Clinical trial results:
An Open-Label, Multi-Center Clinical Trial Of Eculizumab In Adult Patients With Atypical Hemolytic-Uremic Syndrome

Summary

EudraCT number	2010-020326-18
Trial protocol	GB DE FR BE ES NL IT
Global end of trial date	31 October 2013

Results information

Result version number	v1 (current)
This version publication date	29 July 2016
First version publication date	29 July 2016

Trial information

Trial identification

Sponsor protocol code	C10-004

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01194973
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Alexion Pharmaceuticals Incorporated
Sponsor organisation address	352 Knotter Drive, Cheshire, CT, United States, 06410
Public contact	European Clinical Trial Information, Alexion Europe SAS, +33 1 47 10 06 06, clinicaltrials.eu@alxn.com
Scientific contact	European Clinical Trial Information, Alexion Europe SAS, +33 1 47 10 06 06, clinicaltrials.eu@alxn.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	11 February 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 October 2013
Global end of trial reached?	Yes
Global end of trial date	31 October 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of eculizumab in adult patients with aHUS to control TMA as characterized by thrombocytopenia, hemolysis and renal impairment.

Protection of trial subjects:

- vaccination against N. meningitidis at least 14 days prior to study drug initiation or prophylactic antibiotics protection

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 August 2010
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	2 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 2
Country: Number of subjects enrolled	Spain: 4
Country: Number of subjects enrolled	Belgium: 2
Country: Number of subjects enrolled	France: 18
Country: Number of subjects enrolled	Germany: 3
Country: Number of subjects enrolled	Italy: 4
Country: Number of subjects enrolled	United States: 8
Worldwide total number of subjects	41
EEA total number of subjects	33

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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	38
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 44 patients diagnosed with aHUS signed the informed consent and of these, 41 patients were treated. Three patients were excluded from the study due to failed screening procedure and did not receive eculizumab.

Pre-assignment

Screening details:

Patients had to have signs or symptoms of hemolysis; serum creatinine level ≥ ULN and platelet count <LLN.

Pre-assignment period milestones

Number of subjects started	44[1]
Number of subjects completed	41

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Screen failure: 3

Notes:

[1] - The number of subjects reported to have started the pre-assignment period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Informed consent form was obtained for 44 patients. Of these 44 patients, 41 were treated in the study. The 3 other patients were considered as screen failure.

Period 1

Period 1 title	Treatment Period (26wks) and Maintenance
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	eculizumab

Arm description:

All patients received open-label eculizumab administered intravenously on the following dose schedule: Induction dose - 900 mg per week for four weeks and a dose of 1200 mg one week later; Maintenance dose - 1200 mg every two weeks. Patients who received plasma exchange or infusion during the eculizumab treatment period received a supplemental dose of 600 mg within one hour before plasma infusion or within one hour after the completion of each plasma exchange.

Arm type	Experimental
Investigational medicinal product name	eculizumab
Investigational medicinal product code	eculizumab
Other name	Soliris
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Induction dose - 900 mg per week for four weeks and a dose of 1200 mg one week later
Maintenance dose - 1200 mg every two weeks
Patients who received plasma exchange or infusion during the eculizumab treatment period received a supplemental dose of 600 mg within one hour before plasma infusion or within one hour after the completion of each plasma exchange

Number of subjects in period 1	eculizumab
Started	41
Completed	38
Not completed	3
Adverse event, non-fatal	1
Pregnancy	1
Lack of efficacy	1

Period 2

Period 2 title	Post Treatment Period (discontinuation)
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	eculizumab

Arm description:

Patients who discontinue eculizumab treatment at any time during the study will be followed for one year.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 2[2]	eculizumab
Started	11
Completed	11

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Patients who discontinued eculizumab treatment at any time were to be followed for one year. It concerned 11 patients: 3 were withdrawn from the study, and 8 completed the study and were not transitioned to commercial eculizumab.

Baseline characteristics

Reporting groups	
Reporting group title	eculizumab
Reporting group description:	
All patients received open-label eculizumab administered intravenously on the following dose schedule: Induction dose - 900 mg per week for four weeks and a dose of 1200 mg one week later; Maintenance dose - 1200 mg every two weeks. Patients who received plasma exchange or infusion during the eculizumab treatment period received a supplemental dose of 600 mg within one hour before plasma infusion or within one hour after the completion of each plasma exchange.	

Reporting group values	eculizumab	Total	
Number of subjects	41	41	
Age categorical Units: Subjects			
Adults (18-64 years)	38	38	
From 65-84 years	3	3	
Age continuous Units: years			
arithmetic mean	40.3		
standard deviation	± 15.33	-	
Gender categorical Units: Subjects			
Female	28	28	
Male	13	13	
Race Units: Subjects			
Asian	1	1	
American Indian or Alaska Native	0	0	
Black or African American	2	2	
Native Hawaiian or Other Pacific Islander	0	0	
White	38	38	
More than one race	0	0	
Unknown or Not Reported	0	0	
Platelet category Units: Subjects			
< 150 x10^9/L	27	27	
>= 150 x10^9/L	14	14	
LDH category Units: Subjects			
<= ULN	9	9	
> ULN	32	32	
eGFR Units: Subjects			
<15 mL/min/1.73*m^2	27	27	
15-29 mL/min/1.73*m^2	6	6	
30-44 mL/min/1.73*m^2	6	6	
45-59 mL/min/1.73*m^2	2	2	
60-89 mL/min/1.73*m^2	0	0	

>=90 mL/min/1.73*m^2	0	0	
CKD Units: Subjects			
Stage 0	0	0	
Stage 1	0	0	
Stage 2	0	0	
Stage 3a	2	2	
Stage 3b	6	6	
Stage 4	6	6	
Stage 5	27	27	
Plasma Therapy Duration Units: Subjects			
< 2 months	36	36	
>= 2 months	5	5	
Clinical TMA manifestation Units: Subjects			
First clinical	30	30	
Multiple	11	11	
Platelet count Units: x10^9/L			
arithmetic mean	119.1		
standard deviation	± 66.09	-	
LDH Units: U/L			
arithmetic mean	492.9		
standard deviation	± 500.86	-	
Hemoglobin Units: g/L			
arithmetic mean	88.5		
standard deviation	± 16.82	-	
Creatinine Units: umol/L			
arithmetic mean	411		
standard deviation	± 264.59	-	

End points

End points reporting groups

Reporting group title	eculizumab

Reporting group description:

All patients received open-label eculizumab administered intravenously on the following dose schedule: Induction dose - 900 mg per week for four weeks and a dose of 1200 mg one week later; Maintenance dose - 1200 mg every two weeks. Patients who received plasma exchange or infusion during the eculizumab treatment period received a supplemental dose of 600 mg within one hour before plasma infusion or within one hour after the completion of each plasma exchange.

Reporting group title	eculizumab

Reporting group description:

Patients who discontinue eculizumab treatment at any time during the study will be followed for one year.

Primary: Proportion of Patients With Complete TMA Response

End point title	Proportion of Patients With Complete TMA Response[1]

End point description:

Proportion of Patients with Complete TMA response was determined and defined by normalization of hematological parameters (platelet count and LDH) and preservation of renal function (defined as < 25% increase in serum creatinine from baseline) which were sustained for at least two consecutive measurements obtained at least four weeks apart

End point type	Primary

End point timeframe:

Through 26 weeks

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: This study is a single arm trial and the system did not support statistical analyses for this single arm trial.

End point values	eculizumab			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: Percentage of Participants				
number (confidence interval 95%)	73.2 (57.1 to 85.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Proportion of Patients With Modified Complete TMA Response

End point title	Proportion of Patients With Modified Complete TMA Response[2]

End point description:

Proportion of Patients with Modified Complete TMA response through 26 weeks of treatment was determined and defined by normalization of hematological parameters (platelet count and LDH) and improvement in renal function (defined as ≥ 25% reduction from the baseline value in serum creatinine, which were sustained for at least two consecutive measurements obtained at least four weeks apart.

End point type	Primary

End point timeframe:

Through 26 weeks

Notes:

[2] - 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: This study is a single arm trial and the system did not support statistical analyses for this single arm trial.

End point values	eculizumab			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: Percentage of Participants				
number (confidence interval 95%)	56.1 (39.7 to 71.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Patients With Complete Hematologic Response

End point title	Proportion of Patients With Complete Hematologic Response

End point description:

Proportion of Patients with Complete Hematologic response through end of study was determined and defined by normalization of platelet count and LDH sustained for at least two consecutive measurements obtained at least four weeks apart.

End point type	Secondary

End point timeframe:

Through 26 weeks

End point values	eculizumab			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: Percentage of Participants				
number (confidence interval 95%)	87.8 (73.8 to 95.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Patients With Platelet Count Normalization

End point title	Proportion of Patients With Platelet Count Normalization

End point description:

Proportion of Patients with Platelet Count Normalization through 26 weeks of treatment was determined and defined as the platelet count observed to be ≥ 150 x 10^9/L on at least 2 consecutive measurements which span a period of at least 4 weeks

End point type	Secondary

End point timeframe:

Through 26 weeks

End point values	eculizumab			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: Percentage of Participants				
number (confidence interval 95%)	97.6 (87.1 to 99.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Patients With Estimated Glomerular Filtration Rate (eGFR) Improvement

End point title	Proportion of Patients With Estimated Glomerular Filtration Rate (eGFR) Improvement

End point description:

Proportion of Patients with Estimated Glomerular Filtration Rate (eGFR) Improvement was determined and defined as an increase in eGFR by ≥ 15 mL/min/1.73m2 from baseline, sustained for at least two consecutive measurements obtained at least four weeks apart.

End point type	Secondary

End point timeframe:

Through 26 weeks

End point values	eculizumab			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: Percentage of Participants				
number (confidence interval 95%)	53.7 (37.4 to 69.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Platelet Count Change From Baseline to 26 Weeks

End point title	Platelet Count Change From Baseline to 26 Weeks

End point description:

End point type	Secondary

End point timeframe:

Through 26 weeks

End point values	eculizumab			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: 10^9 cells/L				
least squares mean (confidence interval 95%)	117.68 (92.77 to 142.59)			

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Patients With Complete TMA Response

End point title	Proportion of Patients With Complete TMA Response

End point description:

Proportion of Patients with Complete TMA response through end of study was determined and defined by normalization of hematological parameters (platelet count and LDH) and preservation of renal function (defined as < 25% increase in serum creatinine from baseline) which were sustained for at least two consecutive measurements obtained at least four weeks apart.

End point type	Secondary

End point timeframe:

Through End of Study, Median Exposure 52 Weeks

End point values	eculizumab			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: Percentage of Participants				
number (confidence interval 95%)	80.5 (65.1 to 91.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Patients With Modified Complete TMA Response

End point title	Proportion of Patients With Modified Complete TMA Response

End point description:

Proportion of Patients with Modified Complete TMA response through end of study was determined and defined by normalization of hematological parameters (platelet count and LDH) and improvement in

renal function (defined as ≥ 25% reduction from the baseline value in serum creatinine, which were sustained for at least two consecutive measurements obtained at least four weeks apart.

End point type	Secondary

End point timeframe:

Through End of Study, Median Exposure 52 Weeks

End point values	eculizumab			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: Percentage of Participants				
number (confidence interval 95%)	63.4 (46.9 to 77.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Patients With Complete Hematologic Response

End point title	Proportion of Patients With Complete Hematologic Response

End point description:

Proportion of Patients with Complete Hematologic response through end of study of treatment was determined and defined by normalization of platelet count and LDH sustained for at least two consecutive measurements obtained at least four weeks apart.

End point type	Secondary

End point timeframe:

Through End of Study, Median Exposure 52 Weeks

End point values	eculizumab			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: Percentage of Participants				
number (confidence interval 95%)	97.6 (87.1 to 99.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Patients With Platelet Count Normalization

End point title	Proportion of Patients With Platelet Count Normalization

End point description:

Proportion of Patients with Platelet Count Normalization through end of study of treatment was

determined and defined as the platelet count observed to be ≥ 150 x 109/L on at least two consecutive measurements which span a period of at least four weeks

End point type	Secondary

End point timeframe:

Through End of Study, Median Exposure 52 Weeks

End point values	eculizumab			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: Percentage of Participants				
number (confidence interval 95%)	100 (91.4 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Patients With Estimated Glomerular Filtration Rate (eGFR) Improvement

End point title	Proportion of Patients With Estimated Glomerular Filtration Rate (eGFR) Improvement

End point description:

Proportion of Patients with Estimated Glomerular Filtration Rate (eGFR) Improvement was determined and defined as an increase in eGFR by ≥ 15 mL/min/1.73m2 from baseline sustained for at least two consecutive measurements obtained at least four weeks apart

End point type	Secondary

End point timeframe:

Through End of Study, Median Exposure 52 Weeks

End point values	eculizumab			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: Percentage of Participants				
number (confidence interval 95%)	61 (44.5 to 75.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Platelet Count Change From Baseline to 52 Weeks

End point title	Platelet Count Change From Baseline to 52 Weeks

End point description:

End point type	Secondary

End point timeframe:

Through 52 Weeks

End point values	eculizumab			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: 10^9 cells/L				
least squares mean (confidence interval 95%)	102.49 (68.15 to 136.82)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Through end of study; exposure to eculizumab in this study extended for a median duration of 11.9 months and ranged from 2.9 months to 28.8 months.

Adverse event reporting additional description:

At every visit, patients were asked a standard non-leading question to elicit any changes in their medical well-being including inquiry about any hospitalization, accidents and new or changed concomitant medication regimens. AEs were also documented from any data collected (e.g. laboratory values, physical examination findings, ECG changes, etc.).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	15.1

Reporting groups

Reporting group title	eculizumab

Reporting group description:

All patients received open-label eculizumab administered intravenously on the following dose schedule: Induction dose - 900 mg per week for four weeks and a dose of 1200 mg one week later; Maintenance dose - 1200 mg every two weeks. Patients who received plasma exchange or infusion during the eculizumab treatment period received a supplemental dose of 600 mg within one hour before plasma infusion or within one hour after the completion of each plasma exchange.

Serious adverse events	eculizumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	19 / 41 (46.34%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Shunt malfunction			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertensive crisis			

subjects affected / exposed	1 / 41 (2.44%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Venous thrombosis				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Convulsion				
subjects affected / exposed	2 / 41 (4.88%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Haemorrhage intracranial				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Paraesthesia				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Posterior reversible encephalopathy syndrome				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Haemolytic uraemic syndrome				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Thrombotic microangiopathy				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

General disorders and administration site conditions			
Medical device complication			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Kidney transplant rejection			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Pulmonary oedema			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			

subjects affected / exposed	1 / 41 (2.44%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Rash papular			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Skin necrosis			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Renal failure acute			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Renal failure chronic			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Renal impairment			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Renal vessel disorder			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Device related infection				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Device related sepsis				
subjects affected / exposed	2 / 41 (4.88%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Genitourinary tract gonococcal infection				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Meningitis meningococcal				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Meningococcal sepsis				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	2 / 41 (4.88%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Shunt infection				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				

Hyperglycaemia			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypoglycemia			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	eculizumab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	41 / 41 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Parathyroid tumour benign			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Haematoma			
subjects affected / exposed	3 / 41 (7.32%)		
occurrences (all)	3		
Hot flush			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Hypertension			
subjects affected / exposed	5 / 41 (12.20%)		
occurrences (all)	6		
Hypotension			
subjects affected / exposed	7 / 41 (17.07%)		
occurrences (all)	7		
Steal syndrome			

subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Thrombophlebitis			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Venous thrombosis			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	6 / 41 (14.63%)		
occurrences (all)	6		
Calcinosis			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Catheter site discharge			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Catheter site erythema			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Catheter site pruritus			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Chest discomfort			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Chest pain			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Chills			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Device occlusion			

subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Fatigue			
subjects affected / exposed	3 / 41 (7.32%)		
occurrences (all)	3		
Impaired healing			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Influenza like illness			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Malaise			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Medical device complication			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Oedema			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Oedema peripheral			
subjects affected / exposed	9 / 41 (21.95%)		
occurrences (all)	9		
Pyrexia			
subjects affected / exposed	7 / 41 (17.07%)		
occurrences (all)	7		
Reproductive system and breast disorders			
Amenorrhoea			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Atrophic vulvovaginitis			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Breast cyst			

subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Dysmenorrhoea			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Endometriosis			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Haematospermia			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Metrorrhagia			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	7 / 41 (17.07%)		
occurrences (all)	7		
Dyspnoea			
subjects affected / exposed	5 / 41 (12.20%)		
occurrences (all)	5		
Dyspnoea exertional			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Epistaxis			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Nasal septum deviation			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Oropharyngeal pain			
subjects affected / exposed	3 / 41 (7.32%)		
occurrences (all)	3		
Pleural effusion			

subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Productive cough			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Pulmonary congestion			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Pulmonary oedema			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	3		
Rhinitis allergic			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Rhinorrhoea			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Snoring			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Wheezing			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Psychiatric disorders			
Agitation			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Anxiety			
subjects affected / exposed	4 / 41 (9.76%)		
occurrences (all)	4		
Depressed mood			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Depression			
subjects affected / exposed	3 / 41 (7.32%)		
occurrences (all)	3		

Insomnia			
subjects affected / exposed	5 / 41 (12.20%)		
occurrences (all)	5		
Nightmare			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Investigations			
Blood pressure increased			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Cardiac murmur			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Eosinophil count increased			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Free haemoglobin present			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Liver function test abnormal			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Platelet count decreased			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Urine protein/creatinine ratio increased			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Weight decreased			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
White blood cell count increased			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			

Arteriovenous fistula site complication			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Contusion			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Foot fracture			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Infusion related reaction			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Procedural complication			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Shunt malfunction			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Skeletal injury			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Upper limb fracture			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Wound			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Cardiomyopathy			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Palpitations			

subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Tachycardia			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Nervous system disorders			
Amnesia			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Dizziness			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Headache			
subjects affected / exposed	15 / 41 (36.59%)		
occurrences (all)	15		
Loss of consciousness			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Migraine			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Paraesthesia			
subjects affected / exposed	3 / 41 (7.32%)		
occurrences (all)	3		
Polyneuropathy			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Presyncope			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Sciatica			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Syncope			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		

Tremor			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	7 / 41 (17.07%)		
occurrences (all)	7		
Eosinophilia			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Iron deficiency anaemia			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Leukopenia			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	5		
Lymphopenia			
subjects affected / exposed	3 / 41 (7.32%)		
occurrences (all)	3		
Neutropenia			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Spontaneous haematoma			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Thrombocytopenia			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Tinnitus			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Tympanic membrane perforation			

subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Vertigo			
subjects affected / exposed	3 / 41 (7.32%)		
occurrences (all)	3		
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Conjunctivitis			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Eye inflammation			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Lacrimation increased			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Retinopathy hypertensive			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Uveitis			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Vision blurred			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Abdominal pain			
subjects affected / exposed	3 / 41 (7.32%)		
occurrences (all)	4		
Constipation			

subjects affected / exposed	3 / 41 (7.32%)			
occurrences (all)	3			
Diarrhoea				
subjects affected / exposed	13 / 41 (31.71%)			
occurrences (all)	14			
Dry mouth				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Dyspepsia				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Dysphagia				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Enteritis				
subjects affected / exposed	2 / 41 (4.88%)			
occurrences (all)	2			
Gastrointestinal disorder				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Gastrointestinal pain				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Gastrooesophageal reflux disease				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Gingival hypertrophy				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Mouth ulceration				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Nausea				
subjects affected / exposed	5 / 41 (12.20%)			
occurrences (all)	5			
Odynophagia				

subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Stomatitis			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	6 / 41 (14.63%)		
occurrences (all)	6		
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Cholelithiasis			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Cholestasis			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Hepatocellular injury			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	5 / 41 (12.20%)		
occurrences (all)	5		
Dermatitis			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Eczema			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Intertrigo			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Night sweats			

subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Petechiae			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Photosensitivity reaction			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Pruritus			
subjects affected / exposed	4 / 41 (9.76%)		
occurrences (all)	4		
Purpura			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Rash			
subjects affected / exposed	4 / 41 (9.76%)		
occurrences (all)	4		
Rash erythematous			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Rash pruritic			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Skin discolouration			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Urticaria			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Renal and urinary disorders			
Anuria			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Dysuria			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		

Haematuria subjects affected / exposed occurrences (all)	1 / 41 (2.44%) 1		
Proteinuria subjects affected / exposed occurrences (all)	5 / 41 (12.20%) 5		
Renal failure acute subjects affected / exposed occurrences (all)	1 / 41 (2.44%) 2		
Renal failure chronic subjects affected / exposed occurrences (all)	2 / 41 (4.88%) 3		
Renal impairment subjects affected / exposed occurrences (all)	6 / 41 (14.63%) 7		
Renal vessel disorder subjects affected / exposed occurrences (all)	1 / 41 (2.44%) 1		
Tubulointerstitial nephritis subjects affected / exposed occurrences (all)	1 / 41 (2.44%) 1		
Urine abnormality subjects affected / exposed occurrences (all)	1 / 41 (2.44%) 1		
Vesicoureteric reflux subjects affected / exposed occurrences (all)	1 / 41 (2.44%) 1		
Endocrine disorders Hyperparathyroidism subjects affected / exposed occurrences (all)	2 / 41 (4.88%) 2		
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	8 / 41 (19.51%) 8		
Bone pain			

subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Back pain				
subjects affected / exposed	3 / 41 (7.32%)			
occurrences (all)	3			
Chondrocalcinosis				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Haemarthrosis				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Joint effusion				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Joint stiffness				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Muscle spasms				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Musculoskeletal pain				
subjects affected / exposed	2 / 41 (4.88%)			
occurrences (all)	2			
Myalgia				
subjects affected / exposed	4 / 41 (9.76%)			
occurrences (all)	4			
Neck pain				
subjects affected / exposed	2 / 41 (4.88%)			
occurrences (all)	2			
Osteopenia				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Pain in extremity				
subjects affected / exposed	2 / 41 (4.88%)			
occurrences (all)	2			
Rhabdomyolysis				

subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Infections and infestations			
Asymptomatic bacteriuria			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Bacterial infection			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Bacteriuria			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
BK virus infection			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Bronchitis			
subjects affected / exposed	5 / 41 (12.20%)		
occurrences (all)	5		
Bronchitis viral			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Catheter site infection			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Cystitis			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Dental gangrene			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Device related infection			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	2		
Device related sepsis			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	3		

Ear infection				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Erysipelas				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Folliculitis				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Gastroenteritis				
subjects affected / exposed	3 / 41 (7.32%)			
occurrences (all)	3			
Genital infection fungal				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Herpes zoster				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Infection				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Influenza				
subjects affected / exposed	2 / 41 (4.88%)			
occurrences (all)	2			
Laryngitis				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Lung infection				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Lymphangitis				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Nasopharyngitis				
subjects affected / exposed	8 / 41 (19.51%)			
occurrences (all)	8			

Onychomycosis				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Oral fungal infection				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Oral herpes				
subjects affected / exposed	3 / 41 (7.32%)			
occurrences (all)	3			
Otitis media				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Pharyngitis				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Pulmonary sepsis				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Pyelonephritis				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	2			
Respiratory tract infection				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Rhinitis				
subjects affected / exposed	3 / 41 (7.32%)			
occurrences (all)	3			
Sinusitis				
subjects affected / exposed	2 / 41 (4.88%)			
occurrences (all)	2			
Staphylococcal infection				
subjects affected / exposed	2 / 41 (4.88%)			
occurrences (all)	2			
Tinea pedis				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			

Upper respiratory tract infection			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Urinary tract infection			
subjects affected / exposed	7 / 41 (17.07%)		
occurrences (all)	7		
Vaginitis bacterial			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Viral infection			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Decreased appetite			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Dehydration			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Electrolyte imbalance			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Hypercalcaemia			
subjects affected / exposed	1 / 41 (2.44%)		
occurrences (all)	1		
Hypercreatininaemia			
subjects affected / exposed	2 / 41 (4.88%)		
occurrences (all)	2		
Hyperkalaemia			
subjects affected / exposed	4 / 41 (9.76%)		
occurrences (all)	4		
Hyperphosphataemia			

subjects affected / exposed	5 / 41 (12.20%)			
occurrences (all)	5			
Hyperuricaemia				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Hypervolaemia				
subjects affected / exposed	2 / 41 (4.88%)			
occurrences (all)	2			
Hypocalcaemia				
subjects affected / exposed	3 / 41 (7.32%)			
occurrences (all)	3			
Hypoglycaemia				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Hypokalaemia				
subjects affected / exposed	4 / 41 (9.76%)			
occurrences (all)	4			
Hypomagnesaemia				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Hypophosphataemia				
subjects affected / exposed	4 / 41 (9.76%)			
occurrences (all)	4			
Iron deficiency				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Metabolic acidosis				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Overweight				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Type 2 diabetes mellitus				
subjects affected / exposed	1 / 41 (2.44%)			
occurrences (all)	1			
Vitamin D deficiency				

subjects affected / exposed occurrences (all)	4 / 41 (9.76%) 4		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 December 2010	Global modification to clinical study protocol to implement, in particular, a Data Monitoring Committee
07 June 2011	Global modification to the clinical study protocol to increase the number of patients to be enrolled in the clinical study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/25833956