Prevalence of Acute Liver Injury

First published: 21/06/2023

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS104334

Study ID

104335

DARWIN EU® study

No

Study countries

- France
- Germany
- Italy
- Romania
- Spain

Study description

A descriptive study of the yearly prevalence of acute liver injury, overall and stratified by gender and age group, in five EU countries

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Karin Hedenmalm

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 11/04/2022

Actual: 11/04/2022

Study start date
Planned: 11/04/2022

Actual: 11/04/2022

Date of final study report
Planned: 03/06/2022

Actual: 02/06/2022

Sources of funding

- EMA

Study protocol

Analysis-Plan-Simple study- 202112_v2.0_For Publication_CLEAN.pdf (289.06 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

The main objective of the study was to estimate the yearly prevalence of acute liver injury in five EU countries (Germany, France, Italy, Romania, and Spain), overall and stratified by gender and age group (0-17 years, 18-49 years, 50-79 years, 80+ years).

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Descriptive study

Study drug and medical condition

Medical condition to be studied

Liver injury

Population studied

Short description of the study population

The study included patients visiting general practices in France, Italy, Germany, Romania, and Spain to determine the prevalence of acute liver injury, between January 2016 and December 2020, identified from the IMRD databases.

Age groups

- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

Special population of interest

Hepatic impaired

Estimated number of subjects

300.000

Study design details

Data analysis plan

The prevalence was estimated as the number of patients with the condition anytime during the year according to the case definition (i.e. all patients that

were observable during the year and had received a diagnosis of acute liver injury during the year or up to 181 days before the start of the year) per million persons in the population that were observable during the year. The period of 181 days was only applied to the first date when the specific diagnosis was recorded in the patient, but the same patient could contribute to more than one 181-day period if more than one acute liver injury diagnosis was recorded.

Documents

Study results

Report Results - Acute liver injury prevalence_For_Publication_CLEAN_final.pdf (588.65 KB)

Data management

ENCePP Seal

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)

IQVIA Disease Analyzer Germany

THIN® (The Health Improvement Network®)

Disease Analyzer - OMOP

Data sources (types)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

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