

- PGRx : Graves' disease

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General

Identification

Detailed name PGRx : Graves' disease

CNIL registration number,
number and date of CPP
agreement, AFSSAPS (French
Health Products Safety Agency)
authorisation CNIL 907.309

General Aspects

Medical area Endocrinology and metabolism
Internal medicine

Others (details) incident cases of Graves' disease

Keywords Graves, pharmaco-epidemiology

Scientific investigator(s) (Contact)

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Collaborations

Funding

Funding status Private

Details LA-SER

Governance of the database

Sponsor(s) or organisation(s)
responsible LA-SER

Organisation status	Private
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Case control study
Database recruitment is carried out by an intermediary	A selection of health care professionals A selection of health institutions and services
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Cases of Graves' disease are recruited by a network of endocrinology, internal medicine and pediatric centers, and the referents by a network of general practitioners, distributed all across the territory.
Database objective	
Main objective	Surveillance and assessment of the risk of Graves' disease associated with drug or vaccine use in real life situations.
Inclusion criteria	For the cases: patients, males and females aged 0 to 49 years, having clinical or biological signs or symptoms suggesting Graves' disease declared by the specialist, for which the first symptoms of the episode occurred less than 12 months ago. For the controls: patients, males and females aged 0 to 49 years and older, having consulted a general practitioner.
Population type	
Age	Newborns (birth to 28 days) Infant (28 days to 2 years) Early childhood (2 to 5 years) Childhood (6 to 13 years) Adolescence (13 to 18 years) Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years)
Population covered	General population

Gender	Male Woman
Geography area	International
Detail of the geography area	France, Italy, Spain, United Kingdom, Canada
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	04/2008
Size of the database	
Size of the database (number of individuals)	[10 000-20 000[individuals
Details of the number of individuals	- 153 cas/cases - 11125 référents/controls
Data	
Database activity	Current data collection
Type of data collected	Clinical data Declarative data
Clinical data (detail)	Direct physical measures
Declarative data (detail)	Phone interview
Presence of a biobank	No
Health parameters studied	Health event/morbidity
Procedures	
Participant monitoring	No
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Methods for accessing the database are currently being defined

Access to aggregated data

Access on specific project only

Access to individual data

Access on specific project only