

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

Head :Médecin pharmacoépidémiologiste , Eli Lilly France

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General

Identification

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

Medical area	Endocrinology and metabolism
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Keywords	Somatotrope deficiency, adult, treatments, tolerance, quality of life
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Scientific investigator(s) (Contact)

Name of the director	Médecin pharmacoépidémiologiste
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Email	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) responsible	Eli Lilly
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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 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