

- PGRx: Acute Liver Damage

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General

Identification

Detailed name PGRx: Acute Liver Damage

CNIL registration number,
number and date of CPP
agreement, AFSSAPS (French
Health Products Safety Agency)
authorisation 908.025

General Aspects

Others (details) Acute liver damage

Keywords Pharmacoepidemiology

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
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Cases of acute liver damage are recruited by a network of hepatology or gastroenterology centres and by referrals from a network of general practitioners located throughout the territory.
Database objective	
Main objective	Surveillance and assessment of the risk of liver damage from drug exposure during actual treatment.
Inclusion criteria	Case subjects: patients, men or women over 18 years old, with acute liver damage confirmed by a specialist and followed-up for a maximum of 6 months before recruitment. Case-controls: patients (men and women over 18 years old) who have consulted a general practitioner
Population type	
Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
Population covered	General population
Gender	Male Woman
Geography area	International
Detail of the geography area	France, Germany
Data collection	

Dates

Date of first collection (YYYY or MM/YYYY) 2008

Size of the database

Size of the database (number of individuals) [10 000-20 000[individuals

Details of the number of individuals - 60 cas/cases - 13000 témoins/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

Link to the document <http://www.em-consulte.com/en/article/211579>

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Access

Terms of data access (charter for data provision, format of data, availability delay) To be defined

Access to aggregated data

Access on specific project only

Access to individual data

Access on specific project only