

- 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)

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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