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

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 ClAraC 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	ClAraC gruop

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

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/m² 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/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: 2000 mg/m² i.v., (two hour infusion three hours after fludarabine)	

Number of subjects in period 1	ClAraC gruop	FLAMSA group
Started	30	30
Completed	30	30

Baseline characteristics

End points

End points reporting groups	
Reporting group title	ClAraC gruop
Reporting group 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	
Reporting group title	FLAMSA group
Reporting group 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	

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

End point values	ClAraC gruop	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	ClAraC gruop 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

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

End point timeframe:

End of trial

End point values	ClAraC gruop	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

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

End point timeframe:

End of trial

End point values	ClAraC gruop	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	ClAraC gruop 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	ClAraC gruop	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	ClAraC gruop 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	ClAraC gruop	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 ClAraC gruop
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	ClAraC gruop	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	ClAraC gruop 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

Dictionary used	
Dictionary name	MedDRA
Dictionary version	20.0

Reporting groups	
Reporting group title	FLAMSA
Reporting group description: -	
Reporting group title	ClAraC
Reporting group description: -	

Serious adverse events	FLAMSA	ClAraC	
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	ClAraC	
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	1 / 30 (3.33%)	4 / 30 (13.33%)	
occurrences (all)	3	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	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Rhinorrhoea			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	
occurrences (all)	1	1	
Productive cough			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Tachypnoea			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	1 / 30 (3.33%)	2 / 30 (6.67%)	
occurrences (all)	1	2	
Agitation			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	
occurrences (all)	1	1	
Anorexia and bulimia syndrome			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	
occurrences (all)	0	2	
Anxiety			
subjects affected / exposed	1 / 30 (3.33%)	3 / 30 (10.00%)	
occurrences (all)	1	4	
Delirium			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Psychiatric symptom			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Depression			
subjects affected / exposed	3 / 30 (10.00%)	2 / 30 (6.67%)	
occurrences (all)	3	2	
Hallucination			
subjects affected / exposed	1 / 30 (3.33%)	3 / 30 (10.00%)	
occurrences (all)	1	3	

Hallucination, visual			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Insomnia			
subjects affected / exposed	11 / 30 (36.67%)	12 / 30 (40.00%)	
occurrences (all)	14	15	
Mental disorder			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Nightmare			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	
occurrences (all)	0	2	
Sleep disorder			
subjects affected / exposed	0 / 30 (0.00%)	3 / 30 (10.00%)	
occurrences (all)	0	3	
Restlessness			
subjects affected / exposed	2 / 30 (6.67%)	1 / 30 (3.33%)	
occurrences (all)	3	1	
Sopor			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Tension			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	
occurrences (all)	0	2	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	2	0	
Blood pressure diastolic decreased			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Blood pressure abnormal			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	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	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Hilar lymphadenopathy			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Lymphadenopathy			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Splenomegaly			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	
occurrences (all)	0	2	
Thrombotic thrombocytopenic purpura			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Coagulopathy			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	4 / 30 (13.33%)	6 / 30 (20.00%)	
occurrences (all)	5	8	
Deafness neurosensory			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Hypoacusis			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	
occurrences (all)	2	0	
Middle ear effusion			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Eye disorders			
Lacrimation increased			
subjects affected / exposed	1 / 30 (3.33%)	2 / 30 (6.67%)	
occurrences (all)	1	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 erythrodysaesthesia			

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