



Clinical trial results:

A Study of Long-Term Recombinant Human Insulin-Like Growth Factor-1 (rhIGF-1) Treatment of Children With Short Stature Due to Severe Primary IGF-1 Deficiency

Summary

EudraCT number	2025-000222-34
Trial protocol	Outside EU/EEA
Global end of trial date	15 December 2011

Results information

Result version number	v1 (current)
This version publication date	21 December 2025
First version publication date	21 December 2025

Trial information

Trial identification

Sponsor protocol code	1419
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00571727
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Ipsen Biopharmaceuticals Inc
Sponsor organisation address	106 Allen Road, 3rd Floor, Basking Ridge, New Jersey, United States, 07920
Public contact	Medical Director, Ipsen, clinical.trials@ipsen.com
Scientific contact	Medical Director, Ipsen, clinical.trials@ipsen.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	15 December 2011
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	15 December 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to evaluate the safety and efficacy of long-term replacement therapy with mecasermin in children with growth failure due to severe primary insulin-like growth factor-1 (IGF-1) deficiency.

Protection of trial subjects:

The study was conducted in accordance with the ethical and regulatory national or international guidelines and requirements in place at the beginning of the study and updated as appropriate.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 May 1991
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	Argentina: 7
Country: Number of subjects enrolled	Australia: 1
Country: Number of subjects enrolled	Austria: 1
Country: Number of subjects enrolled	Bahamas: 2
Country: Number of subjects enrolled	Brazil: 4
Country: Number of subjects enrolled	Canada: 2
Country: Number of subjects enrolled	Egypt: 7
Country: Number of subjects enrolled	France: 1
Country: Number of subjects enrolled	Germany: 2
Country: Number of subjects enrolled	Iran, Islamic Republic of: 4
Country: Number of subjects enrolled	Israel: 1
Country: Number of subjects enrolled	Italy: 10
Country: Number of subjects enrolled	Kuwait: 4
Country: Number of subjects enrolled	Pakistan: 1
Country: Number of subjects enrolled	Poland: 1
Country: Number of subjects enrolled	Russian Federation: 2
Country: Number of subjects enrolled	Saudi Arabia: 25
Country: Number of subjects enrolled	Spain: 1
Country: Number of subjects enrolled	Sweden: 2
Country: Number of subjects enrolled	Syria: 1

Country: Number of subjects enrolled	Taiwan: 3
Country: Number of subjects enrolled	Ukraine: 1
Country: Number of subjects enrolled	United States: 8
Country: Number of subjects enrolled	Yemen: 1
Worldwide total number of subjects	92
EEA total number of subjects	18

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)	2
Children (2-11 years)	70
Adolescents (12-17 years)	20
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This Phase 3, open-label study was conducted in children with short stature due to severe primary insulin like growth factor-1 deficiency at 2 investigative sites in the US in conjunction with sites in 23 other countries.

Pre-assignment

Screening details:

Participants who had been treated with mecasermin in previous Genentech-sponsored studies (F0206s, F0375g, F0632g, F0671g), as well as new participants naïve to mecasermin treatment, were enrolled in this study.

Period 1

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

Arms

Arm title	Mecasermin
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Arm description:

Participants who were entered from previous studies continued to receive mecasermin 80 to 120 microgram per kilograms (mcg/kg) subcutaneously (SC) twice daily and naïve-to-treatment participants were administered mecasermin 60 to 80 mcg/kg SC twice daily for 1 to 2 weeks, and then increased to 120 mcg/kg as tolerated.

Arm type	Experimental
Investigational medicinal product name	Mecasermin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Mecasermin 80 to 120 mcg/kg SC twice daily was administered for participants who were already treated in previous studies and mecasermin 60 to 80 mcg/kg SC twice daily was administered for participants who were naïve to the treatment. For treatment naïve participants, the dose was administered for 1 to 2 weeks and then increased to 120 mcg/kg.

Number of subjects in period 1	Mecasermin
Started	92
Completed	26
Not completed	66
Poor growth	1
Unable to provide study drug	6
Did not enter in this study	1
Non-compliance	4
On-treatment at end of study	8
Parent/patient decision	2

Lost to follow-up	30
Participant transferred to commercial drug	14

Baseline characteristics

Reporting groups

Reporting group title	Mecasermin
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Reporting group description:

Participants who were entered from previous studies continued to receive mecasermin 80 to 120 microgram per kilograms (mcg/kg) subcutaneously (SC) twice daily and naïve-to-treatment participants were administered mecasermin 60 to 80 mcg/kg SC twice daily for 1 to 2 weeks, and then increased to 120 mcg/kg as tolerated.

Reporting group values	Mecasermin	Total	
Number of subjects	92	92	
Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	7.6 ± 4.3	-	
Gender categorical Units: Subjects			
Female	39	39	
Male	53	53	
Race/Ethnicity Units: Subjects			
Caucasian	77	77	
African American	3	3	
Hispanic	6	6	
Asian	4	4	
Other	2	2	

End points

End points reporting groups

Reporting group title	Mecasermin
Reporting group description:	
Participants who were entered from previous studies continued to receive mecasermin 80 to 120 microgram per kilograms (mcg/kg) subcutaneously (SC) twice daily and naïve-to-treatment participants were administered mecasermin 60 to 80 mcg/kg SC twice daily for 1 to 2 weeks, and then increased to 120 mcg/kg as tolerated.	

Primary: Annualized Height Velocity Up to 12 Years

End point title	Annualized Height Velocity Up to 12 Years ^[1]
End point description:	
Height velocity is the difference between 2 height measurements, divided by years elapsed between measurements. The intention-to-treat population consisted of all 92 participants. Only data from the participants naïve to exogenous recombinant human insulin-like growth factor-1 (rhIGF-1) and whose pre-treatment height velocity were available were reported. Here, n= number of participants analyzed at specific timepoint.	
End point type	Primary
End point timeframe:	
Baseline (Pre-dose) and up to 12 years	
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: Only descriptive statistical analysis was performed for the primary endpoint.	

End point values	Mecasermin			
Subject group type	Reporting group			
Number of subjects analysed	75			
Units: centimeter per year (cm/y)				
arithmetic mean (standard deviation)				
Baseline (Pre-dose) (n=75)	2.6 (± 1.7)			
>= 1 year (n=75)	8.0 (± 2.3)			
>= 2 years (n=63)	5.9 (± 1.7)			
>= 3 years (n=62)	5.5 (± 1.8)			
>= 4 years (n=60)	5.2 (± 1.5)			
>= 5 years (n=53)	4.9 (± 1.5)			
>= 6 years (n=39)	4.8 (± 1.4)			
>= 7 years (n=25)	4.3 (± 1.5)			
>= 8 years (n=19)	4.4 (± 1.5)			
>= 9 years (n=14)	4.4 (± 1.7)			
>= 10 years (n=13)	4.5 (± 2.0)			
>= 11 years (n=12)	4.1 (± 2.0)			
>= 12 years (n=10)	3.9 (± 2.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Naive Participants With Height Velocity <5 cm/y at the End of 1 Year of Study Treatment

End point title	Number of Naive Participants With Height Velocity <5 cm/y at the End of 1 Year of Study Treatment ^[2]
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End point description:

Height measurements were performed using wall-mounted stadiometers for analysis of growth data. The intention-to-treat population consisted of all 92 participants. Only data from the participants naïve to exogenous rhIGF-1 were reported.

End point type	Primary
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End point timeframe:

Baseline (Pre-dose) and 1 year

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: Only descriptive statistical analysis was performed for the primary endpoint.

End point values	Mecasermin			
Subject group type	Reporting group			
Number of subjects analysed	81			
Units: participants	7			

Statistical analyses

No statistical analyses for this end point

Secondary: Height Velocity Standard Deviation Score Up to 12 Years

End point title	Height Velocity Standard Deviation Score Up to 12 Years
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End point description:

Center for disease control growth charts from the US were used as reference for age and gender-dependent mean and standard deviation. Height velocity-standard deviation score was calculated as height velocity minus reference mean height velocity divided by standard deviation of the reference mean height velocity. Greater height velocity standard deviation score indicates better outcome. The intention-to-treat population consisted of all 92 participants. Only data from the participants naïve to exogenous rhIGF-1 and whose pre-treatment height velocity were available were reported. Here, n= number of participants analyzed at specific timepoint.

End point type	Secondary
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End point timeframe:

Baseline (Pre-dose) and up to 12 years

End point values	Mecasermin			
Subject group type	Reporting group			
Number of subjects analysed	75			
Units: standard deviation score				
arithmetic mean (standard deviation)				
Baseline (Pre-dose) (n=75)	-3.4 (± 1.6)			
>= 1 year (n=75)	1.7 (± 2.8)			

>= 2 years (n=62)	-0.0 (± 1.7)			
>= 3 years (n=61)	-0.1 (± 1.9)			
>= 4 years (n=58)	-0.2 (± 1.9)			
>= 5 years (n=50)	-0.3 (± 1.7)			
>= 6 years (n=37)	-0.2 (± 1.6)			
>= 7 years (n=22)	-0.5 (± 1.7)			
>= 8 years (n=15)	-0.2 (± 1.6)			
>= 9 years (n=12)	-0.4 (± 0.8)			
>= 10 years (n=11)	0.1 (± 1.6)			
>= 11 years (n=11)	0.5 (± 2.6)			
>= 12 years (n=8)	-0.1 (± 1.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Height Standard Deviation Score Up to 12 Years

End point title	Height Standard Deviation Score Up to 12 Years
End point description:	
Center for disease control growth charts from the US were used as reference for age and gender-dependent mean and standard deviation. Height standard deviation score was calculated as height minus reference mean height divided by standard deviation of the reference mean height. A higher height standard deviation score indicates a better outcome. The intention-to-treat population consisted of all 92 participants. Only data from the participants naïve to exogenous rhIGF-1 were reported. Here, n= number of participants analyzed at specific timepoint.	
End point type	Secondary
End point timeframe:	
Baseline (Pre-dose) and up to 12 years	

End point values	Mecasermin			
Subject group type	Reporting group			
Number of subjects analysed	81			
Units: standard deviation score				
arithmetic mean (standard deviation)				
Baseline (Pre-dose) (n=81)	-6.9 (± 1.8)			
>= 1 year (n=81)	-6.1 (± 1.8)			
>= 2 years (n=67)	-5.6 (± 1.7)			
>= 3 years (n=66)	-5.3 (± 1.7)			
>= 4 years (n=64)	-5.1 (± 1.7)			
>= 5 years (n=57)	-5.0 (± 1.7)			
>= 6 years (n=41)	-4.9 (± 1.6)			
>= 7 years (n=26)	-4.9 (± 1.7)			
>= 8 years (n=19)	-5.1 (± 1.7)			
>= 9 years (n=14)	-5.0 (± 1.6)			
>= 10 years (n=13)	-5.0 (± 1.7)			
>= 11 years (n=12)	-4.7 (± 1.2)			
>= 12 years (n=10)	-4.4 (± 1.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Approximate Increase in Height Over Expected for Naïve Participants With Near-Adult Height

End point title	Approximate Increase in Height Over Expected for Naïve Participants With Near-Adult Height
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End point description:
Height measurements were performed using wall-mounted stadiometers for analysis of growth data. The intention-to-treat population consisted of all 92 participants. Only data from the participants naïve to exogenous rhIGF-1 and who attained near adult height were reported.

End point type	Secondary
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End point timeframe:
Baseline (Pre-dose) and up to 19 years

End point values	Mecasermin			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: cm				
arithmetic mean (standard deviation)	13.3 (± 8.4)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment-emergent adverse events were collected from first date of mecasermin intake until last dose, approximately 19 years

Adverse event reporting additional description:

The safety population consisted of all participants who had received at least 1 dose of mecasermin treatment. Adverse events were not collected per dose level as pre-specified.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	14.1
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Reporting groups

Reporting group title	Mecasermin
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Reporting group description:

Participants who were entered from previous studies continued to receive mecasermin 80 to 120 mcg/kg SC twice daily and naïve-to-treatment participants were administered mecasermin 60 to 80 mcg/kg SC twice daily for 1 to 2 weeks, and then increased to 120 mcg/kg as tolerated.

Serious adverse events	Mecasermin		
Total subjects affected by serious adverse events			
subjects affected / exposed	18 / 92 (19.57%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Radius fracture			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skull fracture			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Dilatation ventricular			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			

Benign intracranial hypertension subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Grand mal convulsion subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Febrile convulsion subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Haematemesis subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal pain subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Tonsillar hypertrophy subjects affected / exposed	2 / 92 (2.17%)		
occurrences causally related to treatment / all	3 / 3		
deaths causally related to treatment / all	0 / 0		
Adenoidal hypertrophy subjects affected / exposed	3 / 92 (3.26%)		
occurrences causally related to treatment / all	3 / 3		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Nephrolithiasis			

subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Epiphysiolysis			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Flank pain			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Infectious pleural effusion			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Appendicitis			
subjects affected / exposed	2 / 92 (2.17%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemic seizure			
subjects affected / exposed	1 / 92 (1.09%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Mecasermin		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	73 / 92 (79.35%)		
Surgical and medical procedures			
Ear tube insertion			
subjects affected / exposed	7 / 92 (7.61%)		
occurrences (all)	11		
Dental operation			
subjects affected / exposed	6 / 92 (6.52%)		
occurrences (all)	6		
General disorders and administration site conditions			
Injection site hypertrophy			
subjects affected / exposed	32 / 92 (34.78%)		
occurrences (all)	211		
Pyrexia			
subjects affected / exposed	19 / 92 (20.65%)		
occurrences (all)	77		
Fatigue			
subjects affected / exposed	9 / 92 (9.78%)		
occurrences (all)	16		
Injection site haematoma			
subjects affected / exposed	9 / 92 (9.78%)		
occurrences (all)	22		
Hypertrophy			
subjects affected / exposed	8 / 92 (8.70%)		
occurrences (all)	52		
Asthenia			
subjects affected / exposed	5 / 92 (5.43%)		
occurrences (all)	7		
Chest pain			

subjects affected / exposed occurrences (all)	5 / 92 (5.43%) 10		
Reproductive system and breast disorders Gynaecomastia subjects affected / exposed occurrences (all)	6 / 92 (6.52%) 18		
Respiratory, thoracic and mediastinal disorders Snoring subjects affected / exposed occurrences (all) Tonsillar hypertrophy subjects affected / exposed occurrences (all) Cough subjects affected / exposed occurrences (all) Adenoidal hypertrophy subjects affected / exposed occurrences (all) Nasal congestion subjects affected / exposed occurrences (all)	20 / 92 (21.74%) 111 19 / 92 (20.65%) 102 16 / 92 (17.39%) 48 7 / 92 (7.61%) 12 9 / 92 (9.78%) 37		
Investigations Cardiac murmur subjects affected / exposed occurrences (all)	7 / 92 (7.61%) 10		
Cardiac disorders Tachycardia subjects affected / exposed occurrences (all)	6 / 92 (6.52%) 6		
Nervous system disorders Headache subjects affected / exposed occurrences (all) Dizziness	25 / 92 (27.17%) 109		

subjects affected / exposed occurrences (all)	6 / 92 (6.52%) 9		
Blood and lymphatic system disorders Thymus enlargement subjects affected / exposed occurrences (all)	9 / 92 (9.78%) 24		
Lymphadenopathy subjects affected / exposed occurrences (all)	5 / 92 (5.43%) 9		
Ear and labyrinth disorders Conductive deafness subjects affected / exposed occurrences (all)	11 / 92 (11.96%) 70		
Middle ear effusion subjects affected / exposed occurrences (all)	10 / 92 (10.87%) 21		
Deafness subjects affected / exposed occurrences (all)	6 / 92 (6.52%) 50		
Ear pain subjects affected / exposed occurrences (all)	6 / 92 (6.52%) 9		
Ear discomfort subjects affected / exposed occurrences (all)	5 / 92 (5.43%) 27		
Eye disorders Papilloedema subjects affected / exposed occurrences (all)	5 / 92 (5.43%) 7		
Gastrointestinal disorders Vomiting subjects affected / exposed occurrences (all)	16 / 92 (17.39%) 28		
Dental caries subjects affected / exposed occurrences (all)	11 / 92 (11.96%) 45		
Abdominal pain			

subjects affected / exposed	7 / 92 (7.61%)		
occurrences (all)	13		
Constipation			
subjects affected / exposed	6 / 92 (6.52%)		
occurrences (all)	10		
Diarrhoea			
subjects affected / exposed	6 / 92 (6.52%)		
occurrences (all)	14		
Abdominal pain upper			
subjects affected / exposed	5 / 92 (5.43%)		
occurrences (all)	6		
Tooth crowding			
subjects affected / exposed	5 / 92 (5.43%)		
occurrences (all)	24		
Toothache			
subjects affected / exposed	5 / 92 (5.43%)		
occurrences (all)	11		
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	10 / 92 (10.87%)		
occurrences (all)	26		
Dry skin			
subjects affected / exposed	10 / 92 (10.87%)		
occurrences (all)	31		
Skin hypertrophy			
subjects affected / exposed	10 / 92 (10.87%)		
occurrences (all)	36		
Rash			
subjects affected / exposed	6 / 92 (6.52%)		
occurrences (all)	9		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	8 / 92 (8.70%)		
occurrences (all)	24		
Pain in extremity			

subjects affected / exposed	8 / 92 (8.70%)		
occurrences (all)	25		
Back pain			
subjects affected / exposed	7 / 92 (7.61%)		
occurrences (all)	18		
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	23 / 92 (25.00%)		
occurrences (all)	73		
Otitis media			
subjects affected / exposed	19 / 92 (20.65%)		
occurrences (all)	76		
Nasopharyngitis			
subjects affected / exposed	14 / 92 (15.22%)		
occurrences (all)	36		
Influenza			
subjects affected / exposed	12 / 92 (13.04%)		
occurrences (all)	17		
Bronchitis			
subjects affected / exposed	7 / 92 (7.61%)		
occurrences (all)	8		
Ear infection			
subjects affected / exposed	7 / 92 (7.61%)		
occurrences (all)	19		
Gastroenteritis			
subjects affected / exposed	7 / 92 (7.61%)		
occurrences (all)	9		
Pharyngitis			
subjects affected / exposed	7 / 92 (7.61%)		
occurrences (all)	16		
Respiratory tract infection			
subjects affected / exposed	6 / 92 (6.52%)		
occurrences (all)	7		
Tonsillitis			
subjects affected / exposed	6 / 92 (6.52%)		
occurrences (all)	8		

Varicella subjects affected / exposed occurrences (all)	5 / 92 (5.43%) 5		
Metabolism and nutrition disorders Hypoglycaemia subjects affected / exposed occurrences (all)	41 / 92 (44.57%) 175		
Hypoglycaemic seizure subjects affected / exposed occurrences (all)	5 / 92 (5.43%) 13		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 April 2007	Amended to update mecasermin dose of up to 160 mcg/kg SC twice daily was used in some pubertal participants.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported