# SALT-II: Study of Acute Liver Transplant Prolongation and continuation of the SALT-I study “A study of drug-exposed acute liver failure (ALF) in European transplant centres”

**First published:** 13/06/2014

**Last updated:** 23/04/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS5555

**Study ID**

40867

**DARWIN EU® study**

No

**Study countries**

France

**Study description**

The SALT-I study created a network of 55 liver transplant centres in seven European countries. It also accumulated a considerable body of data on drug-exposed acute liver failure in Europe. The national coordinators of these centres have expressed a desire to continue this collaboration and monitor severe acute hepatitis in Europe. Furthermore, the main objective of SALT-I concerned only the risks associated with NSAIDs. One of the main objectives of the SALT-II study is to assess the risks associated with other drugs than NSAID. The incidence of these very severe drug-induced acute liver failure is very low: we could identify only 40 cases associated with NSAIDs over 2005-2007, and fewer still with other drugs except paracetamol. To improve the precision of the measures of incidence, and to be able to identify emergent risks, it would seem desirable to increase the number of cases identified, by continuing the study for the next six years (2008-2013), and studying the possibility of expanding the network to other countries (Germany, Spain, Nordic or Eastern European countries).

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**Study status**

Finalised

# Research institutions and networks

## Institutions

### Bordeaux PharmacoEpi, University of Bordeaux

France

**First published:** 07/02/2023

**Last updated:** 08/12/2025

Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

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# Contact details

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**Primary lead investigator**

Sinem Ezgi Gulmez

Primary lead investigator

# Study timelines

**Date when funding contract was signed**
Actual: 20/12/2013

**Study start date**
Planned: 01/07/2014

Actual: 01/07/2014

**Data analysis start date**
Actual: 12/02/2016

**Date of interim report, if expected**
Actual: 27/11/2015

**Date of final study report**
Planned: 30/12/2016

Actual: 13/07/2016

## Sources of funding

- Non-for-profit organisation (e.g. charity)

## More details on funding

Bordeaux University Foundation

## Regulatory

**Was the study required by a regulatory body?**

No

**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To estimate the risk of drug-exposed ALFT in adults, according to the population exposure to the same drugs.

## Study Design

**Non-interventional study design**

Other

**Non-interventional study design, other**

Case-population study

# Study drug and medical condition

**Medical condition to be studied**

Liver transplant

# Population studied

**Short description of the study population**

The cases fulfilling the following eligibility criteria were considered for data collection:
- Adult patients of ≥18 years of age at the time of registration on the transplantation list,
- Patient registered on the transplantation list between 1st January 2008 and 31st December 2013, whether the transplantation was actually performed or not,
- Patients who are residents of the country where they were registered.

The non-eligibility criteria were:
- Patients <18 years of age at the time of registration on the transplantation list,
- Patients not resident in the selected countries.

**Age groups**

- Adults (18 to < 46 years)

- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

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**Special population of interest**

Hepatic impaired

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**Estimated number of subjects**

360

## Study design details

**Outcomes**

Global frequency of occurrence of the ALFT (without clinically defined cause) listed on the transplant list, in subjects exposed to a drug 30 days prior to index date (ID, date of the onset of the liver disease) in five European countries over the 6-year period (2008-2013). The relative event rates within drugs of the same class,Inclusion of data from SALT-I to determine the overall frequency over nine years (2005-2013), Frequency of occurrence measured using different denominators (number of subjects, DDD, patient-years),Frequency based on the number of drug-exposed cases aged between 18 and 70 years (age range observed for subjects transplanted).

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**Data analysis plan**

Descriptive analysis: A descriptive analysis of all drug-exposed cases of ALFT will be performed. Rate estimations per country: Per country rates of drug-exposed transplantation registered ALF will be computed as the ratio of the number of cases identified in the country to the population exposure. Population exposure will be measured in treatment-years (source: IMS). The

estimation of the rate of drug-exposed ALFT cases within 30 days prior to ID, with a 95% CI from a Poisson distribution, expressed in cases per million treatment-years. The frequency of ALFT will be calculated also for people aged 18 to 70 years.Pooling: Data of SALT-IIEUR will be pooled with data of the previous SALT-I study to estimate the frequency of ALFT identified in nine years (2005-2013). This will allow a greater number of events and a better precision of the risk estimates.

## Documents

**Study results**

SALT-II_Final report_v1.0_20160713.pdf (1.58 MB)

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**Study report**

SALT-II_Study Report_Appendix 1.1.pdf (1.64 MB)

SALT-II_Study report_Appendix 1.2.pdf (3.73 MB)

**Study, other information**

SALT-II_Study report_Appendix 1.2.pdf (3.73 MB)

**Study publications**

Gülmez SE, Lignot-Maleyran S, S deVries C, Sturkenboom M, Micon S, Hamoud F, Bl…

Moore N, Gulmez SE, Larrey D, Pageaux GP, Lignot S, Lassalle R, Jové J, Parient…

Gülmez SE, Larrey D, Pageaux GP, Lignot-Maleyran S, de Vries C, Sturkenboom M, …

Gülmez SE, Larrey D, Pageaux GP, Lignot S, Lassalle R, Jové J, Gatta A, McCormi…

Gulmez SE, Moore N, Pageaux GP, Lignot S, Horsmans Y, Stricker B, Bernuau J, B…

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## Data management

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

# Data sources

**Data source(s), other**

CRISTAL database

**Data sources (types)**

Disease registry

Other

**Data sources (types), other**

National liver transplant registries/waiting lists in France (CRISTAL),Patient medical files at the participating liver transplant centers

# Use of a Common Data Model (CDM)

**CDM mapping**

No

# Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No