HypoCCS - The Global Hypopituitary Control and Complications Study (HypoCCS)-A Global Observational Research Program

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Last update : 01/09/2013 | Version : 2 | ID : 78

General

Identification

Detailed name	The Global Hypopituitary Control and Complications Study (HypoCCS)-A Global Observational Research Program
Sign or acronym	HypoCCS
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL N°903074

General Aspects

Medical area	Endocrinology and metabolism
Keywords	Somatotrope deficiency, adult, treatments, tolerance, quality of life

Scientific investigator(s) (Contact)

Name of the director	Médecin pharmacoépidémiologiste
Email	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) responsible	Eli Lilly

Organisation status	Private

Additional contact

Main features

Type of database

Type of database	Study databases
Study databases (details)	Longitudinal study (except cohorts)
Database recruitment is carried out by an intermediary	A selection of health institutions and services
Database recruitment is is made on the basis of:	Medication(s) taken
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Patients recruited by endocrinologists

Database objective

Main objective	Primary objective: long-term follow-up of the clinical change and of the tolerance in patients with a somatotrope deficiency whether or not treated with somatropin (Umatrope®)
Inclusion criteria	- Adult patients suffering from growth hormone deficiency secondary to a hypothalamic or pituitary disease appearing in adulthood or suffering from a growth hormone deficiency since childhood, - having terminated their growth (epiphyseal closure), - having no contraindications to the treatment such as are specified in the summary of product characteristics.

Population type

Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years)
Population covered	Sick population
Gender	Male Woman

Geography area	International
Detail of the geography area	international

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2003
Date of last collection (YYYY or MM/YYYY)	2013

Size of the database

Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	recruitment closed

Data

Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Paraclinical data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire
Paraclinical data (detail)	ECG, MRI, Scanner (if available)
Biological data (detail)	IGF-I, lipidic and glycemic profile, hormone assays (if available)
Presence of a biobank	No
Health parameters studied	Health event/morbidity Quality of life/health perception

Procedures

Data collection method	Data collection notebook and questionnaire
Participant monitoring	Yes

Details on monitoring of participants	Followed for 10 to 10 years according to the date of inclusion
Links to administrative sources	No

Promotion and access

Promotion

Link to the document	http://tinyurl.com/Pubmed-HYPOCCS
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