An Active Surveillance Study to Monitor the Real-World Long-term Safety of Somatrogon Among Paediatric Patients in Europe

First published: 28/11/2023

Last updated: 28/04/2025

Study Planned

Administrative details

EU PAS number

EUPAS107217

Study ID

107218

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

Study description

The primary purpose of this study will be to assess the long-term safety of somatrogon, a long-acting hGH, under routine clinical care and is intended to reflect outcomes that occur in real-world clinical practice.

Study status

Planned

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Real World Studies, LA-SER Research

☐ France

☐ United Kingdom

First published: 23/03/2012

Last updated: 23/03/2012

Institution | Other | ENCePP partner

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden

First published: 24/03/2010

Last updated: 23/04/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

Cegedim Health Data (CHD)

France

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Other | ENCePP partner

EPIFOCUS

Spain

United Kingdom

First published: 06/03/2025

Last updated: 02/04/2025

Institution | Other | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Kofi Asomaning

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/03/2022

Study start date

Planned: 15/06/2024

Date of final study report

Planned: 15/12/2032

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc

Study protocol

C0311023_SOMATROGON PROTOCOL FINAL_05AUG2022.pdf(744.81 KB)

C0311023_SOMATROGON_PROTOCOL_AMENDMENT_CLEAN_20MAR2023.pdf (472.55 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Main study objective:

Estimate the incidence rates of neoplasms, and diabetes mellitus type 2, the primary safety events of interest in paediatric patients treated with somatrogon, and paediatric patients treated with once daily somatropin, in the course of routine clinical care.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

NGENLA

Study drug International non-proprietary name (INN) or common name

SOMATROGON

Anatomical Therapeutic Chemical (ATC) code

(H01AC08) somatrogon

somatrogon

Population studied

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Estimated number of subjects

1

Study design details

Outcomes

diabetes and neoplasms, immunogenicity, medication errors, long-term efficacy

Data analysis plan

Baseline demographic and clinical characteristics will be described. For all the safety events of interest and efficacy measurements of interest, descriptive statistics, counts and proportions, crude incidence rates (ie, number of events per person years) and age/sex standardized incidence rates with associated two-sided 95% confidence intervals will be calculated as appropriate. Rates will be expressed as events/1,000 person-years of follow-up.

Data management

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

SNDS France, LPD Spain, Swedish Registries Sweden

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Electronic healthcare records (EHR)

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