The Genetics and Neuroendocrinology of Short Stature International Study (GeNeSIS) (GeNeSIS B9R-EW-GDFC)

First published: 28/10/2016

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS15717

Study ID

16405

DARWIN EU® study

No

Study countries

Australia

Austria

Belgium

Canada

- Czechia
- Denmark
- Finland
- France
- Germany
- Greece
- Hungary
- Iceland
- India
- Italy
- Japan
- Kazakhstan
- Lithuania
- Luxembourg
- Netherlands
- Norway
- Pakistan
- Russian Federation
- Singapore
- Slovakia
- South Africa
- Spain
- Sweden
- Taiwan
- Thailand
- United Kingdom
- United States

Study description

Growth failure and short stature during childhood is a frequent cause of referral to a paediatric endocrinologist and may lead to treatment with somatropin. Since the launch of somatropin in the late 1980s, there has been considerable discussion regarding the potential influence of growth hormone (GH) therapy on a variety of safety outcomes, most notably neoplasia due to the general growth-inducing effects of GH. The primary aim of GeNeSIS, which started in 1999, was to monitor the safety and effectiveness of somatropin in paediatric patients with growth failure and short stature in the real-world setting. Untreated patients were also included in specific subpopulations if they were diagnosed with short stature homebox containing gene deficiency (SHOX-D) or had history of neoplastic disease.

Study status

Finalised

Research institutions and networks

Institutions

Eli Lilly and Company

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Christopher Child

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/10/1998

Actual: 19/11/1998

Study start date

Planned: 02/04/1999

Actual: 01/03/1999

Data analysis start date

Actual: 30/11/2015

Date of interim report, if expected

Actual: 25/03/2016

Date of final study report

Planned: 30/09/2016

Actual: 30/08/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

The goal of this study was to evaluate the safety and effectiveness of somatropin treatment in an observational setting. 2 co-primary safety objectives were used to determine the sample size necessary for the core study: 1. incidence of type 2 diabetes in somatropin-treated children,2. incidence of de novo neoplasia in somatropin treated children without a prior history of neoplastic disease

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Open label, multicenter, multi-national observational study

Study drug and medical condition

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

SOMATROPIN

Medical condition to be studied

Growth retardation

Population studied

Short description of the study population

Untreated or treated paediatric patients with growth failure and short stature.

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

Special population of interest

Other

Special population of interest, other

Growth retarded patients

Estimated number of subjects

22845

Study design details

Outcomes

Type 2 diabetes mellitus Neoplasia, Secondary objectives were addressed via substudies on genetic analysis, growth prediction models, SHOX deficiency, and neoplastic disease. In addition, potential factors associated with the risk of developing diabetes mellitus or alterations in glucose metabolism were examined.

Data analysis plan

For key safety outcomes of mortality, diabetes and neoplasm incidence, patient history/case ascertainment required detailed review of study and corporate pharmacovigilance databases. Person-years of follow-up were calculated

between first and last contacts (later of event onset, last study visit, or study summary date). Standardised mortality ratios (SMRs) and standardised incidence ratios (SIRs) were calculated using expected cases from contemporary general population registries adjusted for country, age, sex, and ethnicity (where applicable). Attainment of FH was defined by at least one of the following: closed epiphyses, height velocity <2 cm/year, or last bone age ≥14 years in girls or ≥16 years in boys. Baseline and early somatropin treatment variables that predict FH were investigated using linear regression modelling.

Documents

Study results

GDFC PASS_Redacted.pdf (2.19 MB)

Study publications

Child CJ, Zimmermann AG, Jia N, Robison LL, Brämswig JH, Blum WF. Assessment of…

Child CJ, Zimmermann AG, Scott RS, Cutler Jr GB, Battelino T, Blum WF on behalf…

Woodmansee WW, Zimmermann AG, Child CJ, Rong Q, Erfurth EM, Beck-Peccoz P, Blum…

Blum WF, Deal C, Zimmermann AG, Shavrikova EP, Child CJ, Quigley CA, Drop SLS, …

Child CJ, Blum WF, Deal C, Zimmermann A, Quigley CA, Drop SL, Cutler GB, Rosenf…

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Open label, multi-center, multi-national observational study

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

Unknown