

- PGRx : Myositis

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Last update : 07/10/2012 | Version : 1 | ID : 2413

General

Identification

Detailed name PGRx : Myositis

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

General Aspects

Medical area Internal medicine
Rare diseases
Rheumatology

Others (details) Incident cases of myositis and dermatomyositis

Keywords 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) LA-SER

responsible

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
A population file

Database recruitment is carried out as part of an interventional study

No

Additional information regarding sample selection.

Cases of myositis and dermatomyositis are recruited by a network of internal medicine, dermatology, rheumatology and pediatrics centers and the referents by a network of GPs across the territory.

Database objective

Main objective

Surveillance and assessment of the risk of myositis and/or dermatomyositis associated with drug or vaccine use under real life situations.

Inclusion criteria

For cases: patient, man and woman aged from 0 to 79 years inclusive, with a clinico-biological presentation evocative of myositis/dermatomyositis declared by the specialist, for which the first symptoms of the episode began less than 12 months ago.
For controls: patient, man and woman aged from 0 to 79 years, who have consulted a GP.

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	- 57 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