

GeNesis - The Genetics and Neuroendocrinology of Short Stature International study

Head :Médecin pharmacoépidémiologiste , Eli Lilly France

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General

Identification

Detailed name The Genetics and Neuroendocrinology of Short Stature International study

Sign or acronym GeNesis

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CNIL N° 999310

General Aspects

Medical area Endocrinology and metabolism

Health determinants Genetic

Keywords Growth retardation, auxological measurements, relative efficacy in actual life, children, treatment, tolerance

Scientific investigator(s) (Contact)

Name of the director Médecin pharmacoépidémiologiste

Email fr_mail_pharmacoepepi@lilly.com

Unit Eli Lilly France

Collaborations

Funding

Funding status Private

Details Eli Lilly and Company

Governance of the database

Sponsor(s) or organisation(s) Eli Lilly

responsible

Organisation status

Private

Additional contact

Main features

Type of database

Type of database

Study databases

Study databases (details)

Cohort study

Database recruitment is carried out by an intermediary

A selection of health institutions and services

Database recruitment is carried out as part of an interventional study

No

Additional information regarding sample selection.

For France: recruitment of patients by endocrinologists, pediatricians and pediatric endocrinologists involved in caring for children with a growth disorder and in prescribing growth hormone treatments and located all across the territory

Database objective

Main objective

Evaluate the safety and effectiveness of the treatment via recombinant human growth hormone (Humatrope) using observation data.

Inclusion criteria

Children having a growth disorders whether or not treated via somatropin

Population type

Age

Childhood (6 to 13 years)

Population covered

Sick population

Gender

Male
Woman

Geography area

International

Detail of the geography area

about 30 countries

Data collection

Dates

Date of first collection (YYYY or MM/YYYY) 2000

Date of last collection (YYYY or MM/YYYY) 2015

Size of the database

Size of the database (number of individuals) [10 000-20 000[individuals

Details of the number of individuals 9697 (03/10/2012)

Data

Database activity Current data collection

Type of data collected Clinical data
Biological data

Clinical data (detail) Direct physical measures
Medical registration

Biological data (detail) Fasting glucose, biochemical indicators of the secretion of GH, hormone assays, urine bone marker assays, IGF-1 and IGFBP-3 assays

Presence of a biobank Yes

Contents of biobank DNA

Details of biobank content non-systematic biobank

Health parameters studied Health event/morbidity

Procedures

Data collection method Data collection notebook

Participant monitoring Yes

Details on monitoring of participants follow-up until final size

Links to administrative sources No

Promotion and access

Promotion

Link to the document	http://www.hal.inserm.fr/GENESIS
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Description	List of publications in HAL
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Link to the document	http://tinyurl.com/Pubmed-Cohorte-GENESIS
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Description	List of publications in Pubmed
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Access

Terms of data access (charter for data provision, format of data, availability delay)	Report and publication
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Access to aggregated data	Access on specific project only
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Access to individual data	Access on specific project only
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