SALT-I - Study of Acute Liver Transplant

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General

Identification

Detailed name	Study of Acute Liver Transplant
Sign or acronym	SALT-I
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CCTIRS 08.323, CNIL 908293

General Aspects

Medical area	Gastroenterology et hepatology
Health determinants	Iatrogenic Intoxication
Keywords	Nimesulide, non-steroidal anti-inflammatory drugs (NSAIDs), drug intoxication, retrospective, case-population, liver transplantation, Europe, Pharmacoepidemiology, Department of Pharmacology, Bordeaux

Scientific investigator(s) (Contact)

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Organization	Université Bordeaux

Collaborations

Funding

Funding status	Private
Details	Laboratoire Helsinn Healthcare

Governance of the database

Sponsor(s) or organisation(s) responsible	INSERM
Organisation status	Public

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 is made on the basis of:	Medication(s) taken
Database recruitment is carried out as part of an interventional study	No

Additional information regarding sample selection.	The study was conducted among liver transplant centres in France, Italy, Portugal, Great Britain, the Netherlands, Greece and Ireland. All patients included in the liver transplantation lists between 1 January 2005 and 31 December 2007 were identified by the centres.

Database objective

Main objective	Acute liver failure, Nimesulide, non-steroidal anti-inflammatory drugs (NSAIDs), liver transplantation, drug intoxication, retrospective, case-population, Europe, Pharmacoepidemiology, Department of Pharmacology, Bordeaux
Inclusion criteria	Patient who was at least 18 years old at the time of registration on transplant list; Patient with acute liver failure placed on liver transplantation list and exposed to NSAIDs during the 30 days before the 1st signs or symptoms of liver disease, whether or not transplantation was performed; Patient resident of the participating country; Excluding elective liver transplants for chronic diseases such as cirrhosis, chronic hepatitis or cancer.

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	Sick population
Gender	Male Woman
Geography area	International
Detail of the geography area	Transplant centres in France, Italy, Portugal, Great Britain, the Netherlands, Greece, Ireland

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2009
Date of last collection (YYYY or MM/YYYY)	2011

Size of the database	
Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	500
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Administrative data
Clinical data (detail)	Direct physical measures
Administrative data (detail)	Month and year of birth, city and country of residence, affiliation to social security system
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services
Care consumption (detail)	Medicines consumption
Procedures	
Data collection method	The data collection is performed by a clinical research assistant from medical records via an electronic or paper questionnaire. Some of the data was complemented by the CRISTAL database for France (information system of the Biomedicine Agency), the UKTR database for Ireland and England, and LTX-NL for the Netherlands. The Validation Committee shall determine the date of index events and the first signs or symptoms of liver disease at the origin of acute liver failure and assess causality in these cases exposed to NSAIDs.
Participant monitoring	No
Links to administrative sources	Yes
Linked administrative sources (detail)	CRISTAL databases (France - Biomedicine Agency), UKTR (Ireland and England), LTX-NL (the Netherlands)
Promotion and access	

Promotion Access	
Terms of data access (charter for data provision, format of data, availability delay)	A final study report was submitted to the funder and the CHMP. The final study report and scientific communications (posters, papers, ...) are validated by the study Scientific Committee. Ownership of study data is the subject of an agreement between the University Bordeaux Segalen and the funder. Terms for third-party access to the database are to be defined
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only