



Clinical trial results:

A Multicenter, Open-Label, Single Arm Study Assessing Dyad (Subject And Caregiver) Perception Of Convenience And Preference Of The Newly Developed Mark VII Pen

Summary

EudraCT number	2014-004173-16
Trial protocol	Outside EU/EEA
Global end of trial date	29 January 2010

Results information

Result version number	v1 (current)
This version publication date	15 March 2016
First version publication date	31 May 2015

Trial information

Trial identification

Sponsor protocol code	A6281291
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00965484
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.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	20 May 2010
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	29 January 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the ease of use/convenience as determined by a subject/caregiver dyad self-assessment of ease of use of the new Genotropin Mark VII pen compared to pre-study experience with the Genotropin Pen®

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 October 2009
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	United States: 136
Worldwide total number of subjects	136
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)	0
Children (2-11 years)	48
Adolescents (12-17 years)	86
Adults (18-64 years)	2
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Subjects who used the Genotropin® Pen for at least 3 months prior to enrollment were eligible to participate. Genotropin (somatropin) dose was not adjusted for the purposes of the study, but only based on clinical management requirements as determined by the treating physician.

Period 1

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

Arms

Arm title	Genotropin / Genotropin Mark VII Pen
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Arm description:

Genotropin (somatropin) injection administered using the Genotropin Mark VII Pen subcutaneously (sc) at a dose prescribed by the physician.

Arm type	Experimental
Investigational medicinal product name	Genotropin
Investigational medicinal product code	
Other name	Somatropin
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Genotropin (somatropin) injection administered using the Genotropin Mark VII Pen subcutaneously (sc) at a dose prescribed by the physician.

Number of subjects in period 1	Genotropin / Genotropin Mark VII Pen
Started	136
Completed	134
Not completed	2
Consent withdrawn by subject	1
Protocol Violation	1

Baseline characteristics

Reporting groups

Reporting group title	Genotropin / Genotropin Mark VII Pen
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Reporting group description:

Genotropin (somatropin) injection administered using the Genotropin Mark VII Pen subcutaneously (sc) at a dose prescribed by the physician.

Reporting group values	Genotropin / Genotropin Mark VII Pen	Total	
Number of subjects	136	136	
Age categorical Units: Subjects			
≤10 years of age	37	37	
Between 11 and 12 years of age	30	30	
Between 13 and 14 years of age	40	40	
≥15 years of age	29	29	
Gender categorical Units: Subjects			
Female	45	45	
Male	91	91	

End points

End points reporting groups

Reporting group title	Genotropin / Genotropin Mark VII Pen
Reporting group description:	
Genotropin (somatropin) injection administered using the Genotropin Mark VII Pen subcutaneously (sc) at a dose prescribed by the physician.	

Primary: Percentage of Dyads (Subject and Caregiver or Parent) Reporting no Difference or Easier to Use for New Genotropin Mark VII Injection Pen Compared to Pre-study Experience With the Genotropin Pen®

End point title	Percentage of Dyads (Subject and Caregiver or Parent) Reporting no Difference or Easier to Use for New Genotropin Mark VII Injection Pen Compared to Pre-study Experience With the Genotropin Pen® ^[1]
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End point description:

Ease of use measured using the Injection Pen Assessment Questionnaire (IPAQ) subject-reported outcome (PRO) tool (based on 13 unique characteristics of injection pens). Section I measures ease of use of Genotropin® (very easy, somewhat easy, neither easy nor difficult, somewhat difficult, or very difficult). Section II measures ease of use of new Genotropin Mark VII Pen in comparison to pre-study experience with Genotropin® Pen (Genotropin® pen easier to use, new injection pen easier to use, or no difference) and preference (prefer Genotropin® Pen, prefer new injection pen, or no preference). Full analysis set (FAS): all subjects who used the new pen at least once to administer Genotropin and who completed the 2-month follow-up questionnaire. Dyad defined as the subject (child being treated) and adult partner (parent or caregiver).

End point type	Primary
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End point timeframe:

2 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: Only descriptive data was planned to be reported for this endpoint.

End point values	Genotropin / Genotropin Mark VII Pen			
Subject group type	Reporting group			
Number of subjects analysed	133			
Units: Percentage of dyads				
number (confidence interval 95%)	73.68 (66.2 to 81.17)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Dyads Reporting no Preference or Preference for New Genotropin Mark VII Injection Pen Compared to Pre-study Experience With the Genotropin Pen®

End point title	Percentage of Dyads Reporting no Preference or Preference for New Genotropin Mark VII Injection Pen Compared to Pre-study Experience With the Genotropin Pen®
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End point description:

Preference for use measured using the IPAQ PRO tool (ease of use and preference based on 13 unique characteristics of injection pens). Section I measures ease of use of Genotropin® (very easy, somewhat easy, neither easy nor difficult, somewhat difficult, or very difficult). Section II measures ease of use of new Genotropin Mark VII Pen in comparison to pre-study experience with Genotropin® Pen (Genotropin® Pen easier to use, new injection pen easier to use, or no difference) and preference (prefer Genotropin® Pen, prefer new injection pen, or no preference). FAS.

End point type	Secondary
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End point timeframe:

2 months

End point values	Genotropin / Genotropin Mark VII Pen			
Subject group type	Reporting group			
Number of subjects analysed	132 ^[2]			
Units: Percentage of dyads				
number (confidence interval 95%)	65.15 (57.02 to 73.28)			

Notes:

[2] - N=number of subjects with measurement.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Dyads Reporting New Genotropin Mark VII Injection Pen Easier to Use Compared to Pre-study Experience With the Genotropin Pen®

End point title	Percentage of Dyads Reporting New Genotropin Mark VII Injection Pen Easier to Use Compared to Pre-study Experience With the Genotropin Pen®
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End point description:

Ease of use measured using IPAQ PRO tool (ease of use and preference based on 13 unique characteristics of injection pens). Section I measures ease of use of Genotropin® Pen (very easy, somewhat easy, neither easy nor difficult, somewhat difficult, or very difficult). Section II measures ease of use of new Genotropin Mark VII Pen in comparison to pre-study experience with Genotropin® Pen (Genotropin® Pen easier to use, new injection pen easier to use, or no difference) and preference (prefer Genotropin® Pen, prefer new injection pen, or no preference). FAS.

End point type	Secondary
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End point timeframe:

2 Months

End point values	Genotropin / Genotropin Mark VII Pen			
Subject group type	Reporting group			
Number of subjects analysed	133			
Units: Percentage of dyads				
number (confidence interval 95%)	63.16 (54.96 to 71.36)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Dyads Reporting New Genotropin Mark VII Injection Pen Preferable Compared to Pre-study Experience With the Genotropin Pen®

End point title	Percentage of Dyads Reporting New Genotropin Mark VII Injection Pen Preferable Compared to Pre-study Experience With the Genotropin Pen®
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End point description:

Preference for use measured using IPAQ PRO tool (ease of use and preference based on 13 unique characteristics of injection pens). Section I measures ease of use of Genotropin® (very easy, somewhat easy, neither easy nor difficult, somewhat difficult, or very difficult). Section II measures ease of use of new Genotropin Mark VII Pen in comparison to pre-study experience with Genotropin® Pen (Genotropin® Pen easier to use, new injection pen easier to use, or no difference) and preference (prefer Genotropin® Pen, prefer new injection pen, or no preference). FAS.

End point type	Secondary
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End point timeframe:

2 Months

End point values	Genotropin / Genotropin Mark VII Pen			
Subject group type	Reporting group			
Number of subjects analysed	132 ^[3]			
Units: Percentage of dyads				
number (confidence interval 95%)	59.85 (51.49 to 68.21)			

Notes:

[3] - N=number of subjects with measurement.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline to 7 days after last dose of study drug. For SAE: events were collected 28 days after the last dose.

Adverse event reporting additional description:

The same event may appear as AE and SAE. However, what is presented are distinct events. An event may be categorized as serious in 1 subject and nonserious in another, or 1 subject may have experienced both serious and nonserious event during study. EU BR specific AE tables were generated separately as per EU format using latest coding dictionary.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	17.1

Reporting groups

Reporting group title	Genotropin / Genotropin Mark VII Pen
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Reporting group description:

Genotropin (somatropin) injection administered using the Genotropin Mark VII Pen subcutaneously (sc) at a dose prescribed by the physician.

Serious adverse events	Genotropin / Genotropin Mark VII Pen		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 136 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Genotropin / Genotropin Mark VII Pen		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	28 / 136 (20.59%)		
Injury, poisoning and procedural complications			
Animal scratch			
subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	2		
Contusion			

subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	1		
Fall			
subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	1		
Ligament sprain			
subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	1		
Limb injury			
subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	1		
Laceration			
subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	1		
Nervous system disorders			
Headache			
subjects affected / exposed	7 / 136 (5.15%)		
occurrences (all)	14		
Migraine			
subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	1		
General disorders and administration site conditions			
Chills			
subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	2		
Influenza like illness			
subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	1		
Injection-site bruising			
subjects affected / exposed	3 / 136 (2.21%)		
occurrences (all)	3		
Injection-site pain			
subjects affected / exposed	5 / 136 (3.68%)		
occurrences (all)	7		
Pyrexia			

subjects affected / exposed	4 / 136 (2.94%)		
occurrences (all)	5		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	1		
Abdominal pain upper			
subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	1		
Flatulence			
subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	1		
Toothache			
subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Allergic sinusitis			
subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	1		
Cough			
subjects affected / exposed	2 / 136 (1.47%)		
occurrences (all)	3		
Nasal congestion			
subjects affected / exposed	2 / 136 (1.47%)		
occurrences (all)	3		
Oropharyngeal pain			
subjects affected / exposed	2 / 136 (1.47%)		
occurrences (all)	2		
Pulmonary congestion			
subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	1		
Rhinorrhoea			
subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	1		
Psychiatric disorders			

Depression			
subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	1		
Insomnia			
subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	1		
Musculoskeletal pain			
subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	1		
Infections and infestations			
Gastroenteritis viral			
subjects affected / exposed	2 / 136 (1.47%)		
occurrences (all)	2		
Gastrointestinal viral infection			
subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	1		
Influenza			
subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	1		
Nasopharyngitis			
subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	1		
Pharyngitis streptococcal			
subjects affected / exposed	3 / 136 (2.21%)		
occurrences (all)	3		
Sinusitis			
subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	1		
Staphylococcal infection			
subjects affected / exposed	1 / 136 (0.74%)		
occurrences (all)	1		
Upper respiratory tract infection			

subjects affected / exposed occurrences (all)	4 / 136 (2.94%) 5		
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	1 / 136 (0.74%) 1		

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