# Prevalence of Acute Liver Injury

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# Administrative details

EU PAS number
EUPAS104334
Study ID
104335
DADWIN FILE study
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)

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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

# 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**

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)

# 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