

- PGRx : Immune thrombocytopenic purpura (ITP)

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General

Identification

Detailed name	PGRx : Immune thrombocytopenic purpura (ITP)
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL: 907.309

General Aspects

Medical area	Hematology Internal medicine Rare diseases
Others (details)	Incident cases of idiopathic thrombocytopenic purpura, ITP,
Keywords	pharmaco-epidemiology

Scientific investigator(s) (Contact)

Name of the director	Grimaldi - Bensouda
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Collaborations

Funding

Funding status	Private
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Details	LA-SER
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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 institutions and services
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Cases of immune thrombocytopenic purpura are recruited by a network of internal medicine, hematology 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 immune thrombocytopenic purpura associated with drug or vaccine use in real life situations.
Inclusion criteria	For the cases: patients, males and females aged 0 to 79 years, having clinical or biological signs or symptoms suggesting an immune thrombocytopenic purpura declared by the specialist, for which the first symptoms of the episode occurred less than 6 months ago. For the controls: patients, males and females aged 0 to 79 years, 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)
Elderly (65 to 79 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 357 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
 Health care consumption and services

Care consumption (detail) Medicines consumption

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