Clinical trial results:
"CLINICAL STUDY TO EVALUATE THE PHARMACOKINETICS, SAFETY AND EFFICACY OF OCTAGAM 5% IN PATIENTS WITH PRIMARY IMMUNODEFICIENCY DISEASES"

Summary

EudraCT number	2012-000792-16
Trial protocol	HU CZ DE
Global end of trial date	12 March 2013

Results information

Result version number	v1 (current)
This version publication date	22 July 2016
First version publication date	22 July 2016

Trial information

Trial identification

Sponsor protocol code	GAMr-29

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Octapharma AG
Sponsor organisation address	Seidenstraße 2, Lachen, Switzerland, CH-8853
Public contact	Clinical Research Department, Octapharma Pharmazeutika Produktionsgesellschaft, +43 1 61032 1295, clinical.department@octapharma.com
Scientific contact	Clinical Research Department, Octapharma Pharmazeutika Produktionsgesellschaft, +43 1 61032 1295, clinical.department@octapharma.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	03 February 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 March 2013
Global end of trial reached?	Yes
Global end of trial date	12 March 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the pharmacokinetic (PK) profile of Octagam 5% at steady state on standard prophylactic treatment of Primary Immunodeficiency Disorders (PID).

Protection of trial subjects:

This trial was conducted in accordance to the principles of GCP, ensuring that the rights, safety and well-being of patients are protected and in consistency with the Declaration of Helsinki.
Inclusion and exclusion criteria were carefully defined in order to protect subjects from contraindications, interactions with other medication and safety factors associated with the investigational medicinal product. Short term tolerance parameters (blood pressure, heart rate, temperature, respiratory rate) and safety laboratory parameters (haematology, clinical chemistry, and urinalysis) were evaluated. Relevant drug safety information (AEs and SAEs) was collected according a safety reporting plan.

Background therapy:

NA

Evidence for comparator:

NA

Actual start date of recruitment	04 July 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	Poland: 7
Country: Number of subjects enrolled	Czech Republic: 8
Country: Number of subjects enrolled	Germany: 1
Country: Number of subjects enrolled	Hungary: 11
Worldwide total number of subjects	27
EEA total number of subjects	27

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)	24
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

the study was planned to start enrolment during the 2nd quarter of 2012 with an overall study duration of 6 month per patient, so study was completed by 2nd quarter of 2014.

Pre-assignment

Screening details:

screening was performed between the end of the last pre-study infusion and the first infusion of this study, i.e., at the time the patient´s next treatment with IVIG was due. All results necessary to check the patient´s eligibility had to be available before infusion.

Period 1

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

Blinding implementation details:

NA

Arms

Arm title	Octagam 5% - 4/3-week treatment schedule

Arm description:

Octagam 5%, human normal immunoglobulin 5%, solvent/detergent-treated solution for IV infusion. The dose infused was 200-800 mg/kg body weight every 21 (+/- 3) or 28 (+/-3) days (in Germany and Hungary: "approximately 200-800 mg/kg), with individual doses and intervals being dependent on the patient´s previous IVIG dose and interval before entry into the study. All infusions started with an infusion rate of octagam 5% of 1 mL/kg/h (50 mg/kg/h) for the first 30 minutes; if tolerated, the rate of administration could gradually be increased to a maximum of 5 mL/kg/h (250 mg/kg/h) for the remainder of the infusion.

Arm type	Experimental
Investigational medicinal product name	Octagam 5%, human normal immunoglobulin 5%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

The dose infused was 200–800 mg/kg body weight every 21 (±3) or 28 (±3) days, (in Germany and Hungary: ‘approximately 200–800 mg/kg body weight every 21 [±3] or 28 [±3] days’), with individual doses and intervals being dependent on the patient’s previous IVIG dose and interval before entry into the study.

Number of subjects in period 1	Octagam 5% - 4/3-week treatment schedule
Started	27
Completed	25
Not completed	2
Consent withdrawn by subject	1
Adverse event, non-fatal	1

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	27	27	
Age categorical Units: Subjects			
From 65 - 84 years	3	3	
Adults (18 - 64 years)	24	24	
Age continuous Units: years			
arithmetic mean	42.6		
standard deviation	± 13.82	-	
Gender categorical Units: Subjects			
Female	13	13	
Male	14	14	

Subject analysis sets	
Subject analysis set title	Safety Set
Subject analysis set type	Safety analysis

Subject analysis set description:

The safety set comprised all patients who received at least 1 dose of study medication; it was the set of patients exposed to treatment.

Subject analysis set title	Completed patients
Subject analysis set type	Per protocol

Subject analysis set description:

The per-protocol (PP) set comprised all patients of the FA set excluding those with major protocol violations which may have had an impact on the analysis of efficacy. This was the set of patients who participated in the study as intended and for whom efficacy could be evaluated as planned, even if the PK profile was missing or could not be used for other reasons.

Reporting group values	Safety Set	Completed patients	
Number of subjects	27	25	
Age categorical Units: Subjects			
From 65 - 84 years			
Adults (18 - 64 years)			
Age continuous Units: years			
arithmetic mean			
standard deviation	±	±	
Gender categorical Units: Subjects			
Female	13		
Male	14		

End points

End points reporting groups

Reporting group title	Octagam 5% - 4/3-week treatment schedule

Reporting group description:

Octagam 5%, human normal immunoglobulin 5%, solvent/detergent-treated solution for IV infusion. The dose infused was 200-800 mg/kg body weight every 21 (+/- 3) or 28 (+/-3) days (in Germany and Hungary: "approximately 200-800 mg/kg), with individual doses and intervals being dependent on the patient´s previous IVIG dose and interval before entry into the study. All infusions started with an infusion rate of octagam 5% of 1 mL/kg/h (50 mg/kg/h) for the first 30 minutes; if tolerated, the rate of administration could gradually be increased to a maximum of 5 mL/kg/h (250 mg/kg/h) for the remainder of the infusion.

Subject analysis set title	Safety Set
Subject analysis set type	Safety analysis

Subject analysis set description:

The safety set comprised all patients who received at least 1 dose of study medication; it was the set of patients exposed to treatment.

Subject analysis set title	Completed patients
Subject analysis set type	Per protocol

Subject analysis set description:

The per-protocol (PP) set comprised all patients of the FA set excluding those with major protocol violations which may have had an impact on the analysis of efficacy. This was the set of patients who participated in the study as intended and for whom efficacy could be evaluated as planned, even if the PK profile was missing or could not be used for other reasons.

Primary: IgG Cmax

End point title	IgG Cmax[1]

End point description:

End point type	Primary

End point timeframe:

The total study duration (including screening period) per patient was approximately 6 months.

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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [g/L]				
arithmetic mean (standard deviation)	16.08 (± 2.4334)			

Statistical analyses

No statistical analyses for this end point

Primary: IgG Subclass IGG1 Cmax

End point title	IgG Subclass IGG1 Cmax[2]

End point description:

End point type	Primary

End point timeframe:

The total study duration (including screening period) per patient was approx. 6 months

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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [g/L]				
arithmetic mean (standard deviation)	9.619 (± 1.4805)			

Statistical analyses

No statistical analyses for this end point

Primary: IgG Subclass IGG2 Cmax

End point title	IgG Subclass IGG2 Cmax[3]

End point description:

End point type	Primary

End point timeframe:

the total study duration (including screening period) per patient was approx. 6 months.

Notes:

[3] - 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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [g/L]				
arithmetic mean (standard deviation)	5.744 (± 1.2377)			

Statistical analyses

No statistical analyses for this end point

Primary: IgG Subclass IGG3 Cmax

End point title	IgG Subclass IGG3 Cmax[4]

End point description:

End point type	Primary

End point timeframe:

the total study duration (including screening period) per patient was approx. 6 months.

Notes:

[4] - 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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [g/L]				
arithmetic mean (standard deviation)	0.372 (± 0.1461)			

Statistical analyses

No statistical analyses for this end point

Primary: IgG Cmin

End point title	IgG Cmin[5]

End point description:

End point type	Primary

End point timeframe:

the total study duration (including screeing period) per patient was approx. 6 months.

Notes:

[5] - 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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [g/L]				
arithmetic mean (standard deviation)	8.472 (± 1.5131)			

Statistical analyses

No statistical analyses for this end point

Primary: IgG Subclass IGG1 Cmin

End point title	IgG Subclass IGG1 Cmin[6]

End point description:

End point type	Primary

End point timeframe:

the total study duration (including screening period) per patient was approx. 6 months.

Notes:

[6] - 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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [g/L]				
arithmetic mean (standard deviation)	4.916 (± 1.0257)			

Statistical analyses

No statistical analyses for this end point

Primary: IgG Subclass IGG2 Cmin

End point title	IgG Subclass IGG2 Cmin[7]

End point description:

End point type	Primary

End point timeframe:

the total study duration (including screening period) per patient was approx. 6 months.

Notes:

[7] - 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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [g/L]				
arithmetic mean (standard deviation)	2.938 (± 0.7124)			

Statistical analyses

No statistical analyses for this end point

Primary: IgG Subclass IGG3 Cmin

End point title	IgG Subclass IGG3 Cmin[8]

End point description:

End point type	Primary

End point timeframe:

the total study duration (including screening period) per patient was approx. 6 months.

Notes:

[8] - 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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [g/L]				
arithmetic mean (standard deviation)	0.183 (± 0.1165)			

Statistical analyses

No statistical analyses for this end point

Primary: IgG Subclass IGG4 Cmax

End point title	IgG Subclass IGG4 Cmax[9]

End point description:

End point type	Primary

End point timeframe:

the total study duration (including screening period) per patient was approx. 6 months.

Notes:

[9] - 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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [g/L]				
arithmetic mean (standard deviation)	0.212 (± 0.0512)			

Statistical analyses

No statistical analyses for this end point

Primary: IgG Subclass IGG4 Cmin

End point title	IgG Subclass IGG4 Cmin[10]

End point description:

End point type	Primary

End point timeframe:

the total study duration (including screening period) per patient was approx. 6 months.

Notes:

[10] - 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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [g/L]				
arithmetic mean (standard deviation)	0.091 (± 0.0382)			

Statistical analyses

No statistical analyses for this end point

Primary: IgG AUC0-last

End point title	IgG AUC0-last[11]

End point description:

End point type	Primary

End point timeframe:

the total study duration (including screening period) per patient was approx. 6 months.

Notes:

[11] - 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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [h*g/L]				
arithmetic mean (standard deviation)	6357.927 (± 932.9594)			

Statistical analyses

No statistical analyses for this end point

Primary: IgG Subclass IGG1 AUC0-last

End point title	IgG Subclass IGG1 AUC0-last[12]

End point description:

End point type	Primary

End point timeframe:

the total study duration (including screening period) per patient was approx. 6 months.

Notes:

[12] - 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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [h*g/L]				
arithmetic mean (standard deviation)	3760.376 (± 601.2254)			

Statistical analyses

No statistical analyses for this end point

Primary: IgG Subclass IGG2 AUC0-last

End point title	IgG Subclass IGG2 AUC0-last[13]

End point description:

End point type	Primary

End point timeframe:

the total study duration (including screening period) per patient was approx. 6 months.

Notes:

[13] - 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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [h*g/L]				
arithmetic mean (standard deviation)	2234.955 (± 445.6055)			

Statistical analyses

No statistical analyses for this end point

Primary: IgG Subclass IGG3 AUC0-last

End point title	IgG Subclass IGG3 AUC0-last[14]

End point description:

End point type	Primary

End point timeframe:

the total study duration (including screening period) per patient was approx. 6 months.

Notes:

[14] - 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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [h*g/L]				
arithmetic mean (standard deviation)	141.223 (± 77.325)			

Statistical analyses

No statistical analyses for this end point

Primary: IgG Subclass IGG4 AUC0-last

End point title	IgG Subclass IGG4 AUC0-last[15]

End point description:

End point type	Primary

End point timeframe:

the total study duration (including screening period) per patient was approx. 6 months.

Notes:

[15] - 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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [h*g/L]				
arithmetic mean (standard deviation)	71.361 (± 23.4289)			

Statistical analyses

No statistical analyses for this end point

Primary: IgG t1/2

End point title	IgG t1/2[16]

End point description:

End point type	Primary

End point timeframe:

the total study duration (including screening period) per patient was approx. 6 months.

Notes:

[16] - 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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [day]				
arithmetic mean (standard deviation)	36.374 (± 11.546)			

Statistical analyses

No statistical analyses for this end point

Primary: IgG Subclass IGG1 t1/2

End point title	IgG Subclass IGG1 t1/2[17]

End point description:

End point type	Primary

End point timeframe:

the total study duration (including screening period) per patient was approx. 6 months.

Notes:

[17] - 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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [day]				
arithmetic mean (standard deviation)	33.557 (± 11.0536)			

Statistical analyses

No statistical analyses for this end point

Primary: IgG Subclass IGG2 t1/2

End point title	IgG Subclass IGG2 t1/2[18]

End point description:

End point type	Primary

End point timeframe:

the total study duration (including screening period) per patient was approx. 6 months.

Notes:

[18] - 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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [day]				
arithmetic mean (standard deviation)	34.927 (± 10.9729)			

Statistical analyses

No statistical analyses for this end point

Primary: IgG Subclass IGG3 t1/2

End point title	IgG Subclass IGG3 t1/2[19]

End point description:

End point type	Primary

End point timeframe:

the total study duration (including screening period) per patient was approx. 6 months.

Notes:

[19] - 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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [day]				
arithmetic mean (standard deviation)	41.033 (± 30.6534)			

Statistical analyses

No statistical analyses for this end point

Primary: IgG Subclass IGG4 t1/2

End point title	IgG Subclass IGG4 t1/2[20]

End point description:

End point type	Primary

End point timeframe:

the total study duration (including screening period) per patient was approx. 6 months.

Notes:

[20] - 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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [day]				
arithmetic mean (standard deviation)	26.649 (± 14.7862)			

Statistical analyses

No statistical analyses for this end point

Primary: IgG Vd

End point title	IgG Vd[21]

End point description:

End point type	Primary

End point timeframe:

the total study duration (including screening period) per patient was approx. 6 months.

Notes:

[21] - 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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [L/kg]				
arithmetic mean (standard deviation)	0.079 (± 0.0237)			

Statistical analyses

No statistical analyses for this end point

Primary: IgG Subclass IGG1 Vd

End point title	IgG Subclass IGG1 Vd[22]

End point description:

End point type	Primary

End point timeframe:

the total study duration (including screening period) per patient was approx. 6 months.

Notes:

[22] - 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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [L/kg]				
arithmetic mean (standard deviation)	0.081 (± 0.0247)			

Statistical analyses

No statistical analyses for this end point

Primary: IgG Subclass IGG2 Vd

End point title	IgG Subclass IGG2 Vd[23]

End point description:

End point type	Primary

End point timeframe:

the total study duration (including screening period) per patient was approx. 6 months.

Notes:

[23] - 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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [L/kg]				
arithmetic mean (standard deviation)	0.065 (± 0.0232)			

Statistical analyses

No statistical analyses for this end point

Primary: IgG Subclass IGG3 Vd

End point title	IgG Subclass IGG3 Vd[24]

End point description:

End point type	Primary

End point timeframe:

the total study duration (including screening period) per patient was approx. 6 months.

Notes:

[24] - 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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [L/kg]				
arithmetic mean (standard deviation)	0.11 (± 0.0754)			

Statistical analyses

No statistical analyses for this end point

Primary: IgG Subclass IGG4 Vd

End point title	IgG Subclass IGG4 Vd[25]

End point description:

End point type	Primary

End point timeframe:

the total study duration (including screening period) per patient was approx. 6 months.

Notes:

[25] - 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: Derived PK parameter; no statistical analysis or comparison performed (single-arm study)

End point values	Octagam 5% - 4/3-week treatment schedule			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: [L/kg]				
arithmetic mean (standard deviation)	0.069 (± 0.0196)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 24 hours SAE reporting adverse events	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	12.0
Reporting groups	
Reporting group title	all patients exposed to treatment (safety set)

Reporting group description: -

Serious adverse events	all patients exposed to treatment (safety set)		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 27 (3.70%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Blood and lymphatic system disorders			
Sepsis			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Gastrointestinal disorders			
Enteritis	Additional description: moderate and severe Enteritis		
subjects affected / exposed	1 / 27 (3.70%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	all patients exposed to treatment (safety set)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	24 / 27 (88.89%)		
Cardiac disorders			

Palpitations subjects affected / exposed occurrences (all)	2 / 27 (7.41%) 3		
Nervous system disorders Headache subjects affected / exposed occurrences (all)	6 / 27 (22.22%) 14		
General disorders and administration site conditions Pyrexia subjects affected / exposed occurrences (all)	4 / 27 (14.81%) 4		
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	3 / 27 (11.11%) 4		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Oropharyngeal pain subjects affected / exposed occurrences (all)	3 / 27 (11.11%) 4 2 / 27 (7.41%) 3		
Infections and infestations Bronchitis subjects affected / exposed occurrences (all) Rhinitis subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all) Viral infection subjects affected / exposed occurrences (all)	2 / 27 (7.41%) 2 3 / 27 (11.11%) 5 6 / 27 (22.22%) 6 4 / 27 (14.81%) 4		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported