



## Clinical trial results:

### A Multicenter, Open-Label, Randomized, Two Arm Cross-Over Study Assessing Dyad (Subject and Caregiver) and Adult Subject Perception of Convenience and Preference of the Newly Developed Genotropin Mark VII Pen

#### Summary

|                          |                   |
|--------------------------|-------------------|
| EudraCT number           | 2009-017354-12    |
| Trial protocol           | SE CZ SK DE GB NL |
| Global end of trial date | 26 October 2011   |

#### Results information

|                                |               |
|--------------------------------|---------------|
| Result version number          | v1 (current)  |
| This version publication date  | 15 March 2016 |
| First version publication date | 09 July 2015  |

#### Trial information

##### Trial identification

|                       |          |
|-----------------------|----------|
| Sponsor protocol code | A6281297 |
|-----------------------|----------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT01112865 |
| 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., 1 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com |
| Scientific contact           | Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 1 800-718-1021, 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                       | 09 March 2012   |
| Is this the analysis of the primary completion data? | No              |
| Global end of trial reached?                         | Yes             |
| Global end of trial date                             | 26 October 2011 |
| Was the trial ended prematurely?                     | No              |

Notes:

## General information about the trial

Main objective of the trial:

To evaluate the ease of use or convenience of the new Genotropin Mark VII pen compared to the current 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:

Comparison of subject acceptance of the Genotropin Mark VII pen and the current marketed Genotropin pen.

|   |                |
|---|----------------|
| Actual start date of recruitment                          | 06 August 2010 |
| 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 | Netherlands: 5     |
| Country: Number of subjects enrolled | Slovakia: 13       |
| Country: Number of subjects enrolled | Sweden: 14         |
| Country: Number of subjects enrolled | United Kingdom: 17 |
| Country: Number of subjects enrolled | Czech Republic: 32 |
| Country: Number of subjects enrolled | Germany: 19        |
| Country: Number of subjects enrolled | Turkey: 20         |
| Worldwide total number of subjects   | 120                |
| EEA total number of subjects         | 100                |

Notes:

### Subjects enrolled per age group

|   |   |
|---|---|
| In utero                                  | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days)                      | 0 |
| Infants and toddlers (28 days-23          | 0 |

|                           |    |
|---------------------------|----|
| months)                   |    |
| Children (2-11 years)     | 51 |
| Adolescents (12-17 years) | 27 |
| Adults (18-64 years)      | 40 |
| From 65 to 84 years       | 2  |
| 85 years and over         | 0  |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

A total of 120 subjects were screened from 23 centers of 7 countries worldwide and all subjects were included in the trial. Study started on 06 August 2010 and completed on 26 October 2011.

### Period 1

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

### Arms

|                  |                         |
|------------------|-------------------------|
| <b>Arm title</b> | Entire Study Population |
|------------------|-------------------------|

Arm description:

Included all subjects which were randomized to use either the Mark VII pen first or the current Genotropin® pen first.

|  |  |
|--|--|
| Arm type                               | Experimental                                   |
| Investigational medicinal product name | Genotropin Mark VII pen                        |
| Investigational medicinal product code |  |
| Other name                             |  |
| Pharmaceutical forms                   | Powder and solution for solution for injection |
| Routes of administration               | Subcutaneous use                               |

Dosage and administration details:

Subjects randomized to use the Mark VII pen subcutaneous injections daily for 2 months. Pen provided in 5, 5.3, and 12 mg doses of Genotropin (somatropin [rDNA origin]), doses received by subjects based on body weight.

|  |   |
|--|---|
| Investigational medicinal product name | Genotropin Pen  |
| Investigational medicinal product code |   |
| Other name                             |   |
| Pharmaceutical forms                   | Powder and solvent for solution for injection in pre-filled syringe |
| Routes of administration               | Subcutaneous use  |

Dosage and administration details:

Subjects randomized to use the current Genotropin® pen subcutaneous injections daily for 2 months. Pen provided in 5, 5.3, and 12 mg doses of Genotropin (somatropin [rDNA origin]), doses received by subjects based on body weight.

|                                       |                         |
|---------------------------------------|-------------------------|
| <b>Number of subjects in period 1</b> | Entire Study Population |
| Started                               | 120                     |
| Completed                             | 120                     |



## Baseline characteristics

### Reporting groups

|                       |               |
|-----------------------|---------------|
| Reporting group title | Overall study |
|-----------------------|---------------|

Reporting group description: -

| Reporting group values   | Overall study | Total |  |
|--|---------------|-------|--|
| Number of subjects   | 120           | 120   |  |
| Age categorical  |               |       |  |
| Included all subjects which were randomized to use either the Mark VII pen first or the current Genotropin® pen first. |               |       |  |
| Units: Subjects  |               |       |  |
| Less than or equal to ( $\leq$ ) 7 years   | 28            | 28    |  |
| Between 8 and 17 years   | 50            | 50    |  |
| Between 18 and 44 years  | 18            | 18    |  |
| Between 45 and 64 years  | 22            | 22    |  |
| Greater than or equal to ( $\geq$ ) 5 years  | 2             | 2     |  |
| Gender categorical   |               |       |  |
| Units: Subjects  |               |       |  |
| Female   | 51            | 51    |  |
| Male   | 69            | 69    |  |

## End points

### End points reporting groups

|  |                         |
|--|-------------------------|
| Reporting group title  | Entire Study Population |
| Reporting group description:   |                         |
| Included all subjects which were randomized to use either the Mark VII pen first or the current Genotropin® pen first.   |                         |
| Subject analysis set title   | Mark VII Pen            |
| Subject analysis set type  | Full analysis           |
| Subject analysis set description:  |                         |
| Subjects who used the Mark VII pen any time during the study. Pens provided in 5, 5.3, and 12 mg doses of Genotropin (somatropin [rDNA origin]), doses were received by subjects based on body weight.           |                         |
| Subject analysis set title   | Genotropin® Pen         |
| Subject analysis set type  | Full analysis           |
| Subject analysis set description:  |                         |
| Subjects who used the current Genotropin® pen anytime during the study. Pens provided in 5, 5.3, and 12 mg doses of Genotropin (somatropin [rDNA origin]); doses were received by subjects based on body weight. |                         |

### Primary: Percentage of Dyads (Subject and Caregiver or Parent) and Adult Subjects Reporting no Difference or Easier to Use for the New Genotropin Mark VII Injection Pen Compared to the Genotropin Pen®

|  |  |
|--|--|
| End point title  | Percentage of Dyads (Subject and Caregiver or Parent) and Adult Subjects Reporting no Difference or Easier to Use for the New Genotropin Mark VII Injection Pen Compared to the Genotropin Pen® <sup>[1]</sup> |
| End point description:   |  |
| Subjects were asked the following question from Section II of the Injection Pen Assessment Questionnaire (IPAQ) patient-reported outcome (PRO) tool, "Thinking about the Genotropin pen and the new injection pen you used over the past few months, please compare both injection pens and choose which one is easier to use overall?" Choices included: Genotropin Pen® easier to use, new injection pen easier to use, or no difference. Full Analysis Set (FAS): randomized subjects who used a study pen at least once to administer somatropin. Dyad defined as the subject (child being treated) and adult partner (parent or caregiver). |  |
| End point type   | Primary  |
| End point timeframe:   |  |
| Month 4  |  |
| 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 end point.  |  |

| End point values                           | Entire Study Population |  |  |  |
|--|-------------------------|--|--|--|
| Subject group type                         | Reporting group         |  |  |  |
| Number of subjects analysed                | 119 <sup>[2]</sup>      |  |  |  |
| Units: percentage of dyads, adult subjects |                         |  |  |  |
| number (confidence interval 95%)           | 67.23 (58.79 to 75.66)  |  |  |  |

Notes:

[2] - Number of subjects analyzed (N)= subjects with evaluable data.

## Statistical analyses

No statistical analyses for this end point

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**Secondary: Percentage of Dyads and Adult Subjects Reporting no Preference or Preference for the New Genotropin Mark VII Injection Pen Compared to the Genotropin Pen®**

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|                 |  |
|-----------------|--|
| End point title | Percentage of Dyads and Adult Subjects Reporting no Preference or Preference for the New Genotropin Mark VII Injection Pen Compared to the Genotropin Pen® |
|-----------------|--|

End point description:

Subjects were asked the following question from Section II of the IPAQ PRO tool, "Thinking about both injection pens over the past few months, please choose which injection pen you prefer overall." Choices included: prefer Genotropin Pen®, prefer new injection pen, or no preference. FAS population.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Month 4

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| End point values                           | Entire Study Population |  |  |  |
|--|-------------------------|--|--|--|
| Subject group type                         | Reporting group         |  |  |  |
| Number of subjects analysed                | 120                     |  |  |  |
| Units: percentage of dyads, adult subjects |                         |  |  |  |
| number (confidence interval 95%)           | 64.17 (55.59 to 72.75)  |  |  |  |

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**Statistical analyses**

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No statistical analyses for this end point

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**Secondary: Percentage of Dyads and Adult Subjects Reporting the New Genotropin Mark VII Injection Pen Easier to Use Compared to the Genotropin Pen®**

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|                 |  |
|-----------------|--|
| End point title | Percentage of Dyads and Adult Subjects Reporting the New Genotropin Mark VII Injection Pen Easier to Use Compared to the Genotropin Pen® |
|-----------------|--|

End point description:

Subjects were asked the following question from Section II of the IPAQ PRO tool, "Thinking about the Genotropin pen and the new injection pen you used over the past few months, please compare both injection pens and choose which one is easier to use overall?" Choices included: Genotropin Pen® easier to use, new injection pen easier to use, or no difference. FAS population.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Month 4

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|  |                         |  |  |  |
|--|-------------------------|--|--|--|
| <b>End point values</b>                    | Entire Study Population |  |  |  |
| Subject group type                         | Reporting group         |  |  |  |
| Number of subjects analysed                | 119 <sup>[3]</sup>      |  |  |  |
| Units: percentage of dyads, adult subjects |                         |  |  |  |
| number (confidence interval 95%)           | 51.26 (42.28 to 60.24)  |  |  |  |

Notes:

[3] - Number of subjects analyzed (N)= subjects with evaluable data.

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Dyads and Adult Subjects Reporting the New Genotropin Mark VII Injection Pen Preferable Compared to the Genotropin Pen®

|                 |   |
|-----------------|---|
| End point title | Percentage of Dyads and Adult Subjects Reporting the New Genotropin Mark VII Injection Pen Preferable Compared to the Genotropin Pen® |
|-----------------|---|

End point description:

Subjects were asked the following question from Section II of the IPAQ PRO tool, "Thinking about both injection pens over the past few months, please choose which injection pen you prefer overall." Choices included: prefer Genotropin Pen®, prefer new injection pen, or no preference. FAS population.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Month 4

|  |                         |  |  |  |
|--|-------------------------|--|--|--|
| <b>End point values</b>                    | Entire Study Population |  |  |  |
| Subject group type                         | Reporting group         |  |  |  |
| Number of subjects analysed                | 120                     |  |  |  |
| Units: percentage of dyads, adult subjects |                         |  |  |  |
| number (confidence interval 95%)           | 54.17 (45.25 to 63.08)  |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Dyads and Adult Subjects Who Would Choose the New Genotropin Mark VII Injection Pen in Preference to the Genotropin® Pen

|                 |  |
|-----------------|--|
| End point title | Percentage of Dyads and Adult Subjects Who Would Choose the New Genotropin Mark VII Injection Pen in Preference to the Genotropin® Pen |
|-----------------|--|

End point description:

Investigators were asked the following study treatment continuation question, "Which device did the subject choose for continued treatment?" Choices included the Genotropin® Pen or the new injection pen. FAS subset of subjects located in areas where the new device was available.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Month 4              |           |

|  |                         |  |  |  |
|--|-------------------------|--|--|--|
| <b>End point values</b>                    | Entire Study Population |  |  |  |
| Subject group type                         | Reporting group         |  |  |  |
| Number of subjects analysed                | 55                      |  |  |  |
| Units: percentage of dyads, adult subjects |                         |  |  |  |
| number (confidence interval 95%)           | 47.27 (34.08 to 60.47)  |  |  |  |

|                                   |   |
|-----------------------------------|---|
| <b>Attachments (see zip file)</b> | Statistical Analysis/Percentage of Dyads and Adult Subjects |
|-----------------------------------|---|

### Statistical analyses

No statistical analyses for this end point

### Secondary: Ease of Use of Each Injection Pen

|  |                                   |
|--|-----------------------------------|
| End point title  | Ease of Use of Each Injection Pen |
| End point description:   |                                   |
| Subjects were asked the following question from Section I of the IPAQ PRO tool, "Thinking about the injection pen you have been using for the past few months, how easy or difficult it is for you to use the injection pen overall?" Responses were provided using a 5 point scale which ranged from very easy (5), somewhat easy (4), neither easy nor difficult (3), somewhat difficult (2), or very difficult (1). FAS population. |                                   |
| End point type   | Secondary                         |
| End point timeframe:   |                                   |
| Month 2 and Month 4  |                                   |

|                                      |                      |                      |  |  |
|--------------------------------------|----------------------|----------------------|--|--|
| <b>End point values</b>              | Mark VII Pen         | Genotropin® Pen      |  |  |
| Subject group type                   | Subject analysis set | Subject analysis set |  |  |
| Number of subjects analysed          | 119 <sup>[4]</sup>   | 119 <sup>[5]</sup>   |  |  |
| Units: scores on a scale             |                      |                      |  |  |
| arithmetic mean (standard deviation) | 4.5 (± 0.64)         | 4.2 (± 0.71)         |  |  |

Notes:

[4] - Number of subjects analyzed (N)= subjects with evaluable data.

[5] - Number of subjects analyzed (N)= subjects with evaluable data.

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Baseline up to 7 days after last dose

Adverse event reporting additional description:

The same event may appear as both an adverse event (AE) and a serious AE (SAE). An event may be categorized as serious in one subject and as nonserious in another subject. EU BR specific AE tables were generated separately as per EU format. Latest coding dictionary has been used for EU BR tables.

|                 |                |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

### Dictionary used

|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

|                    |      |
|--------------------|------|
| Dictionary version | 17.1 |
|--------------------|------|

### Reporting groups

|                       |                   |
|-----------------------|-------------------|
| Reporting group title | Safety Population |
|-----------------------|-------------------|

Reporting group description:

All randomized participants who used a study pen (Genotropin® pen or the new Mark VII injection pen) at least once to administer Genotropin.

| Serious adverse events                            | Safety Population |  |  |
|---|-------------------|--|--|
| Total subjects affected by serious adverse events |                   |  |  |
| subjects affected / exposed                       | 2 / 120 (1.67%)   |  |  |
| number of deaths (all causes)                     | 0                 |  |  |
| number of deaths resulting from adverse events    | 0                 |  |  |
| Gastrointestinal disorders                        |                   |  |  |
| Diarrhoea   |                   |  |  |
| subjects affected / exposed                       | 1 / 120 (0.83%)   |  |  |
| occurrences causally related to treatment / all   | 0 / 1             |  |  |
| deaths causally related to treatment / all        | 0 / 0             |  |  |
| Infections and infestations                       |                   |  |  |
| Laryngitis  |                   |  |  |
| subjects affected / exposed                       | 1 / 120 (0.83%)   |  |  |
| occurrences causally related to treatment / all   | 0 / 1             |  |  |
| deaths causally related to treatment / all        | 0 / 0             |  |  |

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

| <b>Non-serious adverse events</b>   | Safety Population  |  |  |
|---|--|--|--|
| Total subjects affected by non-serious adverse events<br>subjects affected / exposed  | 48 / 120 (40.00%)  |  |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps)<br>Melanocytic naevus<br>subjects affected / exposed<br>occurrences (all)   | 1 / 120 (0.83%)<br>1   |  |  |
| Injury, poisoning and procedural complications<br>Accidental overdose<br>subjects affected / exposed<br>occurrences (all)<br><br>Foot fracture<br>subjects affected / exposed<br>occurrences (all)                                    | 1 / 120 (0.83%)<br>1<br><br>1 / 120 (0.83%)<br>1                               |  |  |
| Vascular disorders<br>Flushing<br>subjects affected / exposed<br>occurrences (all)  | 1 / 120 (0.83%)<br>1   |  |  |
| Nervous system disorders<br>Dizziness<br>subjects affected / exposed<br>occurrences (all)<br><br>Headache<br>subjects affected / exposed<br>occurrences (all)<br><br>Paraesthesia<br>subjects affected / exposed<br>occurrences (all) | 1 / 120 (0.83%)<br>2<br><br>11 / 120 (9.17%)<br>26<br><br>1 / 120 (0.83%)<br>2 |  |  |
| General disorders and administration site conditions<br>Application site pain<br>subjects affected / exposed<br>occurrences (all)<br><br>Fatigue<br>subjects affected / exposed<br>occurrences (all)<br><br>Injection site bruising   | 1 / 120 (0.83%)<br>1<br><br>1 / 120 (0.83%)<br>1                               |  |  |

|                             |                 |  |  |
|-----------------------------|-----------------|--|--|
| subjects affected / exposed | 2 / 120 (1.67%) |  |  |
| occurrences (all)           | 2               |  |  |
| Injection site haemorrhage  |                 |  |  |
| subjects affected / exposed | 1 / 120 (0.83%) |  |  |
| occurrences (all)           | 1               |  |  |
| Injection site injury       |                 |  |  |
| subjects affected / exposed | 4 / 120 (3.33%) |  |  |
| occurrences (all)           | 12              |  |  |
| Injection site pain         |                 |  |  |
| subjects affected / exposed | 4 / 120 (3.33%) |  |  |
| occurrences (all)           | 13              |  |  |
| Injection site reaction     |                 |  |  |
| subjects affected / exposed | 1 / 120 (0.83%) |  |  |
| occurrences (all)           | 1               |  |  |
| Oedema peripheral           |                 |  |  |
| subjects affected / exposed | 1 / 120 (0.83%) |  |  |
| occurrences (all)           | 1               |  |  |
| Pyrexia                     |                 |  |  |
| subjects affected / exposed | 1 / 120 (0.83%) |  |  |
| occurrences (all)           | 1               |  |  |
| Ear and labyrinth disorders |                 |  |  |
| Ear pain                    |                 |  |  |
| subjects affected / exposed | 1 / 120 (0.83%) |  |  |
| occurrences (all)           | 3               |  |  |
| Vertigo                     |                 |  |  |
| subjects affected / exposed | 1 / 120 (0.83%) |  |  |
| occurrences (all)           | 1               |  |  |
| Gastrointestinal disorders  |                 |  |  |
| Abdominal pain              |                 |  |  |
| subjects affected / exposed | 1 / 120 (0.83%) |  |  |
| occurrences (all)           | 4               |  |  |
| Diarrhoea                   |                 |  |  |
| subjects affected / exposed | 1 / 120 (0.83%) |  |  |
| occurrences (all)           | 1               |  |  |
| Food poisoning              |                 |  |  |

|  |                                 |  |  |
|--|---------------------------------|--|--|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p>  | <p>1 / 120 (0.83%)</p> <p>1</p> |  |  |
| <p>Inguinal hernia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>   | <p>1 / 120 (0.83%)</p> <p>1</p> |  |  |
| <p>Nausea</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>  | <p>2 / 120 (1.67%)</p> <p>2</p> |  |  |
| <p>Vomiting</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>  | <p>2 / 120 (1.67%)</p> <p>2</p> |  |  |
| <p>Respiratory, thoracic and mediastinal disorders</p> <p>Cough</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>          | <p>3 / 120 (2.50%)</p> <p>3</p> |  |  |
| <p>Oropharyngeal pain</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>  | <p>1 / 120 (0.83%)</p> <p>1</p> |  |  |
| <p>Psychiatric disorders</p> <p>Attention deficit/hyperactivity disorder</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>1 / 120 (0.83%)</p> <p>1</p> |  |  |
| <p>Musculoskeletal and connective tissue disorders</p> <p>Back pain</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>      | <p>1 / 120 (0.83%)</p> <p>1</p> |  |  |
| <p>Muscle spasms</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>   | <p>2 / 120 (1.67%)</p> <p>2</p> |  |  |
| <p>Myalgia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>   | <p>1 / 120 (0.83%)</p> <p>1</p> |  |  |
| <p>Pain in extremity</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>   | <p>3 / 120 (2.50%)</p> <p>3</p> |  |  |

|  |                                 |  |  |
|--|---------------------------------|--|--|
| <p>Infections and infestations</p> <p>Conjunctivitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>       | <p>1 / 120 (0.83%)</p> <p>1</p> |  |  |
| <p>Gastroenteritis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>   | <p>1 / 120 (0.83%)</p> <p>1</p> |  |  |
| <p>Nasopharyngitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>   | <p>7 / 120 (5.83%)</p> <p>8</p> |  |  |
| <p>Otitis media</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>  | <p>1 / 120 (0.83%)</p> <p>1</p> |  |  |
| <p>Otitis media acute</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                                      | <p>2 / 120 (1.67%)</p> <p>2</p> |  |  |
| <p>Pharyngitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>   | <p>4 / 120 (3.33%)</p> <p>4</p> |  |  |
| <p>Respiratory tract infection viral</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                       | <p>1 / 120 (0.83%)</p> <p>1</p> |  |  |
| <p>Rhinitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>  | <p>1 / 120 (0.83%)</p> <p>2</p> |  |  |
| <p>Urinary tract infection</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                                 | <p>1 / 120 (0.83%)</p> <p>1</p> |  |  |
| <p>Viral infection</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>   | <p>6 / 120 (5.00%)</p> <p>7</p> |  |  |
| <p>Metabolism and nutrition disorders</p> <p>Hypocalcaemia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>1 / 120 (0.83%)</p> <p>1</p> |  |  |





## **More information**

### **Substantial protocol amendments (globally)**

Were there any global substantial amendments to the protocol? No

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported