EPIHAM: Drug-induced liver injury leading to hospital admission: a study in national healthcare insurance databases

First published: 29/09/2014

Last updated: 24/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS7549

Study ID

36973

DARWIN EU® study

No

Study countries

☐ France

Study description

EPIHAM is to identify in the national healthcare databases all hospital admissions for toxic or unexplained liver injuries. It will be done within the French national health care systems databases, which include all reimbursed health-care expenses, and all hospital admissions with ICD-10 coded admission diagnoses. The overall methodological approach will be initially that of a case-population study to compare event rates with those found in SALT. This will be completed by other methods: a case-crossover approach, a classical case-control study, and a propensity-score adjusted or matched cohort study of products selected from the case-population data.The routines created for this project may be reused to set up regular surveillance of drug-related hepatic disorders in the French population

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**

Contact details

Study institution contact

Sinem Ezgi Gulmez cecile.droz@u-bordeaux.fr

Study contact

cecile.droz@u-bordeaux.fr

Primary lead investigator

Sinem Ezgi Gulmez

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 17/07/2014

Study start date

Planned: 02/05/2016

Actual: 16/10/2014

Data analysis start date

Planned: 01/09/2016

Actual: 16/10/2014

Date of interim report, if expected

Actual: 17/07/2015

Date of final study report

Planned: 31/12/2016

Actual: 31/01/2017

Sources of funding

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

More details on funding

Institute de Recherche en Santé Publique (IReSP)

Study protocol

EPIHAM_Study Protocol_V2.0_20150715.pdf(1.02 MB)

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 identify the main drugs associated with DILIH in France and the event rates associated with DILIH, for individual drugs and for drug families, in terms of absolute and relative risks

Study Design

Non-interventional study design

Case-control

Case-only

Cohort

Other

Non-interventional study design, other

Case-crossover analysis

Study drug and medical condition

Medical condition to be studied

Acute hepatic failure

Population studied

Short description of the study population

Patients admitted with a primary diagnosis of acute toxic liver injury.

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

4800000

Study design details

Data analysis plan

Descriptive: For categorical and ordinal variables will provide the number and the frequency of each modality as well as missing data. For quantitative variables will provide mean, standard deviation, first quartile, median, third quartile, and extreme values. Case-population: The main study analysis. Number of cases exposed to a given drug is compared to the number of

subjects using the drug within the study time-frame, or to the number of defined daily doses (DDD) dispensed in the database population. Case-crossover: One or more control periods will be selected, one year before ID to take into account possible seasonal variations in drug use, or randomly within the year previous to ID. Case-control: Within the database population, controls will be selected, matched on age, gender, concomitant chronic diseases. Cohort: If events are enough, incident user cohorts and controls, adjusted or matched on propensity scores will be built and followed using cox proportional hazards analyses.

Documents

Study results

EPIHAM-1-Rapport final IReSP-V1.0-20170131.pdf(412.1 KB)

Study publications

Gulmez SE, Unal US, Lassalle R, Chartier A, Grolleau A, Moore N. Risk of hospit…

Moore N, Duret S, Grolleau A, Lassalle R, Barbet V, Duong M, Thurin N, Droz-Per…

Data management

Data sources

Data source(s), other

EGB France, SNIIRAM France

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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