Pfizer Registry of Outcomes in Growth hormone RESearch (PROGRES): A multi country, non-interventional prospective cohort study among patients with human growth hormone (hGH) treatments under routine clinical care

First published: 14/10/2021

Last updated: 02/12/2024

Study | Discontinued

Administrative details

EU PAS number

EUPAS43715

Study ID

47021

DARWIN EU® study

No

Study countries

- Australia
- Austria
- Belgium
- Canada
- Czechia
- Denmark
- France
- Germany
- Greece
- Ireland
- Israel
- Italy
- Japan
- Korea, Republic of
- Netherlands
- Portugal
- Slovakia
- Spain
- Sweden
- Switzerland
- Taiwan
- Türkiye
- United Kingdom
- United States

Study description

This is a multi-country, non-interventional, prospective cohort study of patients exposed to Genotropin, other daily hGH treatments, and Ngenla long-acting hGH once it is licensed and commercially available, as prescribed by the treating physician according to routine clinical practices.

Patient treatment with a particular therapeutic regimen will be determined at the discretion of the treating physician or other healthcare provider specialties in the countries where this non-interventional study (NIS) is being conducted, under routine clinical care.
The study aims to include eligible patients from over 400 participating sites in over 20 countries around the world. Male and female patients of any age meeting the following eligibility criteria will be enrolled into the study.
The purpose of the Pfizer Registry of Outcomes in Growth hormone RESearch (PROGRES) study will be to assess the long-term safety and effectiveness of Genotropin, other daily hGH treatments, and Ngenla, a long-acting hGH, once granted marketing authorization and is commercially available under routine clinical care and is intended to reflect outcomes that occur in real-world clinical practice.

Study status

Discontinued

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Reese Sy

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/02/2021

Actual: 21/02/2021

Study start date

Planned: 18/10/2021

Actual: 19/11/2021

Data analysis start date

Planned: 18/10/2021

Actual: 18/11/2021

Date of interim report, if expected

Planned: 01/10/2022

Actual: 29/04/2024

Date of final study report

Planned: 26/05/2031

Actual: 15/10/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer, Inc.

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Main study objective:

The purpose of this multi-country, non interventional prospective cohort study will be to assess the long term safety and effectiveness of Genotropin, other daily hGH treatments, and Ngenla, a long-acting hGH, once granted marketing authorization and is commercially available, all of which is at the discretion of the treating physician under routine clinical care.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

NGENLA

Anatomical Therapeutic Chemical (ATC) code

(H01AC01) somatropin

somatropin

(H01AC08) somatrogon

somatrogon

Medical condition to be studied

Growth hormone deficiency

Population studied

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

600

Study design details

Outcomes

Primary Objectives:

- To estimate incidence rates (IRs) of safety events of interest among patients on Genotropin, other daily hGH treatments and Ngenla.

- To describe and compare effectiveness of Genotropin, other daily hGH treatments and Ngenla.

Secondary Objectives:
- To evaluate treatment adherence and compliance of Genotropin, other daily hGH treatments and Ngenla.
- To evaluate the health-related quality of life (HRQoL) and treatment experience of patients on Genotropin, other daily hGH treatments and Ngenla.
- To compare incidence rates of safety events in patients on Genotropin, other daily hGH and Ngenla by exploratory analysis

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Data analysis plan

Descriptive analyses will be performed to gain an understanding of the qualitative and quantitative nature of the data collected and the characteristics of the sample studied.
Descriptive statistics for continuous variables include the number of observations, mean, median, standard deviation, interquartile range, and range. Categorical variables will be presented as number of observations, frequency, and percentage, 2-sided 95% confidence intervals (CIs) will be included as appropriate.
All medical history, comorbidities and AEs will be recorded and coded using the most recent version of Medical Dictionary for Regulatory Activities.
All exposures and concomitant medications will be recorded and coded using World Health Organization (WHO) Drug Dictionary.
Safety data will be presented in tabular and/or listing format and summarized descriptively, where appropriate. Event count and AE frequency will be reported. Number (and %) with AEs, SAEs, and discontinuations will be reported.

Documents

Study report

c0311015-report-body.pdf (2.12 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No