- PGRx: Acute Liver Damage

Head :Grimaldi - Bensouda Lamiae

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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)

Name of the director	Grimaldi - Bensouda
Surname	Lamiae
Address	10 place de Catalogne - 75014 Paris
Phone	01 55 42 53 00
Email	contact@la-ser.com

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