WP6 replication study: The risk of liver injury associated with the use of antibiotics: A study using a US database with linkage with hospital data

First published: 26/09/2012

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS2999

Study ID

28271

DARWIN EU® study

No

Study countries

☐ United States

Study status

Finalised

Research institutions and networks

Institutions

Sanofi

First published: 01/02/2024

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Institution

Networks

PROTECT

- [ ] Belgium
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Netherlands
- [ ] Poland
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom

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Network

Contact details

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Primary lead investigator

Stéphanie Tcherny-Lessenot

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/02/2012

Actual: 02/02/2012

Study start date

Planned: 02/04/2012

Actual: 02/04/2012

Data analysis start date

Planned: 01/05/2012

Actual: 01/05/2012

Date of final study report

Planned: 31/12/2013

Actual: 17/04/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

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

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Validation of study variables (exposure outcome covariate)

Data collection methods:

Secondary use of data

Main study objective:

To assess the association between antibiotics use and idiopathic acute liver injury by replicating a nested case-control design in a US claims database

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J01) ANTIBACTERIALS FOR SYSTEMIC USE

ANTIBACTERIALS FOR SYSTEMIC USE

Medical condition to be studied

Liver injury

Population studied

Short description of the study population

Patients of all ages with an active or died registration status during the study period of January 1st, 2004 to December 31st, 2009 in the Clinformatics Data Mart. Patients had to attained one year of enrolment in the database at the beginning of the study period.

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)

Estimated number of subjects

80000

Study design details

Outcomes

To estimate the risk of acute liver injury associated with antibiotics exposure (users and non-users), To estimate the risk of acute liver injury associated with various antibiotics classes, To estimate the risk of acute liver injury associated with specific individual antibiotics, To assess the effect of dose and duration of use for specific individual antibiotics, To validate cases of liver injury using information from patients’ hospital records, To describe the patterns of use of various antibiotics classes and of specific individual antibiotics in the US and to compare with patterns of use in the UK as observed in GPRD, To replicate the analysis using a population-based case-control design

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Data analysis plan

We will compute odds ratios (OR) and 95% confidence intervals of first occurrence of idiopathic acute liver injury associated with current use of antibiotics (as a group and different classes and individual drugs when possible) as compared to non-use with conditional logistic regression.

Documents

Study report

PROTECT WP6 ATB ALI report v1_final 17 april 2014.pdf(197.6 KB)

Study publications

Udo R, Tcherny-Lessenot S, Brauer R, Dolin P, Irvine D, Wang Y, Auclert L, Juha…

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 sources (types)

Administrative healthcare records (e.g., claims)

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

Unknown