-	-

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Baseline characteristics are based on patients who were randomized after successfully completing the screening period and received study medication (Safety Population).

Baseline characteristics

Reporting groups	
Reporting group title	Overall period

Reporting group description:

Safety population (SAF): all subjects who received study drug, irrespective of whether the infusion was completed. Analyses on the SAF were performed according to the actual dose the subjects received.

Reporting group values	Overall period	Total	
Number of subjects	104	104	
Age categorical Units: Subjects			
Adults (18-64 years)	29	29	
From 65 to 84 years	74	74	
85 years and over	1	1	
Gender categorical Units: Subjects			
Female	28	28	
Male	76	76	

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Subjects in this arm were administered a single intravenous administration of placebo with doses corresponding to the IFX-1 dose cohorts. The ratio between IFX-1 and placebo within one dose cohort was 4:1. All four placebo dose cohorts of 1, 2, 4 or 8 mg/kg body weight (bw) are presented combined. Dosing started after completion of anaesthesia and was finished prior to start of surgery.	
Reporting group title	1 mg/kg bw IFX-1
Reporting group description:	
Subjects in this arm were administered a single intravenous administration of 1 mg/kg bw IFX-1. Dosing started after completion of anaesthesia and was finished prior to start of surgery.	
Reporting group title	2 mg/kg bw IFX-1
Reporting group description:	
Subjects in this arm were administered a single intravenous administration of 2 mg/kg bw IFX-1. Dosing started after completion of anaesthesia and was finished prior to start of surgery.	
Reporting group title	4 mg/kg bw IFX-1
Reporting group description:	
Subjects in this arm were administered a single intravenous administration of 4 mg/kg bw IFX-1. Dosing started after completion of anaesthesia and was finished prior to start of surgery.	
Reporting group title	8 mg/kg bw IFX-1
Reporting group description:	
Subjects in this arm were administered a single intravenous administration of 8 mg/kg bw IFX-1. Dosing started after completion of anaesthesia and was finished prior to start of surgery.	

Primary: IL-6 peak level

End point title	IL-6 peak level
End point description:	
IL-6 peak level: For each subject, the highest IL-6 level measured at any time point from prior to study drug administration until 24 hours (h) after start of cardiopulmonary bypass. Values > 1500 pg/mL were set to 1500 pg/mL for the purpose of determining the IL-6 peak. Full Analysis Set (FAS): All randomized and treated subjects who had sufficient IL-6 data. IL-6 data were regarded as sufficient if the available blood samples allowed a statement about the IL-6 peak for the subject. Analyses on the FAS were performed according to the randomized dose group. Subjects who were randomized but not treated were excluded from this analysis set.	
End point type	Primary
End point timeframe:	
From prior to study drug administration until Visit 9, 24 h after start of cardiopulmonary bypass.	

End point values	Placebo	1 mg/kg bw IFX-1	2 mg/kg bw IFX-1	4 mg/kg bw IFX-1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23[1]	21[2]	19[3]	21[4]
Units: pg/mL				
arithmetic mean (standard deviation)	679.21 (± 492.64)	718.19 (± 465.43)	664.31 (± 455.88)	550.09 (± 361.17)

Notes:

[1] - FAS

[2] - FAS

[3] - FAS

[4] - FAS

End point values	8 mg/kg bw IFX-1			
Subject group type	Reporting group			
Number of subjects analysed	20[5]			
Units: pg/mL				
arithmetic mean (standard deviation)	673.92 (± 483.01)			

Notes:

[5] - FAS

Statistical analyses

Statistical analysis title	Kruskal-Wallis test

Statistical analysis description:

For continuous data, the standard statistics (sample size, number of missing values, mean, standard deviation [SD], minimum, Q1, median, Q3, and maximum) were presented. Continuous data at each visit / analysis day / time point were compared using the Kruskal-Wallis test, assessing an overall difference between dose groups.

Comparison groups	Placebo v 1 mg/kg bw IFX-1 v 2 mg/kg bw IFX-1 v 4 mg/kg bw IFX-1 v 8 mg/kg bw IFX-1
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	other[6]
P-value	= 0.8611
Method	Kruskal-wallis

Notes:

[6] - Continuous data at each visit / analysis day / time point were compared using the Kruskal-Wallis test, assessing an overall difference between dose groups.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected from First Patient First Visit until Last Patient Last Visit. All adverse events are reported in this record from first study drug administration on Day 1 until Day 29 (last visit).

Adverse event reporting additional description:

SAF

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	1mg/kg bw IFX-1

Reporting group description:

Subjects in this arm were administered a single intravenous administration of 1 mg/kg bw IFX-1. Dosing started after completion of anaesthesia and was finished prior to start of surgery.

Reporting group title	2mg/kg bw IFX-1

Reporting group description:

Subjects in this arm were administered a single intravenous administration of 2 mg/kg bw IFX-1. Dosing started after completion of anaesthesia and was finished prior to start of surgery.

Reporting group title	4mg/kg bw IFX-1

Reporting group description:

Subjects in this arm were administered a single intravenous administration of 4 mg/kg bw IFX-1. Dosing started after completion of anaesthesia and was finished prior to start of surgery.

Reporting group title	8mg/kg bw IFX-1

Reporting group description:

Subjects in this arm were administered a single intravenous administration of 8 mg/kg bw IFX-1. Dosing started after completion of anaesthesia and was finished prior to start of surgery.

Reporting group title	Placebo

Reporting group description:

Subjects in this arm were administered a single intravenous administration of placebo with doses corresponding to the IFX-1 dose cohorts. The ratio between IFX-1 and placebo within one dose cohort was 4:1. All four placebo dose cohorts of 1, 2, 4 or 8 mg/kg body weight (bw) are presented combined. Dosing started after completion of anaesthesia and was finished prior to start of surgery.

Serious adverse events	1mg/kg bw IFX-1	2mg/kg bw IFX-1	4mg/kg bw IFX-1
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 23 (39.13%)	7 / 18 (38.89%)	6 / 21 (28.57%)
number of deaths (all causes)	2	0	0
number of deaths resulting from adverse events	2	0	0
Vascular disorders			
Haematoma	Additional description: Haematoma		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (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

Haemodynamic instability	Additional description: Haemodynamic instability		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (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
Haemorrhage	Additional description: Haemorrhage		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery thrombosis	Additional description: Peripheral artery thrombosis		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (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
General disorders and administration site conditions			
General physical health deterioration	Additional description: General physical health deterioration		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (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
Impaired healing	Additional description: Impaired healing		
subjects affected / exposed	2 / 23 (8.70%)	0 / 18 (0.00%)	0 / 21 (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
Multiple organ dysfunction syndrome	Additional description: Multiple organ dysfunction syndrome		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome	Additional description: Systemic inflammatory response syndrome		
subjects affected / exposed	2 / 23 (8.70%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Haemothorax	Additional description: Haemothorax		
subjects affected / exposed	1 / 23 (4.35%)	1 / 18 (5.56%)	0 / 21 (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
Mediastinal haemorrhage	Additional description: Mediastinal haemorrhage		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (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
Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	0 / 23 (0.00%)	2 / 18 (11.11%)	0 / 21 (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
Pulmonary oedema	Additional description: Pulmonary oedema		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (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 failure	Additional description: Respiratory failure		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	2 / 21 (9.52%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient psychosis	Additional description: Transient psychosis		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood pressure decreased	Additional description: Blood pressure decreased		

subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (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
Injury, poisoning and procedural complications			
Post procedural haemorrhage	Additional description: Post procedural haemorrhage		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (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 thoracic procedure complication	Additional description: Postoperative thoracic procedure complication		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Arteriospasm coronary	Additional description: Arteriospasm coronary		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation	Additional description: Atrial fibrillation		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete	Additional description: Atrioventricular block complete		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest	Additional description: Cardiac arrest		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade	Additional description: Cardiac tamponade		
subjects affected / exposed	3 / 23 (13.04%)	1 / 18 (5.56%)	0 / 21 (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

Cardiogenic shock	Additional description: Cardiogenic shock		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (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
Haemorrhage coronary artery	Additional description: Haemorrhage coronary artery		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Low cardiac output syndrome	Additional description: Low cardiac output syndrome		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (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
Myocardial haemorrhage	Additional description: Myocardial haemorrhage		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (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
Pericardial effusion	Additional description: Pericardial effusion		
subjects affected / exposed	2 / 23 (8.70%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure	Additional description: Right ventricular failure		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (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
Ventricular fibrillation	Additional description: Ventricular fibrillation		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain injury	Additional description: Brain injury		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (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
Brain stem stroke	Additional description: Brain stem stroke		

subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction	Additional description: Cerebral infarction		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (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
Intensive care unit acquired weakness	Additional description: Intensive care unit acquired weakness		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic stroke	Additional description: Thrombotic stroke		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
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 and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulopathy	Additional description: Coagulopathy		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (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 disorders			
Duodenal ulcer haemorrhage	Additional description: Duodenal ulcer haemorrhage		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (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
Intestinal haemorrhage	Additional description: Intestinal haemorrhage		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Intestinal ischaemia	Additional description: Intestinal ischaemia		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (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
Upper gastrointestinal haemorrhage	Additional description: Upper gastrointestinal haemorrhage		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic failure	Additional description: Hepatic failure		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (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
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End stage renal disease	Additional description: End stage renal disease		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure	Additional description: Renal failure		
subjects affected / exposed	2 / 23 (8.70%)	0 / 18 (0.00%)	0 / 21 (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
Urinary bladder varices	Additional description: Urinary bladder varices		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (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
Infections and infestations			
Abdominal abscess	Additional description: Abdominal abscess		

subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis staphylococcal	Additional description: Endocarditis staphylococcal		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal sepsis	Additional description: Enterococcal sepsis		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus	Additional description: Gastroenteritis norovirus		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mediastinitis	Additional description: Mediastinitis		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nosocomial infection	Additional description: Nosocomial infection		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia haemophilus	Additional description: Pneumonia haemophilus		

subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (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
Sepsis	Additional description: Sepsis		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Severe invasive streptococcal infection	Additional description: Severe invasive streptococcal infection		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (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	Additional description: Urinary tract infection		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
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	Additional description: Wound infection		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	8mg/kg bw IFX-1	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 20 (50.00%)	7 / 22 (31.82%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Vascular disorders			
Haematoma	Additional description: Haematoma		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemodynamic instability	Additional description: Haemodynamic instability		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Haemorrhage	Additional description: Haemorrhage		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery thrombosis	Additional description: Peripheral artery thrombosis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
General physical health deterioration	Additional description: General physical health deterioration		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired healing	Additional description: Impaired healing		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome	Additional description: Multiple organ dysfunction syndrome		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic inflammatory response syndrome	Additional description: Systemic inflammatory response syndrome		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Haemothorax	Additional description: Haemothorax		

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinal haemorrhage	Additional description: Mediastinal haemorrhage		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema	Additional description: Pulmonary oedema		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure	Additional description: Respiratory failure		
subjects affected / exposed	2 / 20 (10.00%)	1 / 22 (4.55%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Delirium	Additional description: Delirium		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient psychosis	Additional description: Transient psychosis		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood pressure decreased	Additional description: Blood pressure decreased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural			

complications			
Post procedural haemorrhage	Additional description: Post procedural haemorrhage		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative thoracic procedure complication	Additional description: Postoperative thoracic procedure complication		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Arteriospasm coronary	Additional description: Arteriospasm coronary		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation	Additional description: Atrial fibrillation		
subjects affected / exposed	2 / 20 (10.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block complete	Additional description: Atrioventricular block complete		
subjects affected / exposed	1 / 20 (5.00%)	1 / 22 (4.55%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest	Additional description: Cardiac arrest		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac tamponade	Additional description: Cardiac tamponade		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiogenic shock	Additional description: Cardiogenic shock		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Haemorrhage coronary artery	Additional description: Haemorrhage coronary artery		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Low cardiac output syndrome	Additional description: Low cardiac output syndrome		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial haemorrhage	Additional description: Myocardial haemorrhage		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion	Additional description: Pericardial effusion		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Right ventricular failure	Additional description: Right ventricular failure		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation	Additional description: Ventricular fibrillation		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Brain injury	Additional description: Brain injury		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain stem stroke	Additional description: Brain stem stroke		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral infarction	Additional description: Cerebral infarction		

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intensive care unit acquired weakness	Additional description: Intensive care unit acquired weakness		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombotic stroke	Additional description: Thrombotic stroke		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	0 / 20 (0.00%)	2 / 22 (9.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coagulopathy	Additional description: Coagulopathy		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Duodenal ulcer haemorrhage	Additional description: Duodenal ulcer haemorrhage		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal haemorrhage	Additional description: Intestinal haemorrhage		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal ischaemia	Additional description: Intestinal ischaemia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Upper gastrointestinal haemorrhage	Additional description: Upper gastrointestinal haemorrhage		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hepatic failure	Additional description: Hepatic failure		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
End stage renal disease	Additional description: End stage renal disease		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure	Additional description: Renal failure		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder varices	Additional description: Urinary bladder varices		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal abscess	Additional description: Abdominal abscess		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis staphylococcal	Additional description: Endocarditis staphylococcal		

subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterococcal sepsis	Additional description: Enterococcal sepsis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis norovirus	Additional description: Gastroenteritis norovirus		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza	Additional description: Influenza		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinitis	Additional description: Mediastinitis		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nosocomial infection	Additional description: Nosocomial infection		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia haemophilus	Additional description: Pneumonia haemophilus		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis	Additional description: Sepsis		

subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Severe invasive streptococcal infection	Additional description: Severe invasive streptococcal infection		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection	Additional description: Wound infection		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	1mg/kg bw IFX-1	2mg/kg bw IFX-1	4mg/kg bw IFX-1
Total subjects affected by non-serious adverse events			
subjects affected / exposed	22 / 23 (95.65%)	17 / 18 (94.44%)	21 / 21 (100.00%)
Vascular disorders			
Haematoma	Additional description: Haematoma		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Haemodynamic instability	Additional description: Haemodynamic instability		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Hypertension	Additional description: Hypertension		
subjects affected / exposed	3 / 23 (13.04%)	1 / 18 (5.56%)	3 / 21 (14.29%)
occurrences (all)	3	1	3
Hypertensive crisis	Additional description: Hypertensive crisis		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	1 / 21 (4.76%)
occurrences (all)	0	1	2

Hypotension	Additional description: Hypotension		
subjects affected / exposed	1 / 23 (4.35%)	1 / 18 (5.56%)	3 / 21 (14.29%)
occurrences (all)	1	1	3
Surgical and medical procedures			
Colectomy	Additional description: Colectomy		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Explorative laparotomy	Additional description: Explorative laparotomy		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia	Additional description: Asthenia		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Chest pain	Additional description: Chest pain		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Drug intolerance	Additional description: Drug intolerance		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gait disturbance	Additional description: Gait disturbance		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Impaired healing	Additional description: Impaired healing		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Malaise	Additional description: Malaise		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Oedema	Additional description: Oedema		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
Oedema peripheral	Additional description: Oedema peripheral		
subjects affected / exposed	4 / 23 (17.39%)	1 / 18 (5.56%)	4 / 21 (19.05%)
occurrences (all)	4	1	5
Peripheral swelling	Additional description: Peripheral swelling		

subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	2 / 23 (8.70%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
Respiratory, thoracic and mediastinal disorders			
Acquired diaphragmatic eventration	Additional description: Acquired diaphragmatic eventration		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Acute respiratory failure	Additional description: Acute respiratory failure		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Aspiration	Additional description: Aspiration		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Atelectasis	Additional description: Atelectasis		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Bronchospasm	Additional description: Bronchospasm		
subjects affected / exposed	2 / 23 (8.70%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	2	0	1
Cough	Additional description: Cough		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	4 / 21 (19.05%)
occurrences (all)	0	1	4
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Emphysema	Additional description: Emphysema		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Increased viscosity of bronchial secretion	Additional description: Increased viscosity of bronchial secretion		

subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Lung disorder	Additional description: Lung disorder		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Lung hypoinflation	Additional description: Lung hypoinflation		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	9 / 23 (39.13%)	6 / 18 (33.33%)	9 / 21 (42.86%)
occurrences (all)	13	6	9
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	2 / 23 (8.70%)	0 / 18 (0.00%)	2 / 21 (9.52%)
occurrences (all)	2	0	2
Pulmonary congestion	Additional description: Pulmonary congestion		
subjects affected / exposed	2 / 23 (8.70%)	0 / 18 (0.00%)	3 / 21 (14.29%)
occurrences (all)	2	0	3
Pulmonary oedema	Additional description: Pulmonary oedema		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Respiratory failure	Additional description: Respiratory failure		
subjects affected / exposed	1 / 23 (4.35%)	3 / 18 (16.67%)	2 / 21 (9.52%)
occurrences (all)	1	3	2
Psychiatric disorders			
Delirium	Additional description: Delirium		
subjects affected / exposed	3 / 23 (13.04%)	3 / 18 (16.67%)	4 / 21 (19.05%)
occurrences (all)	4	3	4
Disorientation	Additional description: Disorientation		
subjects affected / exposed	3 / 23 (13.04%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	3	0	1
Insomnia	Additional description: Insomnia		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Restlessness	Additional description: Restlessness		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0

Sleep disorder	Additional description: Sleep disorder		
subjects affected / exposed	1 / 23 (4.35%)	2 / 18 (11.11%)	6 / 21 (28.57%)
occurrences (all)	1	2	6
Investigations			
Alanine aminotransferase increased	Additional description: Alanine aminotransferase increased		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Antithrombin III decreased	Additional description: Antithrombin III decreased		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased	Additional description: Aspartate aminotransferase increased		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Blood albumin decreased	Additional description: Blood albumin decreased		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Blood alkaline phosphatase increased	Additional description: Blood alkaline phosphatase increased		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Blood bilirubin increased	Additional description: Blood bilirubin increased		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Blood calcium decreased	Additional description: Blood calcium decreased		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Blood creatine phosphokinase MB increased	Additional description: Blood creatine phosphokinase MB increased		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Blood creatine phosphokinase increased	Additional description: Blood creatine phosphokinase increased		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	3 / 21 (14.29%)
occurrences (all)	0	0	3
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Blood fibrinogen decreased	Additional description: Blood fibrinogen decreased		

subjects affected / exposed	1 / 23 (4.35%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
Blood glucose increased	Additional description: Blood glucose increased		
subjects affected / exposed	1 / 23 (4.35%)	2 / 18 (11.11%)	2 / 21 (9.52%)
occurrences (all)	1	2	2
Blood lactate dehydrogenase increased	Additional description: Blood lactate dehydrogenase increased		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Blood pressure decreased	Additional description: Blood pressure decreased		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Blood pressure increased	Additional description: Blood pressure increased		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Blood urea increased	Additional description: Blood urea increased		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Body temperature increased	Additional description: Body temperature increased		
subjects affected / exposed	1 / 23 (4.35%)	2 / 18 (11.11%)	1 / 21 (4.76%)
occurrences (all)	3	2	1
Breath sounds abnormal	Additional description: Breath sounds abnormal		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Cardiac index decreased	Additional description: Cardiac index decreased		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Enterococcus test positive	Additional description: Enterococcus test positive		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Escherichia test positive	Additional description: Escherichia test positive		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	1 / 21 (4.76%)
occurrences (all)	0	1	2

Gamma-glutamyltransferase increased	Additional description: Gamma-glutamyltransferase increased		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
Glutamate dehydrogenase increased	Additional description: Glutamate dehydrogenase increased		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Haematocrit decreased	Additional description: Haematocrit decreased		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Haemoglobin decreased	Additional description: Haemoglobin decreased		
subjects affected / exposed	2 / 23 (8.70%)	3 / 18 (16.67%)	1 / 21 (4.76%)
occurrences (all)	2	3	1
Heart rate decreased	Additional description: Heart rate decreased		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Hepatic enzyme increased	Additional description: Hepatic enzyme increased		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
International normalised ratio increased	Additional description: International normalised ratio increased		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Myocardial necrosis marker increased	Additional description: Myocardial necrosis marker increased		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Oxygen saturation decreased	Additional description: Oxygen saturation decreased		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Red blood cell count decreased	Additional description: Red blood cell count decreased		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	3 / 21 (14.29%)
occurrences (all)	0	0	3
Staphylococcus test positive	Additional description: Staphylococcus test positive		
subjects affected / exposed	1 / 23 (4.35%)	1 / 18 (5.56%)	1 / 21 (4.76%)
occurrences (all)	1	1	1
Venous oxygen saturation decreased	Additional description: Venous oxygen saturation decreased		

subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
White blood cell count increased	Additional description: White blood cell count increased		
subjects affected / exposed	0 / 23 (0.00%)	2 / 18 (11.11%)	1 / 21 (4.76%)
occurrences (all)	0	2	2
Injury, poisoning and procedural complications			
Anaemia postoperative	Additional description: Anaemia postoperative		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Fall	Additional description: Fall		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
Injury	Additional description: Injury		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Laceration	Additional description: Laceration		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Periorbital haemorrhage	Additional description: Periorbital haemorrhage		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Post procedural haematoma	Additional description: Post procedural haematoma		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Post procedural haemorrhage	Additional description: Post procedural haemorrhage		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	2 / 21 (9.52%)
occurrences (all)	0	1	2
Postoperative renal failure	Additional description: Postoperative renal failure		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Postoperative respiratory distress	Additional description: Postoperative respiratory distress		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Postoperative wound complication	Additional description: Postoperative wound complication		

subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Procedural haemorrhage	Additional description: Procedural haemorrhage		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Procedural nausea	Additional description: Procedural nausea		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Procedural vomiting	Additional description: Procedural vomiting		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Wound haemorrhage	Additional description: Wound haemorrhage		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Wound secretion	Additional description: Wound secretion		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Acute myocardial infarction	Additional description: Acute myocardial infarction		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Arrhythmia	Additional description: Arrhythmia		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Atrial fibrillation	Additional description: Atrial fibrillation		
subjects affected / exposed	9 / 23 (39.13%)	4 / 18 (22.22%)	9 / 21 (42.86%)
occurrences (all)	9	4	9
Atrial flutter	Additional description: Atrial flutter		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
Atrioventricular block	Additional description: Atrioventricular block		
subjects affected / exposed	2 / 23 (8.70%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0

Atrioventricular block complete	Additional description: Atrioventricular block complete		
subjects affected / exposed	0 / 23 (0.00%)	3 / 18 (16.67%)	1 / 21 (4.76%)
occurrences (all)	0	3	1
Atrioventricular block second degree	Additional description: Atrioventricular block second degree		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Bradyarrhythmia	Additional description: Bradyarrhythmia		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
Bradycardia	Additional description: Bradycardia		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
Bundle branch block left	Additional description: Bundle branch block left		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Bundle branch block right	Additional description: Bundle branch block right		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Cardiac arrest	Additional description: Cardiac arrest		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Cardiac failure	Additional description: Cardiac failure		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Cardiovascular disorder	Additional description: Cardiovascular disorder		
subjects affected / exposed	2 / 23 (8.70%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	2	1	0
Extrasystoles	Additional description: Extrasystoles		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
Left ventricular dysfunction	Additional description: Left ventricular dysfunction		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion	Additional description: Pericardial effusion		
subjects affected / exposed	1 / 23 (4.35%)	1 / 18 (5.56%)	1 / 21 (4.76%)
occurrences (all)	1	1	1

Pericardial haemorrhage	Additional description: Pericardial haemorrhage		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Pulmonary valve incompetence	Additional description: Pulmonary valve incompetence		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Sinus arrest	Additional description: Sinus arrest		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Supraventricular tachycardia	Additional description: Supraventricular tachycardia		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Tachyarrhythmia	Additional description: Tachyarrhythmia		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	1 / 23 (4.35%)	2 / 18 (11.11%)	0 / 21 (0.00%)
occurrences (all)	1	2	0
Tricuspid valve incompetence	Additional description: Tricuspid valve incompetence		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Ventricular extrasystoles	Additional description: Ventricular extrasystoles		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Ventricular fibrillation	Additional description: Ventricular fibrillation		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Ventricular hypokinesia	Additional description: Ventricular hypokinesia		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Ventricular tachycardia	Additional description: Ventricular tachycardia		
subjects affected / exposed	2 / 23 (8.70%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	2	1	0
Nervous system disorders			
Anticholinergic syndrome	Additional description: Anticholinergic syndrome		

subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Balance disorder	Additional description: Balance disorder		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Brain oedema	Additional description: Brain oedema		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Carotid artery stenosis	Additional description: Carotid artery stenosis		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Cerebral infarction	Additional description: Cerebral infarction		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Disturbance in attention	Additional description: Disturbance in attention		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Headache	Additional description: Headache		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
Hemiparesis	Additional description: Hemiparesis		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
IIIrd nerve paralysis	Additional description: IIIrd nerve paralysis		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Peripheral nerve lesion	Additional description: Peripheral nerve lesion		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
Peripheral nerve paresis	Additional description: Peripheral nerve paresis		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Psychomotor hyperactivity	Additional description: Psychomotor hyperactivity		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Seizure	Additional description: Seizure		

subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Syncope	Additional description: Syncope		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	1 / 21 (4.76%)
occurrences (all)	0	2	1
Tremor	Additional description: Tremor		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	5 / 23 (21.74%)	1 / 18 (5.56%)	6 / 21 (28.57%)
occurrences (all)	6	1	6
Coagulation factor deficiency	Additional description: Coagulation factor deficiency		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Coagulopathy	Additional description: Coagulopathy		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
Disseminated intravascular coagulation	Additional description: Disseminated intravascular coagulation		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Erythropenia	Additional description: Erythropenia		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Haemorrhagic anaemia	Additional description: Haemorrhagic anaemia		
subjects affected / exposed	0 / 23 (0.00%)	2 / 18 (11.11%)	1 / 21 (4.76%)
occurrences (all)	0	2	1
Heparin-induced thrombocytopenia	Additional description: Heparin-induced thrombocytopenia		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Leukocytosis	Additional description: Leukocytosis		
subjects affected / exposed	3 / 23 (13.04%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	3	0	0
Thrombocytopenia	Additional description: Thrombocytopenia		

subjects affected / exposed	4 / 23 (17.39%)	3 / 18 (16.67%)	3 / 21 (14.29%)
occurrences (all)	4	3	3
Ear and labyrinth disorders			
Hypoacusis	Additional description: Hypoacusis		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Eye disorders			
Gaze palsy	Additional description: Gaze palsy		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Pupils unequal	Additional description: Pupils unequal		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Visual impairment	Additional description: Visual impairment		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Anal incontinence	Additional description: Anal incontinence		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Constipation	Additional description: Constipation		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	3 / 21 (14.29%)
occurrences (all)	1	0	3
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	1 / 23 (4.35%)	2 / 18 (11.11%)	0 / 21 (0.00%)
occurrences (all)	1	2	0
Duodenal ulcer	Additional description: Duodenal ulcer		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dysphagia	Additional description: Dysphagia		

subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Flatulence	Additional description: Flatulence		
subjects affected / exposed	1 / 23 (4.35%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
Gastritis	Additional description: Gastritis		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage	Additional description: Gastrointestinal haemorrhage		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Large intestinal ulcer	Additional description: Large intestinal ulcer		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nausea	Additional description: Nausea		
subjects affected / exposed	6 / 23 (26.09%)	0 / 18 (0.00%)	4 / 21 (19.05%)
occurrences (all)	6	0	5
Pancreatitis	Additional description: Pancreatitis		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Subileus	Additional description: Subileus		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Vomiting	Additional description: Vomiting		
subjects affected / exposed	1 / 23 (4.35%)	4 / 18 (22.22%)	2 / 21 (9.52%)
occurrences (all)	1	4	2
Skin and subcutaneous tissue disorders			
Decubitus ulcer	Additional description: Decubitus ulcer		
subjects affected / exposed	1 / 23 (4.35%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
Erythema	Additional description: Erythema		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Rash generalised	Additional description: Rash generalised		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Subcutaneous emphysema	Additional description: Subcutaneous emphysema		
subjects affected / exposed	1 / 23 (4.35%)	2 / 18 (11.11%)	0 / 21 (0.00%)
occurrences (all)	1	2	0
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	3 / 23 (13.04%)	2 / 18 (11.11%)	2 / 21 (9.52%)
occurrences (all)	3	2	2
Acute prerenal failure	Additional description: Acute prerenal failure		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dysuria	Additional description: Dysuria		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Haematuria	Additional description: Haematuria		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Oliguria	Additional description: Oliguria		
subjects affected / exposed	2 / 23 (8.70%)	3 / 18 (16.67%)	2 / 21 (9.52%)
occurrences (all)	2	3	2
Renal failure	Additional description: Renal failure		
subjects affected / exposed	2 / 23 (8.70%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	2	1	0
Urinary incontinence	Additional description: Urinary incontinence		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	2 / 21 (9.52%)
occurrences (all)	0	1	2
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain	Additional description: Back pain		
subjects affected / exposed	2 / 23 (8.70%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	2	1	0
Muscle spasms	Additional description: Muscle spasms		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
Muscular weakness	Additional description: Muscular weakness		

subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain	Additional description: Musculoskeletal chest pain		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
Musculoskeletal pain	Additional description: Musculoskeletal pain		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Infections and infestations			
Bacterial disease carrier	Additional description: Bacterial disease carrier		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Bronchitis	Additional description: Bronchitis		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Clostridial infection	Additional description: Clostridial infection		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Cystitis	Additional description: Cystitis		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
Device related infection	Additional description: Device related infection		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Enterococcal infection	Additional description: Enterococcal infection		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Infection	Additional description: Infection		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Infectious disease carrier	Additional description: Infectious disease carrier		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
Nasopharyngitis	Additional description: Nasopharyngitis		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1

Nosocomial infection	Additional description: Nosocomial infection		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	2 / 21 (9.52%)
occurrences (all)	0	1	2
Pneumonia escherichia	Additional description: Pneumonia escherichia		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pneumonia klebsiella	Additional description: Pneumonia klebsiella		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Tracheobronchitis	Additional description: Tracheobronchitis		
subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	2 / 23 (8.70%)	1 / 18 (5.56%)	3 / 21 (14.29%)
occurrences (all)	2	1	3
Metabolism and nutrition disorders			
Fluid retention	Additional description: Fluid retention		
subjects affected / exposed	0 / 23 (0.00%)	2 / 18 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
Gout	Additional description: Gout		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Hyperkalaemia	Additional description: Hyperkalaemia		
subjects affected / exposed	1 / 23 (4.35%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Hypernatraemia	Additional description: Hypernatraemia		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
Hypoalbuminaemia	Additional description: Hypoalbuminaemia		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia	Additional description: Hyponatraemia		

subjects affected / exposed	0 / 23 (0.00%)	0 / 18 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypovolaemia	Additional description: Hypovolaemia		
subjects affected / exposed	2 / 23 (8.70%)	0 / 18 (0.00%)	1 / 21 (4.76%)
occurrences (all)	2	0	1
Metabolic acidosis	Additional description: Metabolic acidosis		
subjects affected / exposed	1 / 23 (4.35%)	2 / 18 (11.11%)	0 / 21 (0.00%)
occurrences (all)	2	2	0
Protein deficiency	Additional description: Protein deficiency		
subjects affected / exposed	0 / 23 (0.00%)	1 / 18 (5.56%)	2 / 21 (9.52%)
occurrences (all)	0	1	2

Non-serious adverse events	8mg/kg bw IFX-1	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 20 (95.00%)	21 / 22 (95.45%)	
Vascular disorders			
Haematoma	Additional description: Haematoma		
subjects affected / exposed	2 / 20 (10.00%)	1 / 22 (4.55%)	
occurrences (all)	2	1	
Haemodynamic instability	Additional description: Haemodynamic instability		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Hypertension	Additional description: Hypertension		
subjects affected / exposed	3 / 20 (15.00%)	4 / 22 (18.18%)	
occurrences (all)	3	4	
Hypertensive crisis	Additional description: Hypertensive crisis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Hypotension	Additional description: Hypotension		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Surgical and medical procedures			
Colectomy	Additional description: Colectomy		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Explorative laparotomy	Additional description: Explorative laparotomy		

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Asthenia	Additional description: Asthenia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Chest pain	Additional description: Chest pain		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Drug intolerance	Additional description: Drug intolerance		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Gait disturbance	Additional description: Gait disturbance		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Impaired healing	Additional description: Impaired healing		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Malaise	Additional description: Malaise		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Oedema	Additional description: Oedema		
subjects affected / exposed	0 / 20 (0.00%)	2 / 22 (9.09%)	
occurrences (all)	0	2	
Oedema peripheral	Additional description: Oedema peripheral		
subjects affected / exposed	3 / 20 (15.00%)	2 / 22 (9.09%)	
occurrences (all)	3	2	
Peripheral swelling	Additional description: Peripheral swelling		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			

Acquired diaphragmatic eventration	Additional description: Acquired diaphragmatic eventration		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Acute respiratory failure	Additional description: Acute respiratory failure		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Aspiration	Additional description: Aspiration		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Atelectasis	Additional description: Atelectasis		
subjects affected / exposed	0 / 20 (0.00%)	2 / 22 (9.09%)	
occurrences (all)	0	2	
Bronchospasm	Additional description: Bronchospasm		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Cough	Additional description: Cough		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Emphysema	Additional description: Emphysema		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Increased viscosity of bronchial secretion	Additional description: Increased viscosity of bronchial secretion		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Lung disorder	Additional description: Lung disorder		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Lung hypoinflation	Additional description: Lung hypoinflation		

subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Pleural effusion	Additional description: Pleural effusion		
subjects affected / exposed	4 / 20 (20.00%)	9 / 22 (40.91%)	
occurrences (all)	4	9	
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Pulmonary congestion	Additional description: Pulmonary congestion		
subjects affected / exposed	0 / 20 (0.00%)	2 / 22 (9.09%)	
occurrences (all)	0	2	
Pulmonary oedema	Additional description: Pulmonary oedema		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Respiratory failure	Additional description: Respiratory failure		
subjects affected / exposed	2 / 20 (10.00%)	2 / 22 (9.09%)	
occurrences (all)	2	2	
Psychiatric disorders			
Delirium	Additional description: Delirium		
subjects affected / exposed	6 / 20 (30.00%)	6 / 22 (27.27%)	
occurrences (all)	6	6	
Disorientation	Additional description: Disorientation		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Insomnia	Additional description: Insomnia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Restlessness	Additional description: Restlessness		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Sleep disorder	Additional description: Sleep disorder		
subjects affected / exposed	0 / 20 (0.00%)	2 / 22 (9.09%)	
occurrences (all)	0	4	
Investigations			
Alanine aminotransferase increased	Additional description: Alanine aminotransferase increased		

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Antithrombin III decreased	Additional description: Antithrombin III decreased		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Aspartate aminotransferase increased	Additional description: Aspartate aminotransferase increased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Blood albumin decreased	Additional description: Blood albumin decreased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Blood alkaline phosphatase increased	Additional description: Blood alkaline phosphatase increased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Blood bilirubin increased	Additional description: Blood bilirubin increased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Blood calcium decreased	Additional description: Blood calcium decreased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Blood creatine phosphokinase MB increased	Additional description: Blood creatine phosphokinase MB increased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Blood creatine phosphokinase increased	Additional description: Blood creatine phosphokinase increased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Blood fibrinogen decreased	Additional description: Blood fibrinogen decreased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Blood glucose increased	Additional description: Blood glucose increased		

subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Blood lactate dehydrogenase increased	Additional description: Blood lactate dehydrogenase increased		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Blood pressure decreased	Additional description: Blood pressure decreased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Blood pressure increased	Additional description: Blood pressure increased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Blood urea increased	Additional description: Blood urea increased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Body temperature increased	Additional description: Body temperature increased		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Breath sounds abnormal	Additional description: Breath sounds abnormal		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
C-reactive protein increased	Additional description: C-reactive protein increased		
subjects affected / exposed	0 / 20 (0.00%)	2 / 22 (9.09%)	
occurrences (all)	0	2	
Cardiac index decreased	Additional description: Cardiac index decreased		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Enterococcus test positive	Additional description: Enterococcus test positive		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Escherichia test positive	Additional description: Escherichia test positive		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Gamma-glutamyltransferase increased	Additional description: Gamma-glutamyltransferase increased		

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Glutamate dehydrogenase increased	Additional description: Glutamate dehydrogenase increased		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Haematocrit decreased	Additional description: Haematocrit decreased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Haemoglobin decreased	Additional description: Haemoglobin decreased		
subjects affected / exposed	0 / 20 (0.00%)	2 / 22 (9.09%)	
occurrences (all)	0	2	
Heart rate decreased	Additional description: Heart rate decreased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Hepatic enzyme increased	Additional description: Hepatic enzyme increased		
subjects affected / exposed	1 / 20 (5.00%)	2 / 22 (9.09%)	
occurrences (all)	1	2	
International normalised ratio increased	Additional description: International normalised ratio increased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Myocardial necrosis marker increased	Additional description: Myocardial necrosis marker increased		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Oxygen saturation decreased	Additional description: Oxygen saturation decreased		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Red blood cell count decreased	Additional description: Red blood cell count decreased		
subjects affected / exposed	3 / 20 (15.00%)	2 / 22 (9.09%)	
occurrences (all)	3	2	
Staphylococcus test positive	Additional description: Staphylococcus test positive		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Venous oxygen saturation decreased	Additional description: Venous oxygen saturation decreased		

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
White blood cell count increased	Additional description: White blood cell count increased		
subjects affected / exposed	2 / 20 (10.00%)	4 / 22 (18.18%)	
occurrences (all)	2	4	
Injury, poisoning and procedural complications			
Anaemia postoperative	Additional description: Anaemia postoperative		
subjects affected / exposed	1 / 20 (5.00%)	2 / 22 (9.09%)	
occurrences (all)	1	2	
Fall	Additional description: Fall		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Injury	Additional description: Injury		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Laceration	Additional description: Laceration		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Periorbital haemorrhage	Additional description: Periorbital haemorrhage		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Post procedural haematoma	Additional description: Post procedural haematoma		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Post procedural haemorrhage	Additional description: Post procedural haemorrhage		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Postoperative renal failure	Additional description: Postoperative renal failure		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Postoperative respiratory distress	Additional description: Postoperative respiratory distress		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Postoperative wound complication	Additional description: Postoperative wound complication		

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Procedural haemorrhage	Additional description: Procedural haemorrhage		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Procedural nausea	Additional description: Procedural nausea		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Procedural vomiting	Additional description: Procedural vomiting		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Rib fracture	Additional description: Rib fracture		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Wound haemorrhage	Additional description: Wound haemorrhage		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Wound secretion	Additional description: Wound secretion		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Cardiac disorders			
Acute myocardial infarction	Additional description: Acute myocardial infarction		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Arrhythmia	Additional description: Arrhythmia		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Atrial fibrillation	Additional description: Atrial fibrillation		
subjects affected / exposed	9 / 20 (45.00%)	8 / 22 (36.36%)	
occurrences (all)	11	10	
Atrial flutter	Additional description: Atrial flutter		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Atrioventricular block	Additional description: Atrioventricular block		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	

Atrioventricular block complete	Additional description: Atrioventricular block complete		
subjects affected / exposed	1 / 20 (5.00%)	2 / 22 (9.09%)	
occurrences (all)	1	2	
Atrioventricular block second degree	Additional description: Atrioventricular block second degree		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Bradyarrhythmia	Additional description: Bradyarrhythmia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Bradycardia	Additional description: Bradycardia		
subjects affected / exposed	3 / 20 (15.00%)	1 / 22 (4.55%)	
occurrences (all)	3	1	
Bundle branch block left	Additional description: Bundle branch block left		
subjects affected / exposed	0 / 20 (0.00%)	2 / 22 (9.09%)	
occurrences (all)	0	2	
Bundle branch block right	Additional description: Bundle branch block right		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Cardiac arrest	Additional description: Cardiac arrest		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Cardiac failure	Additional description: Cardiac failure		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Cardiovascular disorder	Additional description: Cardiovascular disorder		
subjects affected / exposed	3 / 20 (15.00%)	4 / 22 (18.18%)	
occurrences (all)	3	4	
Extrasystoles	Additional description: Extrasystoles		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Left ventricular dysfunction	Additional description: Left ventricular dysfunction		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Pericardial effusion	Additional description: Pericardial effusion		
subjects affected / exposed	1 / 20 (5.00%)	1 / 22 (4.55%)	
occurrences (all)	1	1	

Pericardial haemorrhage	Additional description: Pericardial haemorrhage		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Pulmonary valve incompetence	Additional description: Pulmonary valve incompetence		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Sinus arrest	Additional description: Sinus arrest		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Supraventricular tachycardia	Additional description: Supraventricular tachycardia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Tachyarrhythmia	Additional description: Tachyarrhythmia		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Tachycardia	Additional description: Tachycardia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Tricuspid valve incompetence	Additional description: Tricuspid valve incompetence		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Ventricular extrasystoles	Additional description: Ventricular extrasystoles		
subjects affected / exposed	2 / 20 (10.00%)	2 / 22 (9.09%)	
occurrences (all)	2	2	
Ventricular fibrillation	Additional description: Ventricular fibrillation		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Ventricular hypokinesia	Additional description: Ventricular hypokinesia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Ventricular tachycardia	Additional description: Ventricular tachycardia		
subjects affected / exposed	2 / 20 (10.00%)	1 / 22 (4.55%)	
occurrences (all)	2	1	
Nervous system disorders			
Anticholinergic syndrome	Additional description: Anticholinergic syndrome		

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Balance disorder	Additional description: Balance disorder		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Brain oedema	Additional description: Brain oedema		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Carotid artery stenosis	Additional description: Carotid artery stenosis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Cerebral infarction	Additional description: Cerebral infarction		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Disturbance in attention	Additional description: Disturbance in attention		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Headache	Additional description: Headache		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Hemiparesis	Additional description: Hemiparesis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
IIIrd nerve paralysis	Additional description: IIIrd nerve paralysis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Peripheral nerve lesion	Additional description: Peripheral nerve lesion		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Peripheral nerve paresis	Additional description: Peripheral nerve paresis		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Psychomotor hyperactivity	Additional description: Psychomotor hyperactivity		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Seizure	Additional description: Seizure		

subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Syncope	Additional description: Syncope		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Tremor	Additional description: Tremor		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	3 / 20 (15.00%)	6 / 22 (27.27%)	
occurrences (all)	3	6	
Coagulation factor deficiency	Additional description: Coagulation factor deficiency		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Coagulopathy	Additional description: Coagulopathy		
subjects affected / exposed	1 / 20 (5.00%)	2 / 22 (9.09%)	
occurrences (all)	1	2	
Disseminated intravascular coagulation	Additional description: Disseminated intravascular coagulation		
subjects affected / exposed	2 / 20 (10.00%)	1 / 22 (4.55%)	
occurrences (all)	2	1	
Erythropenia	Additional description: Erythropenia		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Haemorrhagic anaemia	Additional description: Haemorrhagic anaemia		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Heparin-induced thrombocytopenia	Additional description: Heparin-induced thrombocytopenia		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Leukocytosis	Additional description: Leukocytosis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Thrombocytopenia	Additional description: Thrombocytopenia		

subjects affected / exposed	0 / 20 (0.00%)	2 / 22 (9.09%)	
occurrences (all)	0	2	
Ear and labyrinth disorders			
Hypoacusis	Additional description: Hypoacusis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Gaze palsy	Additional description: Gaze palsy		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Pupils unequal	Additional description: Pupils unequal		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Visual impairment	Additional description: Visual impairment		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Anal incontinence	Additional description: Anal incontinence		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Constipation	Additional description: Constipation		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	1 / 20 (5.00%)	2 / 22 (9.09%)	
occurrences (all)	1	2	
Duodenal ulcer	Additional description: Duodenal ulcer		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Dysphagia	Additional description: Dysphagia		

subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Flatulence	Additional description: Flatulence		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Gastritis	Additional description: Gastritis		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal haemorrhage	Additional description: Gastrointestinal haemorrhage		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Large intestinal ulcer	Additional description: Large intestinal ulcer		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Nausea	Additional description: Nausea		
subjects affected / exposed	2 / 20 (10.00%)	2 / 22 (9.09%)	
occurrences (all)	2	2	
Pancreatitis	Additional description: Pancreatitis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Subileus	Additional description: Subileus		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Vomiting	Additional description: Vomiting		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Decubitus ulcer	Additional description: Decubitus ulcer		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Erythema	Additional description: Erythema		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Rash generalised	Additional description: Rash generalised		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	

Subcutaneous emphysema	Additional description: Subcutaneous emphysema		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Acute kidney injury	Additional description: Acute kidney injury		
subjects affected / exposed	5 / 20 (25.00%)	6 / 22 (27.27%)	
occurrences (all)	5	6	
Acute prerenal failure	Additional description: Acute prerenal failure		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Dysuria	Additional description: Dysuria		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Haematuria	Additional description: Haematuria		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Oliguria	Additional description: Oliguria		
subjects affected / exposed	0 / 20 (0.00%)	2 / 22 (9.09%)	
occurrences (all)	0	2	
Renal failure	Additional description: Renal failure		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Urinary incontinence	Additional description: Urinary incontinence		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	1 / 20 (5.00%)	1 / 22 (4.55%)	
occurrences (all)	1	1	
Musculoskeletal and connective tissue disorders			
Back pain	Additional description: Back pain		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Muscle spasms	Additional description: Muscle spasms		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Muscular weakness	Additional description: Muscular weakness		

subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal chest pain	Additional description: Musculoskeletal chest pain		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	2	
Musculoskeletal pain	Additional description: Musculoskeletal pain		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Bacterial disease carrier	Additional description: Bacterial disease carrier		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Bronchitis	Additional description: Bronchitis		
subjects affected / exposed	1 / 20 (5.00%)	1 / 22 (4.55%)	
occurrences (all)	1	1	
Clostridial infection	Additional description: Clostridial infection		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Cystitis	Additional description: Cystitis		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Device related infection	Additional description: Device related infection		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Enterococcal infection	Additional description: Enterococcal infection		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Infection	Additional description: Infection		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Infectious disease carrier	Additional description: Infectious disease carrier		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis	Additional description: Nasopharyngitis		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	

Nosocomial infection	Additional description: Nosocomial infection		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	1 / 20 (5.00%)	2 / 22 (9.09%)	
occurrences (all)	1	2	
Pneumonia escherichia	Additional description: Pneumonia escherichia		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Pneumonia klebsiella	Additional description: Pneumonia klebsiella		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Tracheobronchitis	Additional description: Tracheobronchitis		
subjects affected / exposed	1 / 20 (5.00%)	0 / 22 (0.00%)	
occurrences (all)	1	0	
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			
Fluid retention	Additional description: Fluid retention		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Gout	Additional description: Gout		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Hyperkalaemia	Additional description: Hyperkalaemia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Hypernatraemia	Additional description: Hypernatraemia		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	
Hypoalbuminaemia	Additional description: Hypoalbuminaemia		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Hyponatraemia	Additional description: Hyponatraemia		

subjects affected / exposed	1 / 20 (5.00%)	1 / 22 (4.55%)	
occurrences (all)	1	1	
Hypovolaemia	Additional description: Hypovolaemia		
subjects affected / exposed	0 / 20 (0.00%)	1 / 22 (4.55%)	
occurrences (all)	0	1	
Metabolic acidosis	Additional description: Metabolic acidosis		
subjects affected / exposed	0 / 20 (0.00%)	2 / 22 (9.09%)	
occurrences (all)	0	2	
Protein deficiency	Additional description: Protein deficiency		
subjects affected / exposed	0 / 20 (0.00%)	0 / 22 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported