

# 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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|--|---|
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| Unit   | Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen |
| Organization   | Université Bordeaux   |
| <b>Collaborations</b>  |   |
| <b>Funding</b>   |   |
| Funding status   | Private   |
| Details  | Laboratoire Helsinn Healthcare  |
| <b>Governance of the database</b>                                      |   |
| Sponsor(s) or organisation(s) responsible                              | INSERM  |
| Organisation status  | Public  |
| <b>Additional contact</b>  |   |
| <b>Main features</b>   |   |
| <b>Type of database</b>  |   |
| 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 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