Clinical trial results:
An Open-Label, Single-Arm, Multicenter Trial to Determine Safety and Efficacy of Eculizumab in the Prevention of Antibody Mediated Rejection (AMR) in Sensitized Recipients of a Kidney Transplant From a Deceased Donor

Summary

EudraCT number	2010-019631-35
Trial protocol	GB ES IT SE
Global end of trial date	24 May 2017

Results information

Result version number	v1 (current)
This version publication date	17 June 2018
First version publication date	17 June 2018

Trial information

Trial identification

Sponsor protocol code	C10-002

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01567085
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Alexion Pharmaceuticals, Inc.
Sponsor organisation address	100 College Street, New Haven, United States, 06510
Public contact	European Clinical Trial Information, Alexion Europe SAS, +33 1 47 10 06 06, clinicaltrials.eu@alexion.com
Scientific contact	European Clinical Trial Information, Alexion Europe SAS, +33 1 47 10 06 06, clinicaltrials.eu@alexion.com

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	24 May 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	24 May 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and potential efficacy of eculizumab to prevent AMR in sensitized recipients of deceased donor kidney transplants

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonisation (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 March 2012
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	Spain: 5
Country: Number of subjects enrolled	Sweden: 6
Country: Number of subjects enrolled	United Kingdom: 6
Country: Number of subjects enrolled	France: 39
Country: Number of subjects enrolled	Italy: 6
Country: Number of subjects enrolled	Australia: 18
Worldwide total number of subjects	80
EEA total number of subjects	62

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)	68
From 65 to 84 years	12
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Eighty participants were enrolled in this study who had been transplanted and had received eculizumab to prevent acute AMR after kidney transplantation.

Period 1

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

Arms

Arm title	Eculizumab

Arm description:

All eculizumab was administered intravenously (IV) over 25 to 45 minutes.
Eculizumab 1200 milligrams (mg) was administered approximately 1 hour prior to kidney allograft reperfusion.
Eculizumab 900 mg was administered IV over 25 to 45 minutes on post-transplantation Days 1 and 7, and on post-transplantation Days 14, 21, and 28, plus or minus 2 days.
Eculizumab 1200 mg was administered IV over 25 to 45 minutes on post-transplantation Days 35, 49, and 63, plus or minus 2 days.

Arm type	Experimental
Investigational medicinal product name	Eculizumab
Investigational medicinal product code	
Other name	Soliris
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Eculizumab 1200 mg was administered IV over 25 to 45 minutes 1 hour prior to kidney allograft reperfusion.

Eculizumab 900 mg was administered IV over 25 to 45 minutes on post-transplantation Days 1 and 7, and on post-transplantation Days 14, 21, and 28, plus or minus 2 days.

Eculizumab 1200 mg was administered IV over 25 to 45 minutes on post-transplantation Days 35, 49, and 63, plus or minus 2 days.

Number of subjects in period 1	Eculizumab
Started	80
Received at Least 1 Dose of Study Drug	80
Completed	60
Not completed	20
Terminal chronic kidney dysfunction	1
Graft loss	2
Adverse event, non-fatal	6

Death	6
Returned to chronic dialysis	1
Lost to follow-up	3
Renal transplantectomy	1

Baseline characteristics

Reporting groups	
Reporting group title	Eculizumab

Reporting group description:

All eculizumab was administered intravenously (IV) over 25 to 45 minutes.
Eculizumab 1200 milligrams (mg) was administered approximately 1 hour prior to kidney allograft reperfusion.
Eculizumab 900 mg was administered IV over 25 to 45 minutes on post-transplantation Days 1 and 7, and on post-transplantation Days 14, 21, and 28, plus or minus 2 days.
Eculizumab 1200 mg was administered IV over 25 to 45 minutes on post-transplantation Days 35, 49, and 63, plus or minus 2 days.

Reporting group values	Eculizumab	Total	
Number of subjects	80	80	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	68	68	
From 65-84 years	12	12	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	50.7		
standard deviation	± 11.26	-	
Gender categorical Units: Subjects			
Female	48	48	
Male	32	32	
Race Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	5	5	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	7	7	
White	59	59	
Unknown or Not Reported	9	9	

End points

End points reporting groups

Reporting group title	Eculizumab

Reporting group description:

All eculizumab was administered intravenously (IV) over 25 to 45 minutes.
Eculizumab 1200 milligrams (mg) was administered approximately 1 hour prior to kidney allograft reperfusion.
Eculizumab 900 mg was administered IV over 25 to 45 minutes on post-transplantation Days 1 and 7, and on post-transplantation Days 14, 21, and 28, plus or minus 2 days.
Eculizumab 1200 mg was administered IV over 25 to 45 minutes on post-transplantation Days 35, 49, and 63, plus or minus 2 days.

Subject analysis set title	Full Analysis Population
Subject analysis set type	Full analysis

Subject analysis set description:

Participants who were enrolled, received a deceased donor kidney transplant, and received at least 1 dose of eculizumab.

Subject analysis set title	Safety Population
Subject analysis set type	Safety analysis

Subject analysis set description:

Enrolled participants who received at least 1 dose of eculizumab.

Primary: Post-transplantation Treatment Failure In The First 9 Weeks Post Transplantation

End point title	Post-transplantation Treatment Failure In The First 9 Weeks Post Transplantation[1]

End point description:

Results are reported for post-transplantation treatment failure and composite endpoints, defined as the occurrence of biopsy-proven acute AMR, graft loss, death, or loss to follow-up (including discontinuation) in the first 9 weeks post transplantation. The diagnosis of acute AMR (occurring within the first 9 weeks post transplantation) was based on kidney allograft dysfunction and a biopsy performed due to suspected rejection, proteinuria, increased serum creatinine, or acute tubular necrosis. Treatment failure was the occurrence of at least 1 of the composite endpoint components by Week 9 post transplantation. A participant experiencing multiple events was only counted once for the composite endpoint. Exact binomial test was performed to analyse treatment failure rate in first 9 weeks post transplantation, using a p-value of <0.001, where the null hypothesis was that the true failure rate = 40% (exact 95% confidence interval [3.6, 17.2]).

End point type	Primary

End point timeframe:

Baseline, Week 9

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: Due to the limitations of the EudraCT database, the process used for the calculation of the p-value and the p-value were reported in the endpoint description.

End point values	Eculizumab			
Subject group type	Reporting group			
Number of subjects analysed	80[2]			
Units: Participants				
Treatment Failure - Yes	7			
Treatment Failure - No	73			
Biopsy proven acute AMR	3			
Graft Loss	4			
Death	1			

Lost to Follow-Up, including discontinuation	1			

Notes:

[2] - Full Analysis Population

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Cumulative Incidence Function (CIF) Of Other Adverse Events (AEs) Of Interest At Month 12

End point title	Cumulative Incidence Function (CIF) Of Other Adverse Events (AEs) Of Interest At Month 12

End point description:

Specific analyses of other AEs of interest that occurred at Month 12 included cumulative incidence of clinically significant infection (CSI); post-transplant lymphoproliferative disease (PTLD); malignancies; biopsy-proven acute cellular rejection (ACR) of any grade meeting Banff 2007 criteria; allograft loss for reasons other than AMR. CSIs were defined as infections (confirmed by culture, biopsy, genomic, or serologic findings) that required hospitalization or anti-infective treatment, or otherwise deemed significant by the Investigator. CSI subcategories of interest included cytomegalovirus (CMV) disease; BK virus disease; encapsulated bacterial infection; fungal infections; aspergillus infections. Results are reported as CIF, where a larger CIF indicates a higher incidence of an AE, and were calculated using Statistical Analysis System software and macro CIF. A summary of serious and all other non-serious AEs regardless of causality is located in the Reported Adverse Events module.

End point type	Other pre-specified

End point timeframe:

Baseline, Month 12

End point values	Eculizumab			
Subject group type	Reporting group			
Number of subjects analysed	80[3]			
Units: Units On A Scale				
number (confidence interval 95%)				
Confirmed CSI	0.7989 (0.69 to 0.87)			
CMV Infection	0.2994 (0.20 to 0.40)			
BK Virus Infection	0.1536 (0.08 to 0.24)			
Encapsulated Bacterial Infection	0.1642 (0.09 to 0.25)			
Fungal Infection	0.1287 (0.07 to 0.21)			
Aspergillus Infection	0 (0 to 0)			
PTLD	0.0264 (0.00 to 0.08)			
Malignancies	0.0264 (0.00 to 0.08)			
Biopsy-proven ACR	0.0375 (0.01 to 0.10)			
Allograft Loss	0.1132 (0.06 to 0.19)			

Notes:

[3] - Safety Population

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Participants That Developed Severe ACR (Other AE Of Interest) At Month 12

End point title	Participants That Developed Severe ACR (Other AE Of Interest) At Month 12

End point description:

This outcome measure focuses on the other AE of interest, severe ACR that occurred at Month 12. It pertains specifically to the number of participants who developed severe ACR that did not respond to thymoglobulin or other lymphocyte-depleting agents. A summary of serious and all other non-serious AEs, regardless of causality, is located in the reported Adverse events module.

End point type	Other pre-specified

End point timeframe:

Baseline, Month 12

End point values	Eculizumab			
Subject group type	Reporting group			
Number of subjects analysed	80[4]			
Units: Participants	3			

Notes:

[4] - Safety Population

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse event data were collected beginning on the day of transplantation, Day 0, through 12 months post transplantation.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.1

Reporting groups

Reporting group title	Eculizumab

Reporting group description:

All eculizumab was administered intravenously (IV) over 25 to 45 minutes.
Eculizumab 1200 milligrams (mg) was administered approximately 1 hour prior to kidney allograft reperfusion.
Eculizumab 900 mg was administered IV over 25 to 45 minutes on post-transplantation Days 1 and 7, and on post-transplantation Days 14, 21, and 28, plus or minus 2 days.
Eculizumab 1200 mg was administered IV over 25 to 45 minutes on post-transplantation Days 35, 49, and 63, plus or minus 2 days.

Serious adverse events	Eculizumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	70 / 80 (87.50%)		
number of deaths (all causes)	6		
number of deaths resulting from adverse events	6		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Ductal adenocarcinoma of pancreas			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Medullary thyroid cancer			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metastatic squamous cell carcinoma			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Neuroendocrine tumour			

subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Refractory anaemia with an excess of blasts				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Arterial disorder				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arteriovenous fistula				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Deep vein thrombosis				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypertension				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypotension				
subjects affected / exposed	2 / 80 (2.50%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Lymphocele				
subjects affected / exposed	2 / 80 (2.50%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Peripheral artery thrombosis				

subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Plastic surgery			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Pre-eclampsia			
subjects affected / exposed[1]	1 / 48 (2.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Premature delivery			
subjects affected / exposed[2]	1 / 48 (2.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Ulcer haemorrhage			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Catheter site pain			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chest pain			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Multiple organ dysfunction syndrome			

subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Non-cardiac chest pain			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Kidney transplant rejection			
subjects affected / exposed	25 / 80 (31.25%)		
occurrences causally related to treatment / all	0 / 25		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Vaginal dysplasia			
subjects affected / exposed[3]	1 / 48 (2.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	5 / 80 (6.25%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			

subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Investigations			
Antibody test positive			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Blood creatinine increased			
subjects affected / exposed	6 / 80 (7.50%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
White blood cell count increased			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Arteriovenous fistula thrombosis			
subjects affected / exposed	3 / 80 (3.75%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Complications of transplanted kidney			
subjects affected / exposed	4 / 80 (5.00%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Delayed graft function			
subjects affected / exposed	10 / 80 (12.50%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		

Fall				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Incisional hernia				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post procedural haematoma				
subjects affected / exposed	3 / 80 (3.75%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Post procedural haematuria				
subjects affected / exposed	2 / 80 (2.50%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Post procedural haemorrhage				
subjects affected / exposed	4 / 80 (5.00%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Traumatic haematoma				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary anastomotic leak				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Wound				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				

Angina pectoris				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Atrial fibrillation				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block complete				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Myocardial ischaemia				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Supraventricular tachycardia				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Disturbance in attention				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Headache				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Loss of consciousness				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Migraine				

subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Seizure				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Toxic encephalopathy				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	4 / 80 (5.00%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Febrile neutropenia				
subjects affected / exposed	2 / 80 (2.50%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Leukopenia				
subjects affected / exposed	3 / 80 (3.75%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 0			
Neutropenia				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pancytopenia				
subjects affected / exposed	4 / 80 (5.00%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Thrombotic microangiopathy				

subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Ascites			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Colitis			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	4 / 80 (5.00%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Gingivitis ulcerative			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Impaired gastric emptying			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal obstruction			

subjects affected / exposed	2 / 80 (2.50%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Intra-abdominal fluid collection				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Palatal disorder				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumoperitoneum				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rectal haemorrhage				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Small intestinal obstruction				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Small intestinal perforation				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Umbilical hernia				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Cholangitis				

subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholecystitis				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholecystitis acute				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholelithiasis				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Drug-induced liver injury				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Jaundice cholestatic				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Skin ulcer				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Acute kidney injury				
subjects affected / exposed	12 / 80 (15.00%)			
occurrences causally related to treatment / all	1 / 12			
deaths causally related to treatment / all	0 / 0			
Anuria				

subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haematuria				
subjects affected / exposed	5 / 80 (6.25%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Hydronephrosis				
subjects affected / exposed	3 / 80 (3.75%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Proteinuria				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal artery thrombosis				
subjects affected / exposed	2 / 80 (2.50%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Renal cyst				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal cyst haemorrhage				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal failure				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal haematoma				

subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal impairment				
subjects affected / exposed	3 / 80 (3.75%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Renal tubular necrosis				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal vascular thrombosis				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal vein thrombosis				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinoma				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Osteoarthritis				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
BK virus infection				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Bacteraemia			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bacterial pyelonephritis			
subjects affected / exposed	5 / 80 (6.25%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bronchitis viral			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Campylobacter infection			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Candiduria			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Catheter site infection			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Clostridium difficile colitis			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Cytomegalovirus colitis			

subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cytomegalovirus infection				
subjects affected / exposed	5 / 80 (6.25%)			
occurrences causally related to treatment / all	1 / 5			
deaths causally related to treatment / all	0 / 0			
Device related sepsis				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diarrhoea infectious				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Encephalitis				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Enterococcal sepsis				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Escherichia pyelonephritis				
subjects affected / exposed	4 / 80 (5.00%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Escherichia sepsis				
subjects affected / exposed	2 / 80 (2.50%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Escherichia urinary tract infection				

subjects affected / exposed	4 / 80 (5.00%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	4 / 80 (5.00%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis norovirus				
subjects affected / exposed	4 / 80 (5.00%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gingival abscess				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haematoma infection				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatic cyst infection				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatitis C				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Incision site infection				

subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infected cyst				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infected fistula				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Klebsiella infection				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Klebsiella sepsis				
subjects affected / exposed	2 / 80 (2.50%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Lung abscess				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Periodontitis				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	5 / 80 (6.25%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Pneumonia cryptococcal				

subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Polyomavirus-associated nephropathy				
subjects affected / exposed	3 / 80 (3.75%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	7 / 80 (8.75%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis acute				
subjects affected / exposed	2 / 80 (2.50%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	2 / 80 (2.50%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Systemic mycosis				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tooth infection				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				

subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	3 / 80 (3.75%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection bacterial				
subjects affected / exposed	2 / 80 (2.50%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Urosepsis				
subjects affected / exposed	3 / 80 (3.75%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Viral infection				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Calciphylaxis				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dehydration				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diabetes mellitus				
subjects affected / exposed	4 / 80 (5.00%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Diabetes mellitus inadequate control				

subjects affected / exposed	2 / 80 (2.50%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hypercalcaemia			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperkalaemia			
subjects affected / exposed	3 / 80 (3.75%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This adverse event is possible in female participants only. The total number of female participants in the study is 48.
[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This adverse event is possible in female participants only. The total number of female participants in the study is 48.
[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This adverse event is possible in female participants only. The total number of female participants in the study is 48.

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

Non-serious adverse events	Eculizumab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	78 / 80 (97.50%)		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	4 / 80 (5.00%)		
occurrences (all)	4		

Haematoma			
subjects affected / exposed	6 / 80 (7.50%)		
occurrences (all)	7		
Hypertension			
subjects affected / exposed	31 / 80 (38.75%)		
occurrences (all)	36		
Hypotension			
subjects affected / exposed	13 / 80 (16.25%)		
occurrences (all)	15		
Lymphocele			
subjects affected / exposed	5 / 80 (6.25%)		
occurrences (all)	6		
Orthostatic hypotension			
subjects affected / exposed	6 / 80 (7.50%)		
occurrences (all)	8		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	13 / 80 (16.25%)		
occurrences (all)	17		
Chest pain			
subjects affected / exposed	7 / 80 (8.75%)		
occurrences (all)	9		
Influenza like illness			
subjects affected / exposed	9 / 80 (11.25%)		
occurrences (all)	9		
Oedema			
subjects affected / exposed	5 / 80 (6.25%)		
occurrences (all)	6		
Oedema peripheral			
subjects affected / exposed	31 / 80 (38.75%)		
occurrences (all)	48		
Pain			
subjects affected / exposed	4 / 80 (5.00%)		
occurrences (all)	4		
Pyrexia			

subjects affected / exposed	20 / 80 (25.00%)		
occurrences (all)	28		
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	5 / 80 (6.25%)		
occurrences (all)	6		
Kidney transplant rejection			
subjects affected / exposed	22 / 80 (27.50%)		
occurrences (all)	32		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	18 / 80 (22.50%)		
occurrences (all)	23		
Dyspnoea			
subjects affected / exposed	19 / 80 (23.75%)		
occurrences (all)	23		
Dyspnoea exertional			
subjects affected / exposed	4 / 80 (5.00%)		
occurrences (all)	4		
Pleural effusion			
subjects affected / exposed	5 / 80 (6.25%)		
occurrences (all)	6		
Productive cough			
subjects affected / exposed	4 / 80 (5.00%)		
occurrences (all)	4		
Rales			
subjects affected / exposed	6 / 80 (7.50%)		
occurrences (all)	6		
Psychiatric disorders			
Depression			
subjects affected / exposed	4 / 80 (5.00%)		
occurrences (all)	4		
Insomnia			
subjects affected / exposed	9 / 80 (11.25%)		
occurrences (all)	13		
Anxiety			

subjects affected / exposed	9 / 80 (11.25%)		
occurrences (all)	10		
Investigations			
Blood creatinine increased			
subjects affected / exposed	15 / 80 (18.75%)		
occurrences (all)	20		
Cardiac murmur			
subjects affected / exposed	5 / 80 (6.25%)		
occurrences (all)	6		
Liver function test abnormal			
subjects affected / exposed	8 / 80 (10.00%)		
occurrences (all)	8		
Weight decreased			
subjects affected / exposed	7 / 80 (8.75%)		
occurrences (all)	7		
Weight increased			
subjects affected / exposed	5 / 80 (6.25%)		
occurrences (all)	6		
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	5 / 80 (6.25%)		
occurrences (all)	10		
Delayed graft function			
subjects affected / exposed	12 / 80 (15.00%)		
occurrences (all)	12		
Incisional hernia			
subjects affected / exposed	4 / 80 (5.00%)		
occurrences (all)	6		
Post procedural haematoma			
subjects affected / exposed	6 / 80 (7.50%)		
occurrences (all)	7		
Procedural pain			
subjects affected / exposed	11 / 80 (13.75%)		
occurrences (all)	13		
Cardiac disorders			

Atrial fibrillation subjects affected / exposed occurrences (all)	4 / 80 (5.00%) 5		
Palpitations subjects affected / exposed occurrences (all)	5 / 80 (6.25%) 5		
Tachycardia subjects affected / exposed occurrences (all)	6 / 80 (7.50%) 7		
Nervous system disorders			
Dizziness subjects affected / exposed occurrences (all)	4 / 80 (5.00%) 5		
Headache subjects affected / exposed occurrences (all)	22 / 80 (27.50%) 33		
Tremor subjects affected / exposed occurrences (all)	7 / 80 (8.75%) 7		
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	51 / 80 (63.75%) 65		
Leukopenia subjects affected / exposed occurrences (all)	30 / 80 (37.50%) 43		
Lymphopenia subjects affected / exposed occurrences (all)	11 / 80 (13.75%) 14		
Neutropenia subjects affected / exposed occurrences (all)	18 / 80 (22.50%) 22		
Pancytopenia subjects affected / exposed occurrences (all)	7 / 80 (8.75%) 9		
Thrombocytopenia			

subjects affected / exposed	12 / 80 (15.00%)		
occurrences (all)	19		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	14 / 80 (17.50%)		
occurrences (all)	19		
Abdominal pain upper			
subjects affected / exposed	9 / 80 (11.25%)		
occurrences (all)	10		
Constipation			
subjects affected / exposed	15 / 80 (18.75%)		
occurrences (all)	17		
Diarrhoea			
subjects affected / exposed	37 / 80 (46.25%)		
occurrences (all)	70		
Dyspepsia			
subjects affected / exposed	4 / 80 (5.00%)		
occurrences (all)	4		
Gastritis			
subjects affected / exposed	4 / 80 (5.00%)		
occurrences (all)	5		
Gastrooesophageal reflux disease			
subjects affected / exposed	12 / 80 (15.00%)		
occurrences (all)	14		
Haemorrhoids			
subjects affected / exposed	4 / 80 (5.00%)		
occurrences (all)	4		
Mouth ulceration			
subjects affected / exposed	7 / 80 (8.75%)		
occurrences (all)	11		
Nausea			
subjects affected / exposed	25 / 80 (31.25%)		
occurrences (all)	36		
Vomiting			
subjects affected / exposed	18 / 80 (22.50%)		
occurrences (all)	22		

Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	6 / 80 (7.50%)		
occurrences (all)	10		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	5 / 80 (6.25%)		
occurrences (all)	6		
Pruritus			
subjects affected / exposed	8 / 80 (10.00%)		
occurrences (all)	9		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	10 / 80 (12.50%)		
occurrences (all)	10		
Dysuria			
subjects affected / exposed	8 / 80 (10.00%)		
occurrences (all)	11		
Haematuria			
subjects affected / exposed	11 / 80 (13.75%)		
occurrences (all)	14		
Oliguria			
subjects affected / exposed	4 / 80 (5.00%)		
occurrences (all)	4		
Polyuria			
subjects affected / exposed	4 / 80 (5.00%)		
occurrences (all)	4		
Proteinuria			
subjects affected / exposed	16 / 80 (20.00%)		
occurrences (all)	18		
Renal artery stenosis			
subjects affected / exposed	4 / 80 (5.00%)		
occurrences (all)	4		
Renal impairment			
subjects affected / exposed	9 / 80 (11.25%)		
occurrences (all)	16		
Renal tubular necrosis			

subjects affected / exposed	13 / 80 (16.25%)		
occurrences (all)	13		
Urinary incontinence			
subjects affected / exposed	8 / 80 (10.00%)		
occurrences (all)	8		
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	12 / 80 (15.00%)		
occurrences (all)	18		
Muscle spasms			
subjects affected / exposed	5 / 80 (6.25%)		
occurrences (all)	5		
Musculoskeletal pain			
subjects affected / exposed	19 / 80 (23.75%)		
occurrences (all)	34		
Infections and infestations			
BK virus infection			
subjects affected / exposed	10 / 80 (12.50%)		
occurrences (all)	18		
Bronchitis			
subjects affected / exposed	9 / 80 (11.25%)		
occurrences (all)	10		
Clostridium difficile infection			
subjects affected / exposed	4 / 80 (5.00%)		
occurrences (all)	5		
Conjunctivitis			
subjects affected / exposed	5 / 80 (6.25%)		
occurrences (all)	5		
Cytomegalovirus infection			
subjects affected / exposed	21 / 80 (26.25%)		
occurrences (all)	33		
Ear infection			
subjects affected / exposed	4 / 80 (5.00%)		
occurrences (all)	4		
Enterococcal infection			

subjects affected / exposed	4 / 80 (5.00%)			
occurrences (all)	4			
Escherichia infection				
subjects affected / exposed	8 / 80 (10.00%)			
occurrences (all)	8			
Escherichia urinary tract infection				
subjects affected / exposed	8 / 80 (10.00%)			
occurrences (all)	18			
Gastroenteritis				
subjects affected / exposed	7 / 80 (8.75%)			
occurrences (all)	10			
Gastroenteritis norovirus				
subjects affected / exposed	6 / 80 (7.50%)			
occurrences (all)	6			
Herpes simplex				
subjects affected / exposed	4 / 80 (5.00%)			
occurrences (all)	4			
Nasopharyngitis				
subjects affected / exposed	11 / 80 (13.75%)			
occurrences (all)	12			
Oral candidiasis				
subjects affected / exposed	6 / 80 (7.50%)			
occurrences (all)	7			
Pneumonia				
subjects affected / exposed	4 / 80 (5.00%)			
occurrences (all)	4			
Polyomavirus-associated nephropathy				
subjects affected / exposed	4 / 80 (5.00%)			
occurrences (all)	4			
Sinusitis				
subjects affected / exposed	4 / 80 (5.00%)			
occurrences (all)	4			
Upper respiratory tract infection				
subjects affected / exposed	10 / 80 (12.50%)			
occurrences (all)	13			

Urinary tract infection subjects affected / exposed occurrences (all)	32 / 80 (40.00%) 65		
Urinary tract infection bacterial subjects affected / exposed occurrences (all)	4 / 80 (5.00%) 11		
Metabolism and nutrition disorders Acidosis subjects affected / exposed occurrences (all)	21 / 80 (26.25%) 27		
Cell death subjects affected / exposed occurrences (all)	4 / 80 (5.00%) 5		
Decreased appetite subjects affected / exposed occurrences (all)	6 / 80 (7.50%) 8		
Dehydration subjects affected / exposed occurrences (all)	5 / 80 (6.25%) 5		
Diabetes mellitus subjects affected / exposed occurrences (all)	11 / 80 (13.75%) 13		
Diabetes mellitus inadequate control subjects affected / exposed occurrences (all)	4 / 80 (5.00%) 6		
Fluid overload subjects affected / exposed occurrences (all)	9 / 80 (11.25%) 10		
Hypercalcaemia subjects affected / exposed occurrences (all)	8 / 80 (10.00%) 10		
Hypercholesterolaemia subjects affected / exposed occurrences (all)	6 / 80 (7.50%) 7		
Hyperglycaemia			

subjects affected / exposed	14 / 80 (17.50%)		
occurrences (all)	15		
Hyperkalaemia			
subjects affected / exposed	23 / 80 (28.75%)		
occurrences (all)	27		
Hyperlipidaemia			
subjects affected / exposed	4 / 80 (5.00%)		
occurrences (all)	4		
Hyperphosphataemia			
subjects affected / exposed	10 / 80 (12.50%)		
occurrences (all)	10		
Hypocalcaemia			
subjects affected / exposed	14 / 80 (17.50%)		
occurrences (all)	18		
Hypoglycaemia			
subjects affected / exposed	8 / 80 (10.00%)		
occurrences (all)	8		
Hypokalaemia			
subjects affected / exposed	18 / 80 (22.50%)		
occurrences (all)	24		
Hypomagnesaemia			
subjects affected / exposed	16 / 80 (20.00%)		
occurrences (all)	20		
Hyponatraemia			
subjects affected / exposed	9 / 80 (11.25%)		
occurrences (all)	10		
Hypophosphataemia			
subjects affected / exposed	11 / 80 (13.75%)		
occurrences (all)	11		
Vitamin D deficiency			
subjects affected / exposed	8 / 80 (10.00%)		
occurrences (all)	9		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 October 2013	The main purpose of this amendment was to reopen the recruitment of participants following the investigator's request.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

None

Notes: