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).

Study status

Finalised

Research institutions and networks

Institutions

Bordeaux PharmacoEpi, University of Bordeaux

France

First published: 07/02/2023

Last updated: 08/02/2023

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

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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

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

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)

Special population of interest

Hepatic impaired

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).

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)

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...

Data management

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