The risk of acute liver injury with the use of antibiotics. A replication study in the Utrecht Patient Oriented Database

First published: 22/10/2014

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS7730

Study ID

9017

DARWIN EU® study

No

Study countries

☐ Netherlands

Study description

The study described in this protocol is performed within the framework of PROTECT (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium). The specific aims of this study are:• to evaluate the external validity of the study protocol on the risk of acute liver injury associated with the use of antibiotics by replicating the study protocol in a Dutch hospital database, • to study the impact of case validation on the effect estimate for the association between antibiotic exposure and acute liver injury.Of the selected drug-adverse event pairs selected in PROTECT, this study will concentrate on the association between antibiotic use and acute liver injury. On this topic, two sub-studies are performed: a descriptive/outcome validation study and an association study. The descriptive/outcome validation study has been conducted within the Utrecht Patient Oriented Database (UPOD). Cases of acute liver injury have been identified using hospital discharge diagnoses and/or abnormal laboratory test results related to liver injury. The proposed association study will be performed using UPOD and GP databases.

Study status

Finalised

Research institutions and networks

Institutions

Division of Pharmacoepidemiology & Clinical Pharmacology (PECP), Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht University

Netherlands

First published: 01/03/2010

Last updated: 23/05/2024

Institution | Educational Institution | ENCePP partner

Networks

PROTECT

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

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Marie L. De Bruin

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/01/2012

Actual: 01/01/2012

Study start date

Planned: 02/04/2012

Actual: 02/04/2012

Data analysis start date

Planned: 01/07/2013

Date of interim report, if expected

Planned: 02/12/2013

Date of final study report

Planned: 30/06/2014

Actual: 30/06/2014

Sources of funding

- EU institutional research programme

More details on funding

IMI-PROTECT

Study protocol

WP6_SAP_UPOD2 PROTECT_AB-ALI_11-7-2013.pdf (737.99 KB)

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

Other

If ‘other’, further details on the scope of the study

Replication study to evaluate external validity

Data collection methods:

Secondary use of data

Main study objective:

To evaluate the external validity of the study protocol on the risk of acute liver injury associated with the use of antibiotics by replicating the study protocol in a Dutch hospital 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 aged 18 years or older hospitalized or referred to the University Medical Centre Utrecht (UMCU) between January 2008 and December 2010.

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

700

Study design details

Outcomes

To estimate the risk of acute liver injury associated with antibiotics exposure.

To assess the impact of varying outcome definitions and time windows at risk on the effect estimates for the association between antibiotic exposure and acute liver injury.

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 compared to non-use with conditional logistic regression.

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), other

UPOD Netherlands, Mondriaan Netherlands

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Hospital registry

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