GeNesis - The Genetics and Neuroendocrinology of Short Stature International study

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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_pharmacoepi@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
Description	List of publications in HAL
Link to the document	http://tinyurl.com/Pubmed-Cohorte-GENESIS
Description	List of publications in Pubmed

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