



Clinical trial results:

Randomized, Multi-centre, Phase II Trial to compare the Event-Free Survival of Clofarabine / Ara-C (ClAraC) or of FLAMSA Treatment in Patients with High Risk AML or Advanced MDS scheduled for Allogeneic Stem Cell Transplantation

Summary

EudraCT number	2010-021944-17
Trial protocol	DE
Global end of trial date	15 May 2017

Results information

Result version number	v1 (current)
This version publication date	14 December 2023
First version publication date	14 December 2023

Trial information

Trial identification

Sponsor protocol code	ClAraC-SCT-01
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01423175
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Hannover Medical School
Sponsor organisation address	Carl-Neuberg-Str. 1, Hannover, Germany, 30625
Public contact	Stabsstelle Zentrum für Klinische Studien, Hannover Medical School, EudraCT@mh-hannover.de
Scientific contact	Stabsstelle Zentrum für Klinische Studien, Hannover Medical School, EudraCT@mh-hannover.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	14 May 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 May 2017
Global end of trial reached?	Yes
Global end of trial date	15 May 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that event-free survival is improved by using CIaRaC instead of the FLAMSA regimen.

Protection of trial subjects:

The clinical trial was conducted in accordance with the ethical principles that have their origins in the Declaration of Helsinki and with the standards of International Conference on Harmonisation (ICH) Good Clinical Practice (GCP). A continuous risk assessment was performed during the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 May 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 60
Worldwide total number of subjects	60
EEA total number of subjects	60

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)	53
From 65 to 84 years	7
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients with high risk acute myeloid leukemia (AML) or advanced myelodysplastic syndrome (MDS) scheduled for allogeneic stem cell transplantation (SCT) were included in this clinical trial.

Pre-assignment

Screening details:

Eligibility will be determined based upon the inclusion and exclusion criteria

Period 1

Period 1 title	overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:
open-label

Arms

Are arms mutually exclusive?	Yes
Arm title	CIARA group

Arm description:

Clofarabine 30 mg/m² i.v., one hour infusion d - 16 to - 12

Ara-C 1000 mg/m² i.v. (two hour infusion three hours after clofarabine) d - 16 to - 12

Arm type	Experimental
Investigational medicinal product name	Clofarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Concentrate for solution for infusion

Dosage and administration details:

Clofarabine 30 mg/m² i.v., one hour infusion

Investigational medicinal product name	Ara-C
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Concentrate for solution for infusion

Dosage and administration details:

1000 mg/m² i.v. (two hour infusion three hours after clofarabine)

Arm title	FLAMSA group
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Arm description:

Fludarabine 30 mg/m² i.v., one hour infusion d - 13 to d - 10

Amsacrine 100 mg/m² i.v., one hour infusion d - 13 to d - 10

Ara-C 2000 mg/m² i.v., (two hour infusion three hours after fludarabine) d - 13 to d - 10

Arm type	Active comparator
Investigational medicinal product name	Fludarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Concentrate for solution for infusion

Dosage and administration details:	
30 mg/m ² i.v., one hour infusion	
Investigational medicinal product name	Amsacrine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Concentrate for solution for infusion
Dosage and administration details:	
Amsacrine 100 mg/m ² i.v., one hour infusion	
Investigational medicinal product name	Ara-C
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Concentrate for solution for infusion
Dosage and administration details:	
2000 mg/m ² i.v., (two hour infusion three hours after fludarabine)	

Number of subjects in period 1	CIaRaC group	FLAMSA group
Started	30	30
Completed	30	30

Baseline characteristics

End points

End points reporting groups

Reporting group title	CIARA group
Reporting group description:	
Clofarabine 30 mg/m ² i.v., one hour infusion d - 16 to - 12	
Ara-C 1000 mg/m ² i.v. (two hour infusion three hours after clofarabine) d - 16 to - 12	
Reporting group title	FLAMSA group
Reporting group description:	
Fludarabine 30 mg/m ² i.v., one hour infusion d - 13 to d - 10	
Amsacrine 100 mg/m ² i.v., one hour infusion d - 13 to d - 10	
Ara-C 2000 mg/m ² i.v., (two hour infusion three hours after fludarabine) d - 13 to d - 10	

Primary: Event-free survival

End point title	Event-free survival
End point description:	
To demonstrate that event-free survival is improved by using CIARA instead of the FLAMSA regimen.	
End point type	Primary
End point timeframe:	
days	

End point values	CIARA group	FLAMSA group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: days				
arithmetic mean (standard error)	656.6 (± 84.6)	565.6 (± 49.2)		

Statistical analyses

Statistical analysis title	event-free survival
Comparison groups	CIARA group v FLAMSA group
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.1774
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	3.13

Secondary: Overall survival

End point title	Overall survival
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End point description:

Overall survival is defined as time from randomisation until date of death due to any cause. Living patients were censored at the end of the trial.

End point type	Secondary
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End point timeframe:

End of trial

End point values	CIArAC group	FLAMSA group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: percentage death				
number (not applicable)	53.3	40.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Relapse-free survival

End point title	Relapse-free survival
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End point description:

Relapse-free survival is defined as time from randomization until the date of first objective documentation of disease recurrence or death due to any cause, whichever occurs first. Patients were censored at the end of the trial if no event had been observed. The p-value of the stratified Logrank-test is 0.2518.

End point type	Secondary
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End point timeframe:

End of trial

End point values	CIArAC group	FLAMSA group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: No. events/ no. patients				
number (not applicable)	17	13		

Statistical analyses

Statistical analysis title	stratified Cox regression
Statistical analysis description: A stratified Cox regression model was used to compare the two treatment arms. The model shows a Hazard Ratio > 1 for the experimental treatment. adjusted for center and remission state, all patients	
Comparison groups	CIARA group v FLAMSA group
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3101
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Confidence interval	
level	95 %
sides	1-sided
lower limit	0.706
upper limit	3.084
Variability estimate	Standard deviation
Dispersion value	0.3101

Secondary: Cardiac toxicity

End point title	Cardiac toxicity
End point description: A logistic regression analysis was performed to compare the two treatment arms. The stratified analysis included only remission state and not center due to convergence problems for maximum likelihood estimates of variable center.	
End point type	Secondary
End point timeframe: Cardiac toxicity was observed from the first administration of IMP until day 30 after SCT.	

End point values	CIARA group	FLAMSA group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: no. events/ no. events				
number (not applicable)	26	27		

Statistical analyses

Statistical analysis title	Regressions Analysis
Statistical analysis description: A logistic regression analysis was performed to compare the two treatment arms. The stratified analysis included only remission state and not center due to convergence problems for maximum likelihood estimates of variable center	
Comparison groups	CIARA group v FLAMSA group

Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7304
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.146
upper limit	3.846
Variability estimate	Standard deviation
Dispersion value	0.75

Secondary: Rate of engraftment

End point title	Rate of engraftment
End point description:	
Engraftment was defined in the study protocol by leukocytes > 1.000/μl or neutrophils >500/μl during the course of the study. However, in order to comply with more recent EBMT guidelines, the definition of only neutrophils > 500/μl seems to be more suitable. Both definitions lead to the same results	
End point type	Secondary
End point timeframe:	
during study	

End point values	CIaRaC group	FLAMSA group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: No. Events /No. Patients				
number (not applicable)	28	28		

Statistical analyses

Statistical analysis title	Regression analysis
Comparison groups	FLAMSA group v CIaRaC group
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9704
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.134
upper limit	8.056
Variability estimate	Standard deviation
Dispersion value	1.04

Secondary: Kinetics of chimerism after SCT

End point title	Kinetics of chimerism after SCT
End point description:	
Analysis of chimerism refers to the measurement of donor cells after SCT. If the transplantation is successful, it is anticipated that the percentage of donor cells will ideally be at 100%. The more the measurement deviates from 100% (i.e. decreases), the more likely is a relapse of the disease	
End point type	Secondary
End point timeframe:	
Results are presented for the 18 months time-point (the minimum observation time of the trial) because it is of interest whether the patients develop an early relapse and are able to keep the transplant over time.	

End point values	CIARaC group	FLAMSA group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: No. Events /No. Patients				
number (not applicable)	11	10		

Statistical analyses

Statistical analysis title	Regression analysis
Comparison groups	CIARaC group v FLAMSA group
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7698
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.404
upper limit	3.404
Variability estimate	Standard deviation
Dispersion value	1.173

Adverse events

Adverse events information

Timeframe for reporting adverse events:

from the first administration of one of the IMPs until day 30 after stem cell transplantation.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20.0
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Reporting groups

Reporting group title	FLAMSA
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Reporting group description: -

Reporting group title	CIaRaC
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Reporting group description: -

Serious adverse events	FLAMSA	CIaRaC	
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 30 (23.33%)	7 / 30 (23.33%)	
number of deaths (all causes)	3	4	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Vascular disorders			
Capillary leak syndrome			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Venoocclusive disease			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			

subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Disease progression			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Investigations			
Blood lactic acid increased			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Injury, poisoning and procedural complications			
Transplant failure			

subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Cardiac arrest			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Coma			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Oesophagitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hepatic failure			

subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	2 / 30 (6.67%)	1 / 30 (3.33%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Renal failure			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Cytomegalovirus infection			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Sepsis			
subjects affected / exposed	2 / 30 (6.67%)	2 / 30 (6.67%)	
occurrences causally related to treatment / all	1 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Intestinal sepsis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterococcal infection			

subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral haemorrhagic cystitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypervolaemia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour lysis syndrome			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	

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

Non-serious adverse events	FLAMSA	CIaRaC	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	30 / 30 (100.00%)	30 / 30 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Vascular disorders			
Capillary leak syndrome			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Arterial haemorrhage			

subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Circulatory collapse		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Extremity necrosis		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Pallor		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Hypotension		
subjects affected / exposed	7 / 30 (23.33%)	12 / 30 (40.00%)
occurrences (all)	10	20
Hypertensive crisis		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Hypertension		
subjects affected / exposed	16 / 30 (53.33%)	19 / 30 (63.33%)
occurrences (all)	28	30
Hot flush		
subjects affected / exposed	0 / 30 (0.00%)	3 / 30 (10.00%)
occurrences (all)	0	3
Haemorrhage		
subjects affected / exposed	1 / 30 (3.33%)	5 / 30 (16.67%)
occurrences (all)	1	5
Haematoma		
subjects affected / exposed	4 / 30 (13.33%)	2 / 30 (6.67%)
occurrences (all)	4	2
Flushing		
subjects affected / exposed	3 / 30 (10.00%)	4 / 30 (13.33%)
occurrences (all)	4	4
Peripheral coldness		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Thrombophlebitis		

subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Venoocclusive disease			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Catheter site erythema			
subjects affected / exposed	5 / 30 (16.67%)	3 / 30 (10.00%)	
occurrences (all)	6	3	
Catheter site haematoma			
subjects affected / exposed	2 / 30 (6.67%)	1 / 30 (3.33%)	
occurrences (all)	2	1	
Catheter site haemorrhage			
subjects affected / exposed	3 / 30 (10.00%)	3 / 30 (10.00%)	
occurrences (all)	5	4	
Catheter site inflammation			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Administration site papule			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Asthenia			
subjects affected / exposed	1 / 30 (3.33%)	2 / 30 (6.67%)	
occurrences (all)	1	2	
Axillary pain			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	
occurrences (all)	1	1	
Catheter site pain			
subjects affected / exposed	6 / 30 (20.00%)	5 / 30 (16.67%)	
occurrences (all)	8	9	
Catheter site related reaction			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	
occurrences (all)	2	0	
Catheter site swelling			

subjects affected / exposed	4 / 30 (13.33%)	1 / 30 (3.33%)
occurrences (all)	4	1
Chest discomfort		
subjects affected / exposed	1 / 30 (3.33%)	2 / 30 (6.67%)
occurrences (all)	1	2
Chest pain		
subjects affected / exposed	5 / 30 (16.67%)	7 / 30 (23.33%)
occurrences (all)	10	7
Chills		
subjects affected / exposed	18 / 30 (60.00%)	12 / 30 (40.00%)
occurrences (all)	22	16
Early satiety		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	2	0
Face oedema		
subjects affected / exposed	1 / 30 (3.33%)	2 / 30 (6.67%)
occurrences (all)	1	2
Facial pain		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	2	0
Injection site reaction		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Malaise		
subjects affected / exposed	1 / 30 (3.33%)	2 / 30 (6.67%)
occurrences (all)	1	3
Mucosal dryness		
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)
occurrences (all)	1	1
Injection site extravasation		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	2
Gait disturbance		
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)
occurrences (all)	0	2
Feeling hot		

subjects affected / exposed	1 / 30 (3.33%)	2 / 30 (6.67%)
occurrences (all)	1	2
Fatigue		
subjects affected / exposed	18 / 30 (60.00%)	24 / 30 (80.00%)
occurrences (all)	25	34
Mucosal haemorrhage		
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)
occurrences (all)	2	0
Mucosal pain		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Mucosal inflammation		
subjects affected / exposed	13 / 30 (43.33%)	12 / 30 (40.00%)
occurrences (all)	16	18
Mucosal ulceration		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Oedema		
subjects affected / exposed	11 / 30 (36.67%)	15 / 30 (50.00%)
occurrences (all)	19	20
Oedema peripheral		
subjects affected / exposed	13 / 30 (43.33%)	14 / 30 (46.67%)
occurrences (all)	21	31
Pain		
subjects affected / exposed	2 / 30 (6.67%)	8 / 30 (26.67%)
occurrences (all)	2	9
Polyp		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Pyrexia		
subjects affected / exposed	27 / 30 (90.00%)	28 / 30 (93.33%)
occurrences (all)	68	81
Sensation of foreign body		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Peripheral swelling		

subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 3	4 / 30 (13.33%) 5	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	2 / 30 (6.67%)	2 / 30 (6.67%)	
occurrences (all)	3	2	
Engraftment syndrome			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Reproductive system and breast disorders			
Genital rash			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Genital blister			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Dysmenorrhoea			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Breast pain			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Genital swelling			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Menstrual discomfort			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Menstrual disorder			
subjects affected / exposed	2 / 30 (6.67%)	1 / 30 (3.33%)	
occurrences (all)	2	1	
Pelvic pain			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	
occurrences (all)	1	1	
Vaginal haemorrhage			

subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	
occurrences (all)	1	1	
Vulvovaginal pruritus			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Vulvovaginal burning sensation			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	
occurrences (all)	0	2	
Bronchial haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Cough			
subjects affected / exposed	5 / 30 (16.67%)	9 / 30 (30.00%)	
occurrences (all)	6	15	
Dysphonia			
subjects affected / exposed	2 / 30 (6.67%)	2 / 30 (6.67%)	
occurrences (all)	2	2	
Dyspnoea			
subjects affected / exposed	6 / 30 (20.00%)	7 / 30 (23.33%)	
occurrences (all)	9	8	
Nasal discomfort			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Epistaxis			
subjects affected / exposed	11 / 30 (36.67%)	6 / 30 (20.00%)	
occurrences (all)	15	11	
Haemoptysis			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	
occurrences (all)	3	0	
Hiccups			

subjects affected / exposed	2 / 30 (6.67%)	4 / 30 (13.33%)
occurrences (all)	2	5
Hypoxia		
subjects affected / exposed	1 / 30 (3.33%)	2 / 30 (6.67%)
occurrences (all)	2	3
Laryngeal pain		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Dyspnoea exertional		
subjects affected / exposed	2 / 30 (6.67%)	3 / 30 (10.00%)
occurrences (all)	3	3
Nasal dryness		
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)
occurrences (all)	0	2
Oropharyngeal pain		
subjects affected / exposed	5 / 30 (16.67%)	3 / 30 (10.00%)
occurrences (all)	5	3
Orthopnoea		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Pharyngeal erythema		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Pleural effusion		
subjects affected / exposed	2 / 30 (6.67%)	3 / 30 (10.00%)
occurrences (all)	2	4
Sneezing		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Pulmonary congestion		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Pulmonary oedema		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Respiratory failure		

subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0	1 / 30 (3.33%) 1	
Rhinorrhoea subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1	1 / 30 (3.33%) 1	
Productive cough subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0	1 / 30 (3.33%) 1	
Tachypnoea subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0	1 / 30 (3.33%) 1	
Psychiatric disorders Confusional state subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1	2 / 30 (6.67%) 2	
Agitation subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1	1 / 30 (3.33%) 1	
Anorexia and bulimia syndrome subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0	2 / 30 (6.67%) 2	
Anxiety subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1	3 / 30 (10.00%) 4	
Delirium subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0	1 / 30 (3.33%) 1	
Psychiatric symptom subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1	0 / 30 (0.00%) 0	
Depression subjects affected / exposed occurrences (all)	3 / 30 (10.00%) 3	2 / 30 (6.67%) 2	
Hallucination subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1	3 / 30 (10.00%) 3	

Hallucination, visual subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1	0 / 30 (0.00%) 0	
Insomnia subjects affected / exposed occurrences (all)	11 / 30 (36.67%) 14	12 / 30 (40.00%) 15	
Mental disorder subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0	1 / 30 (3.33%) 1	
Nightmare subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0	2 / 30 (6.67%) 2	
Sleep disorder subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0	3 / 30 (10.00%) 3	
Restlessness subjects affected / exposed occurrences (all)	2 / 30 (6.67%) 3	1 / 30 (3.33%) 1	
Sopor subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1	0 / 30 (0.00%) 0	
Tension subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0	2 / 30 (6.67%) 2	
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 2	0 / 30 (0.00%) 0	
Blood pressure diastolic decreased subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0	1 / 30 (3.33%) 1	
Blood pressure abnormal subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1	0 / 30 (0.00%) 0	
Blood potassium decreased			

subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)
occurrences (all)	0	2
Aspartate aminotransferase increased		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	2	0
Blood glucose increased		
subjects affected / exposed	3 / 30 (10.00%)	3 / 30 (10.00%)
occurrences (all)	3	8
Blood creatinine increased		
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)
occurrences (all)	1	1
Blood bilirubin increased		
subjects affected / exposed	1 / 30 (3.33%)	2 / 30 (6.67%)
occurrences (all)	1	5
Blood pH decreased		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Immunoglobulins decreased		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Hepatic enzyme increased		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Heart rate irregular		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
General physical condition abnormal		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Gamma-glutamyltransferase increased		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Enterococcus test positive		

subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Coagulation factor decreased		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Coagulation factor XIII level decreased		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Cardiac imaging procedure abnormal		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Inflammatory marker increased		
subjects affected / exposed	2 / 30 (6.67%)	2 / 30 (6.67%)
occurrences (all)	2	2
C-reactive protein increased		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
International normalised ratio increased		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Lipase increased		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Pancreatic enzymes decreased		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Neutrophil count decreased		
subjects affected / exposed	6 / 30 (20.00%)	3 / 30 (10.00%)
occurrences (all)	24	10
Oxygen saturation decreased		
subjects affected / exposed	0 / 30 (0.00%)	4 / 30 (13.33%)
occurrences (all)	0	4
Lymphocyte count decreased		

subjects affected / exposed	4 / 30 (13.33%)	1 / 30 (3.33%)
occurrences (all)	17	2
Polyomavirus test positive		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Pulmonary function test abnormal		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Roseolovirus test positive		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Transaminases increased		
subjects affected / exposed	1 / 30 (3.33%)	8 / 30 (26.67%)
occurrences (all)	1	9
Urine lactic acid increased		
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)
occurrences (all)	2	0
Viral titre increased		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Vital capacity decreased		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Weight decreased		
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)
occurrences (all)	0	2
Weight increased		
subjects affected / exposed	19 / 30 (63.33%)	23 / 30 (76.67%)
occurrences (all)	28	39
White blood cell count decreased		
subjects affected / exposed	6 / 30 (20.00%)	7 / 30 (23.33%)
occurrences (all)	36	24
Platelet count decreased		
subjects affected / exposed	6 / 30 (20.00%)	7 / 30 (23.33%)
occurrences (all)	65	91
pH urine decreased		

subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	
occurrences (all)	0	2	
Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Joint injury			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Anal injury			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Post procedural haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Procedural dizziness			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Scratch			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Spinal fracture			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Sternal fracture			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Subdural haematoma			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Vascular access site pain			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Thermal burn			

subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	2 / 30 (6.67%)	1 / 30 (3.33%)	
occurrences (all)	2	2	
Bradycardia			
subjects affected / exposed	7 / 30 (23.33%)	7 / 30 (23.33%)	
occurrences (all)	8	10	
Cardiac failure			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	
occurrences (all)	0	2	
Cardiomegaly			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Sinus bradycardia			
subjects affected / exposed	1 / 30 (3.33%)	2 / 30 (6.67%)	
occurrences (all)	1	2	
Cardiovascular insufficiency			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Cyanosis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Extrasystoles			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Pericardial effusion			
subjects affected / exposed	1 / 30 (3.33%)	2 / 30 (6.67%)	
occurrences (all)	1	2	
Cardiovascular disorder			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Sinus tachycardia			
subjects affected / exposed	3 / 30 (10.00%)	3 / 30 (10.00%)	
occurrences (all)	4	5	

Tachyarrhythmia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Tachycardia			
subjects affected / exposed	17 / 30 (56.67%)	14 / 30 (46.67%)	
occurrences (all)	27	26	
Ventricular extrasystoles			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Ventricular tachycardia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Aphasia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Burning sensation			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	
occurrences (all)	1	1	
Depressed level of consciousness			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Dizziness			
subjects affected / exposed	13 / 30 (43.33%)	11 / 30 (36.67%)	
occurrences (all)	15	14	
Dysarthria			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Headache			
subjects affected / exposed	13 / 30 (43.33%)	17 / 30 (56.67%)	
occurrences (all)	23	33	
Polyneuropathy			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	
occurrences (all)	0	4	
Hypertonia			

subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	
occurrences (all)	2	0	
Hypoaesthesia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Hypotonia			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	
occurrences (all)	5	0	
Orthostatic intolerance			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Paraesthesia			
subjects affected / exposed	6 / 30 (20.00%)	3 / 30 (10.00%)	
occurrences (all)	6	3	
Hyperaesthesia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Seizure			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Somnolence			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	
occurrences (all)	1	1	
Syncope			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	
occurrences (all)	1	1	
Tremor			
subjects affected / exposed	5 / 30 (16.67%)	3 / 30 (10.00%)	
occurrences (all)	5	4	
VIth nerve disorder			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	6 / 30 (20.00%)	6 / 30 (20.00%)	
occurrences (all)	73	51	

Febrile neutropenia subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1	0 / 30 (0.00%) 0	
Hilar lymphadenopathy subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0	1 / 30 (3.33%) 1	
Lymphadenopathy subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1	0 / 30 (0.00%) 0	
Splenomegaly subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0	2 / 30 (6.67%) 2	
Thrombotic thrombocytopenic purpura subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1	0 / 30 (0.00%) 0	
Coagulopathy subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0	1 / 30 (3.33%) 1	
Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all)	4 / 30 (13.33%) 5	6 / 30 (20.00%) 8	
Deafness neurosensory subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0	1 / 30 (3.33%) 1	
Hypoacusis subjects affected / exposed occurrences (all)	2 / 30 (6.67%) 2	0 / 30 (0.00%) 0	
Middle ear effusion subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0	1 / 30 (3.33%) 1	
Eye disorders Lacrimation increased subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1	2 / 30 (6.67%) 2	
Conjunctival oedema			

subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Dry eye			
subjects affected / exposed	3 / 30 (10.00%)	3 / 30 (10.00%)	
occurrences (all)	3	3	
Eye haemorrhage			
subjects affected / exposed	4 / 30 (13.33%)	2 / 30 (6.67%)	
occurrences (all)	4	2	
Eye irritation			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	
occurrences (all)	1	1	
Eyelid oedema			
subjects affected / exposed	3 / 30 (10.00%)	2 / 30 (6.67%)	
occurrences (all)	3	2	
Conjunctival haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	
occurrences (all)	0	2	
Ocular discomfort			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Ocular hyperaemia			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	
occurrences (all)	0	2	
Photopsia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Vision blurred			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Vitreous haemorrhage			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Visual impairment			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			

Abdominal discomfort		
subjects affected / exposed	4 / 30 (13.33%)	4 / 30 (13.33%)
occurrences (all)	6	4
Abdominal distension		
subjects affected / exposed	2 / 30 (6.67%)	1 / 30 (3.33%)
occurrences (all)	2	1
Abdominal pain		
subjects affected / exposed	10 / 30 (33.33%)	12 / 30 (40.00%)
occurrences (all)	15	18
Abdominal pain upper		
subjects affected / exposed	12 / 30 (40.00%)	8 / 30 (26.67%)
occurrences (all)	22	10
Constipation		
subjects affected / exposed	13 / 30 (43.33%)	16 / 30 (53.33%)
occurrences (all)	22	25
Anorectal disorder		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Aphthous ulcer		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Ascites		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Coating in mouth		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Anal haemorrhage		
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)
occurrences (all)	1	1
Diarrhoea		
subjects affected / exposed	22 / 30 (73.33%)	22 / 30 (73.33%)
occurrences (all)	36	42
Dry mouth		
subjects affected / exposed	1 / 30 (3.33%)	2 / 30 (6.67%)
occurrences (all)	1	2

Dyspepsia		
subjects affected / exposed	6 / 30 (20.00%)	1 / 30 (3.33%)
occurrences (all)	8	1
Dysphagia		
subjects affected / exposed	2 / 30 (6.67%)	2 / 30 (6.67%)
occurrences (all)	2	2
Enteritis		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Epigastric discomfort		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Eructation		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Flatulence		
subjects affected / exposed	2 / 30 (6.67%)	3 / 30 (10.00%)
occurrences (all)	2	3
Gastric disorder		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	2	0
Gastritis		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Gastrooesophageal reflux disease		
subjects affected / exposed	2 / 30 (6.67%)	3 / 30 (10.00%)
occurrences (all)	2	3
Intestinal haemorrhage		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Haemorrhoids		
subjects affected / exposed	2 / 30 (6.67%)	4 / 30 (13.33%)
occurrences (all)	2	4
Impaired gastric emptying		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1

Lip blister		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Lip pruritus		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Nausea		
subjects affected / exposed	27 / 30 (90.00%)	29 / 30 (96.67%)
occurrences (all)	68	69
Melaena		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Mouth haemorrhage		
subjects affected / exposed	4 / 30 (13.33%)	2 / 30 (6.67%)
occurrences (all)	8	2
Mouth swelling		
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)
occurrences (all)	0	3
Mouth ulceration		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Lip swelling		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Oesophagitis		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Oesophageal pain		
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)
occurrences (all)	1	1
Odynophagia		
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)
occurrences (all)	1	1
Oral discomfort		
subjects affected / exposed	1 / 30 (3.33%)	3 / 30 (10.00%)
occurrences (all)	1	3

Oral pain		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Oral mucosal erythema		
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)
occurrences (all)	0	2
Oral mucosal blistering		
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)
occurrences (all)	1	1
Pancreatitis		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Proctalgia		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Rectal haemorrhage		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Small intestinal obstruction		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Stomatitis		
subjects affected / exposed	8 / 30 (26.67%)	10 / 30 (33.33%)
occurrences (all)	12	19
Tongue ulceration		
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)
occurrences (all)	2	0
Vomiting		
subjects affected / exposed	25 / 30 (83.33%)	22 / 30 (73.33%)
occurrences (all)	65	53
Toothache		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Tongue coated		
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)
occurrences (all)	1	2

Hepatobiliary disorders			
Jaundice			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Hyperbilirubinaemia			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	
occurrences (all)	0	3	
Hepatotoxicity			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	
occurrences (all)	0	2	
Ocular icterus			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	
occurrences (all)	0	2	
Skin and subcutaneous tissue disorders			
Blister			
subjects affected / exposed	2 / 30 (6.67%)	1 / 30 (3.33%)	
occurrences (all)	3	1	
Pain of skin			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Night sweats			
subjects affected / exposed	0 / 30 (0.00%)	3 / 30 (10.00%)	
occurrences (all)	0	3	
Nail disorder			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Hyperhidrosis			
subjects affected / exposed	2 / 30 (6.67%)	3 / 30 (10.00%)	
occurrences (all)	2	3	
Erythema			
subjects affected / exposed	4 / 30 (13.33%)	8 / 30 (26.67%)	
occurrences (all)	5	9	
Dry skin			
subjects affected / exposed	1 / 30 (3.33%)	9 / 30 (30.00%)	
occurrences (all)	2	12	
Dermatitis			

subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Decubitus ulcer		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Cold sweat		
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)
occurrences (all)	1	1
Blood blister		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Petechiae		
subjects affected / exposed	4 / 30 (13.33%)	9 / 30 (30.00%)
occurrences (all)	4	13
Pruritus		
subjects affected / exposed	6 / 30 (20.00%)	10 / 30 (33.33%)
occurrences (all)	10	21
Purpura		
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)
occurrences (all)	1	1
Rash		
subjects affected / exposed	19 / 30 (63.33%)	14 / 30 (46.67%)
occurrences (all)	35	25
Rash maculo-papular		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Skin lesion		
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)
occurrences (all)	1	1
Skin exfoliation		
subjects affected / exposed	2 / 30 (6.67%)	2 / 30 (6.67%)
occurrences (all)	2	2
Skin fissures		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Palmar-plantar erythrodysesthesia		

syndrome			
subjects affected / exposed	8 / 30 (26.67%)	9 / 30 (30.00%)	
occurrences (all)	8	10	
Palmar erythema			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Rash pruritic			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Skin maceration			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Swelling face			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	
occurrences (all)	1	1	
Renal and urinary disorders			
Azotaemia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Acute kidney injury			
subjects affected / exposed	2 / 30 (6.67%)	2 / 30 (6.67%)	
occurrences (all)	2	2	
Dysuria			
subjects affected / exposed	5 / 30 (16.67%)	5 / 30 (16.67%)	
occurrences (all)	7	5	
Chromaturia			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	
occurrences (all)	0	3	
Haematuria			
subjects affected / exposed	5 / 30 (16.67%)	4 / 30 (13.33%)	
occurrences (all)	5	4	
Urinary retention			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Renal pain			

subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Renal impairment			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	
occurrences (all)	0	2	
Renal failure			
subjects affected / exposed	3 / 30 (10.00%)	1 / 30 (3.33%)	
occurrences (all)	3	1	
Polyuria			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	
occurrences (all)	0	2	
Pollakiuria			
subjects affected / exposed	0 / 30 (0.00%)	4 / 30 (13.33%)	
occurrences (all)	0	5	
Oliguria			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	
occurrences (all)	1	1	
Nocturia			
subjects affected / exposed	3 / 30 (10.00%)	3 / 30 (10.00%)	
occurrences (all)	3	3	
Urinary tract pain			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	
occurrences (all)	1	1	
Adrenal disorder			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Flank pain			
subjects affected / exposed	2 / 30 (6.67%)	1 / 30 (3.33%)	
occurrences (all)	2	1	
Coccydynia			

subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Muscle spasms		
subjects affected / exposed	3 / 30 (10.00%)	1 / 30 (3.33%)
occurrences (all)	3	1
Limb discomfort		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Jaw cyst		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Groin pain		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	2
Arthralgia		
subjects affected / exposed	4 / 30 (13.33%)	4 / 30 (13.33%)
occurrences (all)	4	5
Back pain		
subjects affected / exposed	8 / 30 (26.67%)	10 / 30 (33.33%)
occurrences (all)	9	16
Bone pain		
subjects affected / exposed	3 / 30 (10.00%)	5 / 30 (16.67%)
occurrences (all)	3	8
Muscle tightness		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Sjogren's syndrome		
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)
occurrences (all)	2	0
Plantar fasciitis		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Pain in jaw		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Pain in extremity		

subjects affected / exposed	4 / 30 (13.33%)	7 / 30 (23.33%)	
occurrences (all)	6	9	
Spinal pain			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Myosclerosis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal pain			
subjects affected / exposed	4 / 30 (13.33%)	4 / 30 (13.33%)	
occurrences (all)	4	4	
Musculoskeletal disorder			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Muscular weakness			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Neck pain			
subjects affected / exposed	4 / 30 (13.33%)	3 / 30 (10.00%)	
occurrences (all)	4	3	
Tendon disorder			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
Atypical pneumonia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Candida infection			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Bronchitis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Bacterial sepsis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	2	

Bacterial infection		
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)
occurrences (all)	1	1
Catheter site abscess		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Conjunctivitis		
subjects affected / exposed	2 / 30 (6.67%)	3 / 30 (10.00%)
occurrences (all)	2	3
Cellulitis orbital		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	2
Catheter site infection		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Corynebacterium bacteraemia		
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)
occurrences (all)	0	2
Cystitis		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Cytomegalovirus gastroenteritis		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Cytomegalovirus infection		
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)
occurrences (all)	0	2
Herpes virus infection		
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)
occurrences (all)	0	2
Enterococcal infection		
subjects affected / exposed	2 / 30 (6.67%)	3 / 30 (10.00%)
occurrences (all)	2	4
Escherichia sepsis		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1

Genital infection fungal		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Herpes simplex		
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)
occurrences (all)	0	2
Cytomegalovirus viraemia		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Parainfluenzae virus infection		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Paronychia		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Pneumonia		
subjects affected / exposed	1 / 30 (3.33%)	2 / 30 (6.67%)
occurrences (all)	1	2
Pneumonia fungal		
subjects affected / exposed	2 / 30 (6.67%)	2 / 30 (6.67%)
occurrences (all)	2	2
Pseudomonas infection		
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)
occurrences (all)	1	1
Rash pustular		
subjects affected / exposed	1 / 30 (3.33%)	3 / 30 (10.00%)
occurrences (all)	1	3
Rhinitis		
subjects affected / exposed	3 / 30 (10.00%)	1 / 30 (3.33%)
occurrences (all)	3	2
Sepsis		
subjects affected / exposed	1 / 30 (3.33%)	3 / 30 (10.00%)
occurrences (all)	1	3
Intestinal sepsis		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0

Listeriosis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Micrococcal sepsis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Oral herpes			
subjects affected / exposed	2 / 30 (6.67%)	2 / 30 (6.67%)	
occurrences (all)	2	2	
Stenotrophomonas infection			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	
occurrences (all)	2	0	
Staphylococcal infection			
subjects affected / exposed	1 / 30 (3.33%)	3 / 30 (10.00%)	
occurrences (all)	1	3	
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Sphingomonas paucimobilis infection			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Sinusitis			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	
occurrences (all)	1	2	
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	
occurrences (all)	1	1	
Viral infection			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	2	
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	4 / 30 (13.33%)	3 / 30 (10.00%)	
occurrences (all)	4	3	
Fluid overload			

subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Dehydration		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Decreased appetite		
subjects affected / exposed	14 / 30 (46.67%)	12 / 30 (40.00%)
occurrences (all)	15	17
Hyperkalaemia		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Hypocalcaemia		
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)
occurrences (all)	3	0
Hyperuricaemia		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Hypernatraemia		
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	1	0
Hyponatraemia		
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)
occurrences (all)	1	1
Hypomagnesaemia		
subjects affected / exposed	2 / 30 (6.67%)	2 / 30 (6.67%)
occurrences (all)	2	2
Hypokalaemia		
subjects affected / exposed	2 / 30 (6.67%)	2 / 30 (6.67%)
occurrences (all)	2	2
Hypoglycaemia		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Malnutrition		
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	1
Polydipsia		

subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Vitamin K deficiency			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Hypophosphataemia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	

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