- PGRx : Central demyelination

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General

Identification

Detailed name	PGRx : Central demyelination
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL : 907.069

General Aspects

Medical area	Neurology
Others (details)	First central demyelinating event, Demyelination, Multiple Sclerosis (MS)
Keywords	pharmaco-epidemiology

Scientific investigator(s) (Contact)

Name of the director	Grimaldi - Bensouda
Surname	Lamiae
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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 as part of an interventional study	No
Additional information regarding sample selection.	Cases of central demyelination are recruited by a network of neurology 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 central demyelination associated with drug or vaccine use in real life situations.
Inclusion criteria	For the cases: patients, males and females aged from 0 to 79 years, having a first central demyelinating event reported by the neurologist, for which the first symptoms of the episode occurred less than 12 months ago. For the controls: patients, males and females aged from 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)	2007
Size of the database	
Size of the database (number of individuals)	[10 000-20 000[individuals
Details of the number of individuals	517 cas et 11125 référents
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