

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
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Sign or acronym	GeNesis
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CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL N° 999310
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General Aspects

Medical area	Endocrinology and metabolism
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Health determinants	Genetic
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Keywords	Growth retardation, auxological measurements, relative efficacy in actual life, children, treatment, tolerance
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Scientific investigator(s) (Contact)

Name of the director	Médecin pharmacoépidémiologiste
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Email	fr_mail_pharmacoepi@lilly.com
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Unit	Eli Lilly France
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Collaborations

Funding

Funding status	Private
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Details	Eli Lilly and Company
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Governance of the database

Sponsor(s) or organisation(s)	Eli Lilly
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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