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

PURI
https://redirect.ema.europa.eu/resource/36973

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 institution and networks

Institutions

Bordeaux PharmacoEpi, University of Bordeaux

France
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08/02/2023

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

Contact details

Study institution contact
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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 data collection

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 data (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