WP6 negative control study: The risk of myocardial infarction not associated with the use of antibiotics: A study using a US database

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/28276

EU PAS number

EUPAS3025

Study ID

28276

DARWIN EU® study

No

Study countries

☐ United States

Study status

Finalised

Research institutions and networks

Institutions

Sanofi

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Networks

PROTECT

☐ Belgium

☐ Denmark

☐ France

☐ Germany

☐ Italy

☐ Netherlands

☐ Poland

☐ Spain

☐ Sweden

☐ Switzerland

☐ United Kingdom

First published: 26/06/2013

Last updated: 14/01/2025

Network

Contact details

Study institution contact

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Study contact

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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: 01/11/2012

Actual: 15/11/2012

Data analysis start date
Planned: 01/11/2012

Actual: 15/11/2012

Date of final study report
Planned: 31/12/2013

Actual: 21/07/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

Study protocol

PROTECT_WP6_protocol_Antibiotics_MI_negative control_invision datamart_final_02022012.pdf(137.95 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 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

Negative control

Data collection methods:

Secondary use of data

Main study objective:

to assess the absence of association between antibiotics use and myocardial infarction by replicationg a nested case-control design in a US claims database (LabRx)

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

Myocardial infarction

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 Invision Data Mart. Patients must have 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 myocardial infarction associated with antibiotics exposure (users and non-users)To estimate the risk of myocardial infarction associated with various antibiotics classesTo estimate the risk of myocardial infarction associated with specific individual antibioticsTo assess the effect of dose and duration of use for specific individual antibiotics, 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 acute myocardial infarction 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. Age, sex, calendar year, and other variables will be introduced in the model to control for potential confounding. Also, dose and duration-relationships will be examined.

Documents

Study results

PROTECT WP6 ATB AMI REPORT 21072014_final.pdf(217.03 KB)

Data management

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