



Clinical trial results:

An international randomised, multicentre, parallel-group, Phase III comparative study of inolimomab against usual care in the Treatment of Primary Steroid Refractory Acute Graft versus Host Disease (aGvHD) following allogeneic Stem Cell Transplantation in adult patients.

Summary

EudraCT number	2007-005009-24
Trial protocol	FR BE
Global end of trial date	16 February 2015

Results information

Result version number	v1 (current)
This version publication date	23 July 2016
First version publication date	23 July 2016

Trial information

Trial identification

Sponsor protocol code	INO-0107
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	EUSA Pharma
Sponsor organisation address	3 allée des Séquoias, Limonest, France, 69 760
Public contact	Jacques GUARDIOLA, EUSA Pharma, +33 (0)4 37 49 86 01, Jacques.guardiola@eusapharma.comm
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Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	16 February 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 February 2015
Global end of trial reached?	Yes
Global end of trial date	16 February 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Therapy success defined as overall survival at one year without replacement of the baseline allocated treatment

Protection of trial subjects:

N/A

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 April 2009
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 2
Country: Number of subjects enrolled	France: 98
Worldwide total number of subjects	100
EEA total number of subjects	100

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)	91
From 65 to 84 years	9
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	100
Number of subjects completed	100

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive? Yes

Arm title Arm A

Arm description:

inolimomab

Arm type	Experimental
Investigational medicinal product name	Inolimomab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

During the Induction Phases, inolimomab was administered at a dosage of 0.3 mg/kg/day over 8 consecutive days. During the Maintenance Phase, inolimomab was administered at a dosage of 0.4 mg/kg, 3 times a week. Inolimomab was administered via intravenous infusion over 30 minutes, and was to have been given at approximately the same time every dosing day.

Arm title Arm B

Arm description:

usual care

Arm type	usual care
Investigational medicinal product name	Antithymocyte globulin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Antithymocyte globulin administered in the dose and dosing regimen corresponding to usual care at each study centre

Number of subjects in period 1	Arm A	Arm B
Started	49	51
Completed	49	51

Baseline characteristics

Reporting groups

Reporting group title	Arm A
Reporting group description: inolimomab	
Reporting group title	Arm B
Reporting group description: usual care	

Reporting group values	Arm A	Arm B	Total
Number of subjects	49	51	100
Age categorical			
Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			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)			0
From 65-84 years			0
85 years and over			0
Age continuous			
Units: years			
arithmetic mean	46.2	47.1	
standard deviation	± 12.56	± 12.96	-
Gender categorical			
Units: Subjects			
Female	27	25	52
Male	22	26	48

End points

End points reporting groups

Reporting group title	Arm A
Reporting group description:	
inolimomab	
Reporting group title	Arm B
Reporting group description:	
usual care	

Primary: Higher therapy success rate with inolimomab

End point title	Higher therapy success rate with inolimomab ^[1]
End point description:	
The primary objective of the study was to demonstrate a higher therapy success rate with inolimomab treatment as compared to usual care in patients presenting with steroid-refractory aGvHD. Therapy success being defined as overall survival at 1 year without replacement of the baseline allocated treatment.	
End point type	Primary
End point timeframe:	
1 year-post	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There was no statistically significant difference between treatment arms in time from randomisation to treatment failure (defined as death or change in baseline treatment regimen; $p=0.2804$).

End point values	Arm A	Arm B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	51		
Units: Adjusted hazard rate				
number (confidence interval 95%)	0.722 (0.445 to 1.173)	0.722 (0.445 to 1.173)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From provision of informed consent through the follow-up period.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	13
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Reporting groups

Reporting group title	Arm A
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Reporting group description:

Inolimomab

Reporting group title	Arm B
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Reporting group description:

Usual care

Serious adverse events	Arm A	Arm B	
Total subjects affected by serious adverse events			
subjects affected / exposed	47 / 49 (95.92%)	46 / 51 (90.20%)	
number of deaths (all causes)	26	30	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Mycosis fungoides recurrent			
subjects affected / exposed	1 / 49 (2.04%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasma cell leukaemia			
subjects affected / exposed	1 / 49 (2.04%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Acute myeloid leukaemia			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Leukaemia recurrent			

subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Non-Hodgkin's lymphoma recurrent			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Vascular disorders			
Shock haemorrhagic			
subjects affected / exposed	2 / 49 (4.08%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hypertension			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Gastrointestinal surgery			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Disease progression			
subjects affected / exposed	7 / 49 (14.29%)	8 / 51 (15.69%)	
occurrences causally related to treatment / all	1 / 7	0 / 8	
deaths causally related to treatment / all	1 / 5	0 / 6	
Multi-organ failure			
subjects affected / exposed	3 / 49 (6.12%)	2 / 51 (3.92%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 3	0 / 2	
Pyrexia			
subjects affected / exposed	1 / 49 (2.04%)	2 / 51 (3.92%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Condition aggravated			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
General physical health deterioration			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothermia			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Graft versus host disease			
subjects affected / exposed	5 / 49 (10.20%)	7 / 51 (13.73%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 2	0 / 2	
Acute graft versus host disease			
subjects affected / exposed	2 / 49 (4.08%)	3 / 51 (5.88%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 3	
Acute graft versus host disease in skin			
subjects affected / exposed	2 / 49 (4.08%)	2 / 51 (3.92%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Chronic graft versus host disease			
subjects affected / exposed	3 / 49 (6.12%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Graft versus host disease in gastrointestinal tract			
subjects affected / exposed	2 / 49 (4.08%)	2 / 51 (3.92%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	

Acute graft versus host disease in intestine			
subjects affected / exposed	1 / 49 (2.04%)	2 / 51 (3.92%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Graft versus host disease in skin			
subjects affected / exposed	1 / 49 (2.04%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Graft versus host disease in liver			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	4 / 49 (8.16%)	3 / 51 (5.88%)	
occurrences causally related to treatment / all	0 / 4	1 / 3	
deaths causally related to treatment / all	0 / 3	1 / 2	
Lung disorder			
subjects affected / exposed	1 / 49 (2.04%)	5 / 51 (9.80%)	
occurrences causally related to treatment / all	0 / 1	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	2 / 49 (4.08%)	4 / 51 (7.84%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 2	
Acute respiratory failure			
subjects affected / exposed	2 / 49 (4.08%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Epistaxis			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Psychiatric disorders			
Confusional state			
subjects affected / exposed	2 / 49 (4.08%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Astrovirus test positive			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biopsy liver			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Full blood count decreased			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Hip fracture			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transfusion-related acute lung injury			

subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiogenic shock			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Myocardial infarction			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	1 / 49 (2.04%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Disturbance in attention			
subjects affected / exposed	1 / 49 (2.04%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Anterograde amnesia			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haematoma			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Convulsion			

subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hemiplegia			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic coma			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningorrhagia			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord compression			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Pancytopenia			
subjects affected / exposed	1 / 49 (2.04%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	1 / 49 (2.04%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asplastic anaemia			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coagulopathy			

subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile bone marrow aplasia			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Histiocytosis haematophagic			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	3 / 49 (6.12%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	2 / 49 (4.08%)	2 / 51 (3.92%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Abdominal pain			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ulcerative			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroduodenal ulcer			

subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatotoxicity			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	1 / 49 (2.04%)	2 / 51 (3.92%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Haematuria			

subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (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			
Sepsis			
subjects affected / exposed	5 / 49 (10.20%)	10 / 51 (19.61%)	
occurrences causally related to treatment / all	0 / 6	0 / 10	
deaths causally related to treatment / all	0 / 0	1 / 3	
Septic shock			
subjects affected / exposed	2 / 49 (4.08%)	8 / 51 (15.69%)	
occurrences causally related to treatment / all	0 / 2	1 / 10	
deaths causally related to treatment / all	0 / 2	1 / 6	
Pneumonia			
subjects affected / exposed	1 / 49 (2.04%)	2 / 51 (3.92%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bacteraemia			
subjects affected / exposed	1 / 49 (2.04%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Bacterial infection			
subjects affected / exposed	1 / 49 (2.04%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial sepsis			
subjects affected / exposed	0 / 49 (0.00%)	2 / 51 (3.92%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopulmonary aspergillosis			
subjects affected / exposed	1 / 49 (2.04%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	1 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Cytomegalovirus colitis			
subjects affected / exposed	1 / 49 (2.04%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytomegalovirus infection			
subjects affected / exposed	1 / 49 (2.04%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	2 / 49 (4.08%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenoviral hepatitis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Aspergillus infection			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Brain abscess			

subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Bronchiolitis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic sinusitis			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cryptosporidiosis infection			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermo-hypodermatitis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			

subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Disseminated cryptococcosis		
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalitis		
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis bacterial		
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epstein-Barr virus infection		
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia bacteraemia		
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia sepsis		
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fungal infection		
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes simplex meningoencephalitis		

subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Infection		
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0
Klebsiella bacteraemia		
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Klebsiella sepsis		
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis externa		
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia haemophilus		
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia pseudomonal		
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomonal sepsis		
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomonas bronchitis		

subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomonas infection			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis bacterial			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral diarrhoea			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral haemorrhagic cystitis			
subjects affected / exposed	1 / 49 (2.04%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	1 / 49 (2.04%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			

subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypernatraemia			
subjects affected / exposed	0 / 49 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Arm A	Arm B	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	49 / 49 (100.00%)	51 / 51 (100.00%)	
Vascular disorders			
Hypotension			
subjects affected / exposed	7 / 49 (14.29%)	12 / 51 (23.53%)	
occurrences (all)	9	16	
Hypertension			
subjects affected / exposed	8 / 49 (16.33%)	4 / 51 (7.84%)	
occurrences (all)	11	5	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	25 / 49 (51.02%)	21 / 51 (41.18%)	
occurrences (all)	52	54	
Pyrexia			
subjects affected / exposed	17 / 49 (34.69%)	23 / 51 (45.10%)	
occurrences (all)	45	56	
Oedema peripheral			
subjects affected / exposed	14 / 49 (28.57%)	21 / 51 (41.18%)	
occurrences (all)	20	43	
Chest pain			
subjects affected / exposed	5 / 49 (10.20%)	9 / 51 (17.65%)	
occurrences (all)	7	9	
Oedema			

subjects affected / exposed occurrences (all)	5 / 49 (10.20%) 9	9 / 51 (17.65%) 12	
Fatigue subjects affected / exposed occurrences (all)	4 / 49 (8.16%) 7	7 / 51 (13.73%) 19	
Chills subjects affected / exposed occurrences (all)	1 / 49 (2.04%) 1	6 / 51 (11.76%) 7	
Generalised oedema subjects affected / exposed occurrences (all)	3 / 49 (6.12%) 3	2 / 51 (3.92%) 2	
Hypothermia subjects affected / exposed occurrences (all)	1 / 49 (2.04%) 1	4 / 51 (7.84%) 8	
Hyperthermia subjects affected / exposed occurrences (all)	3 / 49 (6.12%) 6	1 / 51 (1.96%) 3	
Immune system disorders Hypogammaglobulinaemia subjects affected / exposed occurrences (all)	5 / 49 (10.20%) 5	4 / 51 (7.84%) 4	
Graft versus host disease in liver subjects affected / exposed occurrences (all)	3 / 49 (6.12%) 7	2 / 51 (3.92%) 3	
Chronic graft versus host disease subjects affected / exposed occurrences (all)	0 / 49 (0.00%) 0	3 / 51 (5.88%) 3	
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	15 / 49 (30.61%) 23	17 / 51 (33.33%) 25	
Dyspnoea subjects affected / exposed occurrences (all)	6 / 49 (12.24%) 6	5 / 51 (9.80%) 5	
Epistaxis			

subjects affected / exposed occurrences (all)	3 / 49 (6.12%) 3	7 / 51 (13.73%) 19	
Lung disorder subjects affected / exposed occurrences (all)	2 / 49 (4.08%) 3	8 / 51 (15.69%) 9	
Pleural effusion subjects affected / exposed occurrences (all)	3 / 49 (6.12%) 3	4 / 51 (7.84%) 4	
Rhinorrhoea subjects affected / exposed occurrences (all)	4 / 49 (8.16%) 4	3 / 51 (5.88%) 3	
Rales subjects affected / exposed occurrences (all)	2 / 49 (4.08%) 2	3 / 51 (5.88%) 3	
Respiratory distress subjects affected / exposed occurrences (all)	3 / 49 (6.12%) 3	2 / 51 (3.92%) 2	
Tachypnoea subjects affected / exposed occurrences (all)	1 / 49 (2.04%) 1	4 / 51 (7.84%) 4	
Productive cough subjects affected / exposed occurrences (all)	4 / 49 (8.16%) 5	0 / 51 (0.00%) 0	
Psychiatric disorders			
Anxiety subjects affected / exposed occurrences (all)	14 / 49 (28.57%) 28	13 / 51 (25.49%) 18	
Depression subjects affected / exposed occurrences (all)	9 / 49 (18.37%) 12	9 / 51 (17.65%) 11	
Confusional state subjects affected / exposed occurrences (all)	7 / 49 (14.29%) 7	9 / 51 (17.65%) 9	
Insomnia subjects affected / exposed occurrences (all)	2 / 49 (4.08%) 2	5 / 51 (9.80%) 5	

Investigations			
Weight decreased			
subjects affected / exposed	7 / 49 (14.29%)	7 / 51 (13.73%)	
occurrences (all)	8	8	
Oxygen saturation decreased			
subjects affected / exposed	0 / 49 (0.00%)	3 / 51 (5.88%)	
occurrences (all)	0	3	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	4 / 49 (8.16%)	9 / 51 (17.65%)	
occurrences (all)	6	18	
Eschar			
subjects affected / exposed	1 / 49 (2.04%)	4 / 51 (7.84%)	
occurrences (all)	2	5	
Cardiac disorders			
Tachycardia			
subjects affected / exposed	10 / 49 (20.41%)	8 / 51 (15.69%)	
occurrences (all)	14	11	
Atrial fibrillation			
subjects affected / exposed	0 / 49 (0.00%)	3 / 51 (5.88%)	
occurrences (all)	0	4	
Nervous system disorders			
Headache			
subjects affected / exposed	7 / 49 (14.29%)	8 / 51 (15.69%)	
occurrences (all)	11	21	
Tremor			
subjects affected / exposed	4 / 49 (8.16%)	2 / 51 (3.92%)	
occurrences (all)	6	4	
Somnolence			
subjects affected / exposed	2 / 49 (4.08%)	3 / 51 (5.88%)	
occurrences (all)	2	3	
Syncope			
subjects affected / exposed	3 / 49 (6.12%)	0 / 51 (0.00%)	
occurrences (all)	3	0	
Blood and lymphatic system disorders			

Thrombocytopenia subjects affected / exposed occurrences (all)	7 / 49 (14.29%) 11	11 / 51 (21.57%) 13	
Pancytopenia subjects affected / exposed occurrences (all)	3 / 49 (6.12%) 3	13 / 51 (25.49%) 14	
Leukopenia subjects affected / exposed occurrences (all)	6 / 49 (12.24%) 8	7 / 51 (13.73%) 10	
Neutropenia subjects affected / exposed occurrences (all)	6 / 49 (12.24%) 10	7 / 51 (13.73%) 16	
Anaemia subjects affected / exposed occurrences (all)	6 / 49 (12.24%) 12	5 / 51 (9.80%) 5	
Febrile neutropenia subjects affected / exposed occurrences (all)	3 / 49 (6.12%) 4	1 / 51 (1.96%) 2	
Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all)	3 / 49 (6.12%) 3	3 / 51 (5.88%) 8	
Eye disorders Dry eye subjects affected / exposed occurrences (all)	7 / 49 (14.29%) 8	7 / 51 (13.73%) 9	
Gastrointestinal disorders General physical health deterioration subjects affected / exposed occurrences (all)	2 / 49 (4.08%) 3	3 / 51 (5.88%) 3	
Abdominal pain subjects affected / exposed occurrences (all)	22 / 49 (44.90%) 44	25 / 51 (49.02%) 61	
Nausea subjects affected / exposed occurrences (all)	17 / 49 (34.69%) 30	23 / 51 (45.10%) 69	
Vomiting			

subjects affected / exposed	18 / 49 (36.73%)	19 / 51 (37.25%)
occurrences (all)	33	68
Diarrhoea		
subjects affected / exposed	12 / 49 (24.49%)	10 / 51 (19.61%)
occurrences (all)	16	18
Rectal haemorrhage		
subjects affected / exposed	7 / 49 (14.29%)	7 / 51 (13.73%)
occurrences (all)	7	9
Dry mouth		
subjects affected / exposed	8 / 49 (16.33%)	5 / 51 (9.80%)
occurrences (all)	9	5
Oral lichen planus		
subjects affected / exposed	5 / 49 (10.20%)	6 / 51 (11.76%)
occurrences (all)	6	7
Abdominal pain upper		
subjects affected / exposed	3 / 49 (6.12%)	6 / 51 (11.76%)
occurrences (all)	3	11
Constipation		
subjects affected / exposed	4 / 49 (8.16%)	5 / 51 (9.80%)
occurrences (all)	8	5
Ascites		
subjects affected / exposed	2 / 49 (4.08%)	6 / 51 (11.76%)
occurrences (all)	2	6
Haematemesis		
subjects affected / exposed	3 / 49 (6.12%)	4 / 51 (7.84%)
occurrences (all)	3	4
Mouth ulceration		
subjects affected / exposed	2 / 49 (4.08%)	4 / 51 (7.84%)
occurrences (all)	2	5
Gastrointestinal haemorrhage		
subjects affected / exposed	2 / 49 (4.08%)	3 / 51 (5.88%)
occurrences (all)	2	4
Melaena		
subjects affected / exposed	0 / 49 (0.00%)	4 / 51 (7.84%)
occurrences (all)	0	6
Haemorrhoids		

subjects affected / exposed occurrences (all)	0 / 49 (0.00%) 0	3 / 51 (5.88%) 3	
Hepatobiliary disorders			
Hepatocellular injury			
subjects affected / exposed	9 / 49 (18.37%)	13 / 51 (25.49%)	
occurrences (all)	11	15	
Cholestasis			
subjects affected / exposed	6 / 49 (12.24%)	8 / 51 (15.69%)	
occurrences (all)	6	10	
Jaundice			
subjects affected / exposed	2 / 49 (4.08%)	3 / 51 (5.88%)	
occurrences (all)	2	3	
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	8 / 49 (16.33%)	9 / 51 (17.65%)	
occurrences (all)	11	16	
Erythema			
subjects affected / exposed	4 / 49 (8.16%)	9 / 51 (17.65%)	
occurrences (all)	8	12	
Dry skin			
subjects affected / exposed	4 / 49 (8.16%)	6 / 51 (11.76%)	
occurrences (all)	5	7	
Blister			
subjects affected / exposed	3 / 49 (6.12%)	2 / 51 (3.92%)	
occurrences (all)	4	2	
Pain of skin			
subjects affected / exposed	2 / 49 (4.08%)	3 / 51 (5.88%)	
occurrences (all)	2	3	
Skin exfoliation			
subjects affected / exposed	1 / 49 (2.04%)	4 / 51 (7.84%)	
occurrences (all)	1	5	
Lichen planus			
subjects affected / exposed	3 / 49 (6.12%)	0 / 51 (0.00%)	
occurrences (all)	3	0	
Rash			

subjects affected / exposed occurrences (all)	3 / 49 (6.12%) 3	0 / 51 (0.00%) 0	
Renal and urinary disorders			
Renal failure			
subjects affected / exposed occurrences (all)	9 / 49 (18.37%) 10	11 / 51 (21.57%) 18	
Haematuria			
subjects affected / exposed occurrences (all)	7 / 49 (14.29%) 7	7 / 51 (13.73%) 10	
Dysuria			
subjects affected / exposed occurrences (all)	3 / 49 (6.12%) 7	7 / 51 (13.73%) 8	
Renal failure acute			
subjects affected / exposed occurrences (all)	4 / 49 (8.16%) 5	3 / 51 (5.88%) 3	
Cystitis haemorrhagic			
subjects affected / exposed occurrences (all)	2 / 49 (4.08%) 3	4 / 51 (7.84%) 4	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed occurrences (all)	10 / 49 (20.41%) 12	12 / 51 (23.53%) 30	
Back pain			
subjects affected / exposed occurrences (all)	8 / 49 (16.33%) 13	9 / 51 (17.65%) 14	
Pain in extremity			
subjects affected / exposed occurrences (all)	3 / 49 (6.12%) 3	8 / 51 (15.69%) 11	
Amyotrophy			
subjects affected / exposed occurrences (all)	2 / 49 (4.08%) 2	7 / 51 (13.73%) 7	
Infections and infestations			
Sepsis			
subjects affected / exposed occurrences (all)	3 / 49 (6.12%) 3	5 / 51 (9.80%) 6	
Sinusitis			

subjects affected / exposed occurrences (all)	2 / 49 (4.08%) 2	6 / 51 (11.76%) 6	
Oral fungal infection subjects affected / exposed occurrences (all)	2 / 49 (4.08%) 2	4 / 51 (7.84%) 4	
Rhinitis subjects affected / exposed occurrences (all)	2 / 49 (4.08%) 4	3 / 51 (5.88%) 3	
Cystitis subjects affected / exposed occurrences (all)	3 / 49 (6.12%) 3	1 / 51 (1.96%) 1	
Bronchopulmonary aspergillosis subjects affected / exposed occurrences (all)	3 / 49 (6.12%) 3	0 / 51 (0.00%) 0	
Metabolism and nutrition disorders			
Hypokalaemia subjects affected / exposed occurrences (all)	8 / 49 (16.33%) 10	4 / 51 (7.84%) 6	
Diabetes mellitus subjects affected / exposed occurrences (all)	4 / 49 (8.16%) 4	6 / 51 (11.76%) 7	
Hypoalbuminaemia subjects affected / exposed occurrences (all)	2 / 49 (4.08%) 2	7 / 51 (13.73%) 8	
Decreased appetite subjects affected / exposed occurrences (all)	3 / 49 (6.12%) 3	5 / 51 (9.80%) 5	
Malnutrition subjects affected / exposed occurrences (all)	3 / 49 (6.12%) 3	5 / 51 (9.80%) 6	
Fluid retention subjects affected / exposed occurrences (all)	4 / 49 (8.16%) 4	3 / 51 (5.88%) 5	
Hyperglycaemia subjects affected / exposed occurrences (all)	2 / 49 (4.08%) 2	4 / 51 (7.84%) 7	

Hypernatraemia			
subjects affected / exposed	4 / 49 (8.16%)	2 / 51 (3.92%)	
occurrences (all)	4	2	
Metabolic acidosis			
subjects affected / exposed	4 / 49 (8.16%)	2 / 51 (3.92%)	
occurrences (all)	4	2	
Dyslipidaemia			
subjects affected / exposed	1 / 49 (2.04%)	3 / 51 (5.88%)	
occurrences (all)	1	3	

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