

# Prevalence of Acute Liver Injury

**First published:** 21/06/2023

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

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/104335>

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### EU PAS number

EUPAS104334

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### Study ID

104335

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### DARWIN EU® study

No

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### Study countries

- ☐ France
- ☐ Germany
- ☐ Italy
- ☐ Romania

☐ Spain

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### 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

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### Study status

Finalised

## Research institutions and networks

### Institutions

European Medicines Agency (EMA)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

## Contact details

### Study institution contact

Karin Hedenmalm

Study contact

[Karin.Hedenmalm@ema.europa.eu](mailto:Karin.Hedenmalm@ema.europa.eu)

### Primary lead investigator

Karin Hedenmalm

## Study timelines

### **Date when funding contract was signed**

Planned: 11/04/2022

Actual: 11/04/2022

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### **Study start date**

Planned: 11/04/2022

Actual: 11/04/2022

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### **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

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## 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:**

Disease epidemiology

#### **Data collection methods:**

Secondary use of data

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#### **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

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## **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.

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## **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)

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## Special population of interest

Hepatic impaired

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## Estimated number of subjects

300000

# 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)

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## Data management

## Data sources

**Data source(s)**

IQVIA Disease Analyzer Germany

THIN® (The Health Improvement Network®)

Disease Analyzer - OMOP

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**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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No