Clinical trial results:
Multi-center, Open-label, Uncontrolled Clinical Study of Palivizumab in Japanese Newborns, Infants and Young Children at the Age of 24 Months or Less with Immunocompromised Medical Conditions

Summary

EudraCT number	2014-004491-31
Trial protocol	Outside EU/EEA
Global end of trial date	25 April 2012

Results information

Result version number	v1 (current)
This version publication date	20 April 2016
First version publication date	14 June 2015

Trial information

Trial identification

Sponsor protocol code	M12-420

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01466062
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AbbVie
Sponsor organisation address	1 North Waukegan Road, North Chicago, IL, United States, 60064
Public contact	Global Medical Information, AbbVie, 001 800-633-9110,
Scientific contact	Shigeki Hashimoto, AbbVie, shigeki.hashimoto@abbvie.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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	25 April 2012
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	25 April 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate safety, efficacy and pharmacokinetics of palivizumab in children at the age of 24 months or less with immunocompromised medical conditions.

Protection of trial subjects:

Participant's parent or legal guardian read and understood information provided about the study and gave written permission.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 August 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Japan: 28
Worldwide total number of subjects	28
EEA total number of subjects	0

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)	28
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study included a screening period of 4 weeks.

Period 1

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

Arms

Arm title	Palivizumab

Arm description:

15 mg/kg at 30-day intervals; at least 4 intramuscular injections up to a maximum of 7 intramuscular injections as appropriate for prophylaxis of respiratory syncytial virus (RSV) during the RSV season.

Arm type	Experimental
Investigational medicinal product name	Palivizumab
Investigational medicinal product code	
Other name	ABT-315, Synagis
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Palivizumab administered by intramuscular injection

Number of subjects in period 1	Palivizumab
Started	28
Completed	26
Not completed	2
Consent withdrawn by subject	1
Adverse event	1

Baseline characteristics

Reporting groups	
Reporting group title	Palivizumab
Reporting group description:	
15 mg/kg at 30-day intervals; at least 4 intramuscular injections up to a maximum of 7 intramuscular injections as appropriate for prophylaxis of respiratory syncytial virus (RSV) during the RSV season.	

Reporting group values	Palivizumab	Total	
Number of subjects	28	28	
Age categorical Units: Subjects			

Age Continuous Units: months			
arithmetic mean	14.2		
standard deviation	± 6.2	-	
Gender, Male/Female Units: participants			
Female	11	11	
Male	17	17	

End points

End points reporting groups

Reporting group title	Palivizumab

Reporting group description:

15 mg/kg at 30-day intervals; at least 4 intramuscular injections up to a maximum of 7 intramuscular injections as appropriate for prophylaxis of respiratory syncytial virus (RSV) during the RSV season.

Primary: Serum Palivizumab Trough Concentrations at Day 1, Day 31, and Day 121

End point title	Serum Palivizumab Trough Concentrations at Day 1, Day 31, and Day 121[1]

End point description:

Serum trough concentrations of palivizumab were assessed at Screening, at Day 31 (30 days after the 1st dose) and Day 121 (30 days after the 4th dose). N=number of non-missing observations.

End point type	Primary

End point timeframe:

Day 1 (Screening), Day 31, Day 121

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: Descriptive data are summarized for this end point per protocol.

End point values	Palivizumab			
Subject group type	Reporting group			
Number of subjects analysed	28[2]			
Units: µg/mL				
arithmetic mean (standard deviation)				
Day 1 (Screening); n=28	0 (± 0)			
Day 31; n=28	59 (± 12.9)			
Day 121; n=26	91.8 (± 40.6)			

Notes:

[2] - All participants

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Requiring Hospitalization For Respiratory Syncytial Virus (RSV) Infection

End point title	Percentage of Participants Requiring Hospitalization For Respiratory Syncytial Virus (RSV) Infection

End point description:

End point type	Secondary

End point timeframe:

From the first administration of palivizumab to 30 days after the last administration of palivizumab. Mean (SD) duration of treatment was 183 (37.29) days.

End point values	Palivizumab			
Subject group type	Reporting group			
Number of subjects analysed	28[3]			
Units: percentage of participants				
number (confidence interval 95%)	0 (0 to 12.3)			

Notes:

[3] - All participants

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Required Treatment for Respiratory Syncytial Virus (RSV) Infection

End point title	Percentage of Participants Who Required Treatment for Respiratory Syncytial Virus (RSV) Infection

End point description:

Percentage of participants who required any of the investigated treatments (admission in the intensive care unit [ICU], oxygen supplementation, mechanical ventilation, extracorporeal membrane oxygenation, continuous positive airway pressure and other mechanical respiratory support) for disease caused by RSV infection after the initial dose to 30 days after the last dose of the study drug.

End point type	Secondary

End point timeframe:

From the first administration of palivizumab to 30 days after the last administration of palivizumab. Mean (SD) duration of treatment was 183 (37.29) days.

End point values	Palivizumab			
Subject group type	Reporting group			
Number of subjects analysed	28[4]			
Units: percentage of participants				
number (confidence interval 95%)				
Intensive-care unit	0 (0 to 12.3)			
Oxygen supplementation	0 (0 to 12.3)			
Mechanical ventilation	0 (0 to 12.3)			
Extracorporeal membrane oxygenation	0 (0 to 12.3)			
Continuous positive airway pressure	0 (0 to 12.3)			
Other mechanical respiratory support	0 (0 to 12.3)			

Notes:

[4] - All participants

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Hospitalization Caused by Respiratory Syncytial Virus (RSV)

Infection	
End point title	Duration of Hospitalization Caused by Respiratory Syncytial Virus (RSV) Infection

End point description:

Number of days of hospitalization caused by RSV infection.

End point type	Secondary

End point timeframe:

From the first administration of palivizumab to 30 days after the last administration of palivizumab. Mean (SD) duration of treatment was 183 (37.29) days.

End point values	Palivizumab			
Subject group type	Reporting group			
Number of subjects analysed	0[5]			
Units: days				
number (not applicable)				

Notes:

[5] - No subject had RSV infection from first dose of palivizumab to 30 days after administration

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Required Treatment for Respiratory Syncytial Virus (RSV) Infection	
End point title	Duration of Required Treatment for Respiratory Syncytial Virus (RSV) Infection

End point description:

Duration (days) of requirement for any of the investigated treatments (admission in the intensive care unit [ICU], oxygen supplementation, mechanical ventilation, extracorporeal membrane oxygenation, continuous positive airway pressure and other mechanical respiratory support) for disease caused by RSV infection after the initial dose to 30 days after the last dose of the study drug.

End point type	Secondary

End point timeframe:

From the first administration of palivizumab to 30 days after the last administration of palivizumab. Mean (SD) duration of treatment was 183 (37.29) days.

End point values	Palivizumab			
Subject group type	Reporting group			
Number of subjects analysed	0[6]			
Units: days				
number (not applicable)				

Notes:

[6] - No subject had RSV infection from first dose of palivizumab to 30 days after administration

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Adverse Events (AEs), Serious Adverse Events (SAEs), and Discontinuations Due to AEs

End point title	Number of Participants with Adverse Events (AEs), Serious Adverse Events (SAEs), and Discontinuations Due to AEs

End point description:

An adverse event (AE) is defined as any untoward medical occurrence in a participant, which does not necessarily have a causal relationship with treatment. If an adverse event meets any of the following criteria, it is considered a serious adverse event (SAE): results in death or is life-threatening, results in admission or prolongation of hospitalization, results in congenital anomaly or persistent or significant disability/incapacity, or is an important medical event requiring medical or surgical intervention to prevent serious outcome. AEs were categorized by severity (mild, moderate, severe) and relationship to treatment (probably, possibly, probably not, not related). Please see Adverse Events section below for more details.

End point type	Secondary

End point timeframe:

From the first administration of palivizumab to 100 days after the last administration of palivizumab. Mean (SD) duration of treatment was 183 (37.29) days.

End point values	Palivizumab			
Subject group type	Reporting group			
Number of subjects analysed	28[7]			
Units: participants				
number (not applicable)				
Any AE	27			
Any AE at least "possibly" drug related	0			
Any AE at least "probably not" drug related	7			
Any "severe" AE	2			
Any SAE	7			
Any AE leading to discontinuation of study drug	1			
Any AE leading to death	0			
Death	0			

Notes:

[7] - All participants

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Baseline and Mean Change From Baseline in Systolic/Diastolic Blood Pressure at Day 121

End point title	Mean Baseline and Mean Change From Baseline in Systolic/Diastolic Blood Pressure at Day 121

End point description:

N=number of participants with measurements at given time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Day 121 (30 days after the 4th dose)

End point values	Palivizumab			
Subject group type	Reporting group			
Number of subjects analysed	28[8]			
Units: mm Hg				
arithmetic mean (standard deviation)				
Baseline Systolic Blood Pressure (SBP); n=26	96.1 (± 9.44)			
Change from Baseline in SBP at Day 121; n=26	-2.4 (± 10.23)			
Baseline Diastolic Blood Pressure (DBP); n=25	55 (± 9.16)			
Change from Baseline in DBP at Day 121; n=25	3 (± 14.56)			

Notes:

[8] - All participants

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Baseline and Mean Change From Baseline in Body Temperature at Day 121

End point title	Mean Baseline and Mean Change From Baseline in Body Temperature at Day 121

End point description:

End point type	Secondary

End point timeframe:

Baseline (Day 1), Day 121 (30 days after the 4th dose)

End point values	Palivizumab			
Subject group type	Reporting group			
Number of subjects analysed	26[9]			
Units: degrees Celcius				
arithmetic mean (standard deviation)				
Baseline Body Temperature (BT)	36.77 (± 0.346)			
Change from Baseline in BT at Day 12	-0.11 (± 0.4)			

Notes:

[9] - All participants with measurements at given time points

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Baseline and Mean Change From Baseline in Respiratory Rate at Day 121

End point title	Mean Baseline and Mean Change From Baseline in Respiratory Rate at Day 121

End point description:

End point type	Secondary

End point timeframe:

Baseline (Day 1), Day 121 (30 days after the 4th dose)

End point values	Palivizumab			
Subject group type	Reporting group			
Number of subjects analysed	26[10]			
Units: respirations per minute				
arithmetic mean (standard deviation)				
Baseline Respiratory Rate (RR)	33.4 (± 8.59)			
Change from Baseline in RR at Day 121	1.5 (± 8.21)			

Notes:

[10] - All participants with measurements at given time points

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Baseline and Mean Change From Baseline in Pulse Rate at Day 121

End point title	Mean Baseline and Mean Change From Baseline in Pulse Rate at Day 121

End point description:

End point type	Secondary

End point timeframe:

Baseline (Day 1), Day 121 (30 days after the 4th dose)

End point values	Palivizumab			
Subject group type	Reporting group			
Number of subjects analysed	26[11]			
Units: beats per minute				
arithmetic mean (standard deviation)				
Baseline Pulse Rate (PR)	126.6 (± 21.91)			
Change from Baseline PR at Day 121	-6.7 (± 26.66)			

Notes:

[11] - All participants with measurements at given time points

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Baseline and Mean Change From Baseline in Body Weight at Day 121

End point title	Mean Baseline and Mean Change From Baseline in Body Weight at Day 121

End point description:

End point type	Secondary

End point timeframe:

Baseline (Day 1), Day 121 (30 days after the 4th dose)

End point values	Palivizumab			
Subject group type	Reporting group			
Number of subjects analysed	26[12]			
Units: kilograms				
arithmetic mean (standard deviation)				
Baseline Body Weight (BW)	8.76 (± 1.9)			
Change from Baseline in BW at Day 121	1.23 (± 0.71)			

Notes:

[12] - All participants with measurements at given time points

Statistical analyses

No statistical analyses for this end point

Secondary: Hematology: Mean Baseline and Mean Change From Baseline in Hemoglobin at Day 121

End point title	Hematology: Mean Baseline and Mean Change From Baseline in Hemoglobin at Day 121

End point description:

Normal range for hemoglobin varied by the monthly age of the participant.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Day 121 (30 days after the 4th dose)

End point values	Palivizumab			
Subject group type	Reporting group			
Number of subjects analysed	25[13]			
Units: g/dL				
arithmetic mean (standard deviation)				
Baseline Hemoglobin	11.57 (± 1.56)			
Change from Baseline in Hemoglobin at Day 121	0.14 (± 1.87)			

Notes:

[13] - All participants with measurements at given time points

Statistical analyses

No statistical analyses for this end point

Secondary: Hematology: Mean Baseline and Mean Change From Baseline in Hematocrit at Day 121

End point title	Hematology: Mean Baseline and Mean Change From Baseline in Hematocrit at Day 121

End point description:

Normal range for hematocrit varied by the monthly age of the participant.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Day 121 (30 days after the 4th dose)

End point values	Palivizumab			
Subject group type	Reporting group			
Number of subjects analysed	25[14]			
Units: percentage of red blood cells				
arithmetic mean (standard deviation)				
Baseline Hematocrit	34.32 (± 4.72)			
Change from Baseline in Hematocrit at Day 121	0.96 (± 5.43)			

Notes:

[14] - All participants with measurements at given time points

Statistical analyses

No statistical analyses for this end point

Secondary: Hematology: Mean Baseline and Mean Change From Baseline in White Blood Cells (WBC), Neutrophils, Eosinophils, Basophils, Lymphocytes, and Monocytes at Day 121

End point title	Hematology: Mean Baseline and Mean Change From Baseline in White Blood Cells (WBC), Neutrophils, Eosinophils, Basophils, Lymphocytes, and Monocytes at Day 121

End point description:

Normal ranges for WBC, neutrophils, eosinophils, basophils, lymphocytes, and monocytes varied by the monthly age of the participant.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Day 121 (30 days after the 4th dose)

End point values	Palivizumab			
Subject group type	Reporting group			
Number of subjects analysed	28[15]			
Units: cells *10^3/µL				
arithmetic mean (standard deviation)				
Baseline White Blood Cells (WBC); n=25	6.74 (± 3.93)			
Change from Baseline in WBC at Day 121; n=25	0.24 (± 2.53)			
Baseline (BL) Neutrophils; n=24	2.6 (± 2.17)			
Change from BL in Neutrophils at Day 121; n=24	-0.05 (± 1.6)			
Baseline Eosinophils; n=24	0.25 (± 0.26)			
Change from BL in Eosinophils at Day 121; n=24	0 (± 0.31)			
Baseline Basophils; n=24	0.04 (± 0.05)			
Change from Baseline in Basophils at Day 121; n=24	0.02 (± 0.07)			
Baseline Lymphocytes; n=24	3.36 (± 2.35)			
Change from BL in Lymphocytes at Day 121; n=24	0.31 (± 1.69)			
Baseline Monocytes; n=24	0.51 (± 0.44)			
Change from Baseline in Monocytes at Day 121; n=24	-0.02 (± 0.38)			

Notes:

[15] - All participants with measurements at given time points

Statistical analyses

No statistical analyses for this end point

Secondary: Hematology: Mean Baseline and Mean Change From Baseline in Red Blood Cells (RBC) and Platelet Count at Day 121

End point title	Hematology: Mean Baseline and Mean Change From Baseline in Red Blood Cells (RBC) and Platelet Count at Day 121

End point description:

Normal ranges for RBC and platelet count varied by the monthly age of the participant.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Day 121 (30 days after the 4th dose)

End point values	Palivizumab			
Subject group type	Reporting group			
Number of subjects analysed	25[16]			
Units: cells *10^4/µL				
arithmetic mean (standard deviation)				
Baseline Red Blood Cells (RBC)	410.6 (± 70.83)			

Change from Baseline in RBC at Day 121	22.3 (± 74.74)			
Baseline Platelet Count	31.29 (± 19.8)			
Change from Baseline in Platelet Count at Day 121	1.72 (± 18.35)			

Notes:

[16] - All participants with measurements at given time points

Statistical analyses

No statistical analyses for this end point

Secondary: Blood Chemistry: Mean Baseline and Change From Baseline in Alkaline Phosphatase (ALP), Aspartate Aminotransferase (AST), and Alanine Aminotransferase (ALT) at Day 121

End point title	Blood Chemistry: Mean Baseline and Change From Baseline in Alkaline Phosphatase (ALP), Aspartate Aminotransferase (AST), and Alanine Aminotransferase (ALT) at Day 121

End point description:

Normal ranges for ALP, AST, and ALT varied by the monthly age of the participant.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Day 121 (30 days after the 4th dose)

End point values	Palivizumab			
Subject group type	Reporting group			
Number of subjects analysed	24[17]			
Units: U/L				
arithmetic mean (standard deviation)				
Baseline ALP	943 (± 519.1)			
Change from Baseline in ALP at Day 121	-18 (± 368.35)			
Baseline AST	39.08 (± 12.95)			
Change from Baseline in AST at Day 121	1.54 (± 8.09)			
Baseline ALT	31.13 (± 25.7)			
Change from Baseline in ALT at Day 121	-3.17 (± 14.07)			

Notes:

[17] - All participants with measurements at given time points

Statistical analyses

No statistical analyses for this end point

Secondary: Blood Chemistry: Mean Baseline and Change From Baseline in Total Bilirubin, Blood Urea Nitrogen (BUN), Creatinine, and C-reactive Protein (CRP) at Day 121

End point title	Blood Chemistry: Mean Baseline and Change From Baseline in Total Bilirubin, Blood Urea Nitrogen (BUN), Creatinine, and C-reactive Protein (CRP) at Day 121

End point description:

Normal ranges for total bilirubin, BUN, creatinine, and CRP varied by the monthly age of the participant.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Day 121 (30 days after the 4th dose)

End point values	Palivizumab			
Subject group type	Reporting group			
Number of subjects analysed	24[18]			
Units: mg/dL				
arithmetic mean (standard deviation)				
Baseline Total Bilirubin	0.3 (± 0.14)			
Change from Baseline in Total Bilirubin at Day 121	0.04 (± 0.15)			
Baseline BUN	11.46 (± 4.52)			
Change from Baseline in BUN at Day 121	0.87 (± 4.64)			
Baseline Creatinine	0.23 (± 0.04)			
Change from Baseline in Creatinine at Day 121	0.01 (± 0.04)			
Baseline CRP	0.29 (± 0.42)			
Change from Baseline in CRP at Day 121	0.03 (± 0.62)			

Notes:

[18] - All participants with measurements at given time points

Statistical analyses

No statistical analyses for this end point

Secondary: Urinalysis: Presence of Urine Protein, Glucose, and Occult Blood at Screening and Day 121

End point title	Urinalysis: Presence of Urine Protein, Glucose, and Occult Blood at Screening and Day 121

End point description:

The values -, -/+, 1+, 2+, 3+, and 4+ represent a range from none (-) to highest (4+) presence of protein, glucose, and occult blood in the urine. Table presents the number of participants with each value. Those categories with 0 participants to report at either time point are not included in the table below.

End point type	Secondary

End point timeframe:

Screening, Day 121 (30 days after the 4th dose)

End point values	Palivizumab			
Subject group type	Reporting group			
Number of subjects analysed	28[19]			
Units: participants				
number (not applicable)				
Protein "-" at Screening; n=24	21			
Protein "+/-" at Screening; n=24	3			
Protein "-" at Day 121; n=22	21			
Protein "+/-" at Day 121; n=22	1			
Glucose "-" at Screening; n=24	24			
Glucose "-" at Day 121; n=22	22			
Occult Blood "-" at Screening; n=24	21			
Occult Blood "+/-" at Screening; n=24	2			
Occult Blood "1+" at Screening; n=24	1			
Occult Blood "-" at Day 121; n=22	21			
Occult Blood "+/-" at Day 121; n=22	0			
Occult Blood "1+" at Day 121; n=22	1			

Notes:

[19] - All participants with measurements at given time points

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs:from time of initial study drug administration (Day 1) to 100 days after final administration of the study drug. SAEs:from screening period until 100 days after final administration of study drug. Mean (SD) duration of treatment was 183 (37.29) days.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	14.1

Reporting groups

Reporting group title	Palivizumab

Reporting group description:

15 mg/kg at 30-day intervals; at least 4 intramuscular injections up to a maximum of 7 intramuscular injections as appropriate for prophylaxis of respiratory syncytial virus (RSV) during the RSV season.

Serious adverse events	Palivizumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 28 (25.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Nervous system disorders			
Encephalopathy			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Enterocolitis			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Duodenal stenosis			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal perforation			

subjects affected / exposed	1 / 28 (3.57%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Bronchitis			
subjects affected / exposed	2 / 28 (7.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Croup infectious			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peritonitis			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia bacterial			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	3 / 28 (10.71%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Palivizumab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 28 (92.86%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	3		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Immune system disorders			
Hypogammaglobulinaemia			
subjects affected / exposed	4 / 28 (14.29%)		
occurrences (all)	8		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Bronchitis chronic			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Respiratory depression			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Rhinorrhoea			
subjects affected / exposed	2 / 28 (7.14%)		
occurrences (all)	2		
Investigations			
Antithrombin III decreased			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Neutrophil count decreased			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Bacterial test positive			

subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
White blood cells urine positive			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			
Arthropod sting			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Contusion			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Subcutaneous haematoma			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Thermal burn			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Congenital, familial and genetic disorders			
Antithrombin III deficiency			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	2		
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Hypercoagulation			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	2		
Iron deficiency anaemia			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		

Leukopenia subjects affected / exposed occurrences (all)	3 / 28 (10.71%) 23		
Thrombocytopenia subjects affected / exposed occurrences (all)	4 / 28 (14.29%) 10		
Anaemia subjects affected / exposed occurrences (all)	4 / 28 (14.29%) 18		
Eye disorders Conjunctivitis subjects affected / exposed occurrences (all)	2 / 28 (7.14%) 2		
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	2 / 28 (7.14%) 2		
Dyspepsia subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1		
Enterocolitis subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1		
Rectal prolapse subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1		
Constipation subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1		
Hepatobiliary disorders Hepatic function abnormal subjects affected / exposed occurrences (all)	4 / 28 (14.29%) 5		
Skin and subcutaneous tissue disorders Dermatitis atopic subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1		

Dermatitis contact subjects affected / exposed occurrences (all)	2 / 28 (7.14%) 3		
Dermatitis diaper subjects affected / exposed occurrences (all)	5 / 28 (17.86%) 5		
Dry skin subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1		
Eczema asteatotic subjects affected / exposed occurrences (all)	3 / 28 (10.71%) 3		
Eczema subjects affected / exposed occurrences (all)	6 / 28 (21.43%) 6		
Eczema infantile subjects affected / exposed occurrences (all)	3 / 28 (10.71%) 3		
Hyperkeratosis palmaris and plantaris subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1		
Rash subjects affected / exposed occurrences (all)	5 / 28 (17.86%) 6		
Renal and urinary disorders Azotaemia subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1		
Musculoskeletal and connective tissue disorders Muscular weakness subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1		
Infections and infestations Bronchitis subjects affected / exposed occurrences (all)	2 / 28 (7.14%) 2		

Conjunctivitis infective				
subjects affected / exposed	1 / 28 (3.57%)			
occurrences (all)	1			
Cystitis				
subjects affected / exposed	2 / 28 (7.14%)			
occurrences (all)	2			
Exanthema subitum				
subjects affected / exposed	1 / 28 (3.57%)			
occurrences (all)	2			
Gastroenteritis				
subjects affected / exposed	6 / 28 (21.43%)			
occurrences (all)	8			
Gastroenteritis viral				
subjects affected / exposed	1 / 28 (3.57%)			
occurrences (all)	1			
Impetigo				
subjects affected / exposed	1 / 28 (3.57%)			
occurrences (all)	1			
Influenza				
subjects affected / exposed	6 / 28 (21.43%)			
occurrences (all)	7			
Molluscum contagiosum				
subjects affected / exposed	1 / 28 (3.57%)			
occurrences (all)	1			
Nasopharyngitis				
subjects affected / exposed	4 / 28 (14.29%)			
occurrences (all)	4			
Otitis media acute				
subjects affected / exposed	1 / 28 (3.57%)			
occurrences (all)	1			
Otitis media				
subjects affected / exposed	2 / 28 (7.14%)			
occurrences (all)	2			
Pharyngitis				
subjects affected / exposed	3 / 28 (10.71%)			
occurrences (all)	4			

Pseudomonas infection subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1		
Respiratory tract infection subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 2		
Rotavirus infection subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1		
Rhinitis subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1		
Sinusitis subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1		
Tinea cruris subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1		
Tonsillitis subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	7 / 28 (25.00%) 16		
Upper respiratory tract infection bacterial subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1		
Viral infection subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1		
Metabolism and nutrition disorders Hypoalbuminaemia subjects affected / exposed occurrences (all)	2 / 28 (7.14%) 2		

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