A pharmacoepidemiological study on the risk of bleeding in new users of low-dose aspirin (ASA) in The Health Improvement Network (THIN), UK (EPISAT)

First published: 02/09/2015

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10837

Study ID

45784

DARWIN EU® study

No

Study countries

United Kingdom

Study description

To investigate the risk of major bleeding (including gastrointestinal and intracranial bleeding episodes) among new users of low-dose acetylsalicylic acid (ASA) in clinical practice. These will be based on population-based cohorts using data from a primary care database in the UK: The Health Improvement Network (THIN) and will serve to make a clinically meaningful benefit–risk assessment regarding major bleeding consequences of ASA exposure in general population.

Study status

Finalised

Research institutions and networks

Institutions

Fundación Centro Español de Investigación Farmacoepidemiológica (CEIFE)

Spain

First published: 15/03/2010

Last updated: 15/02/2024

Institution | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Luis Alberto García Rodríguez

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/08/2015

Actual: 10/08/2015

Study start date

Planned: 01/09/2015

Actual: 01/09/2015

Date of final study report

Planned: 15/04/2017

Actual: 31/03/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer Pharma AG

Study protocol

Study 18116_Protocol_ OS EPISAT_PASS_10-Aug-2015.pdf (691.84 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

Data collection methods:

Secondary use of data

Main study objective:

The main objective of this study is to investigate the risk of major bleeding (including gastrointestinal and intracranial bleeding episodes) among new users of low-dose acetylsalicylic acid (ASA) in clinical practice.

Study Design

Non-interventional study design

Case-control

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AC) Platelet aggregation inhibitors excl. heparin

Platelet aggregation inhibitors excl. heparin

Medical condition to be studied

Haemorrhage intracranial

Upper gastrointestinal haemorrhage

Lower gastrointestinal haemorrhage

Population studied

Short description of the study population

Individuals will be required to be aged between 40-84 years, to be enrolled with the PCP for at least 2 years, to have a history of computerized prescriptions for at least 1 year prior, to have at least one encounter/visit recorded in the last three years and to be free of ASA, cancer, alcohol abuse, coagulopathies, esophageal varices and chronic liver disease to become a member of the study population. The date an individual met all these criteria will be considered as entry date. Individuals will be followed up from entry date up to one of the following endpoints, whichever came first: first prescription of low-dose ASA, diagnosis of cancer, alcohol abuse, coagulopathies, oesophageal varices, chronic liver disease, aged 85 years, death or end of the study period.

Inclusion criteria to qualify as member of the study population
- Aged 40-84 years
- Enrolled with the PCP for at least 2 years,
- To have a history of computerized prescriptions for at least 1 year prior
- To have at least one encounter/visit recorded in the last three years

• Exclusion criteria to qualify as member of the study population
- To be exposed to low dose ASA before entering in the study
- Having a diagnosis of cancer before entering in the study
- Having a diagnosis of alcohol abuse before entering in the study
- Having a diagnosis of coagulopathies before entering in the study
- Having a diagnosis of esophageal varices before entering in the study
- Having a diagnosis of chronic liver disease before entering in the study

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Age groups

- Adults (18 to < 46 years)

- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)

Estimated number of subjects

400.000

Study design details

Outcomes

-Incidence of Intracranial bleeding, Upper gastrointestinal(UG) bleeding and Lower gastrointestinal(LG) bleeding among new users of low-dose Acetylsalicylic acid(ASA) -Time to Intracranial bleeding, UG bleeding and LG bleeding among new users of low-dose ASA -Relative risk of Intracranial bleeding, UG bleeding and LG bleeding among new users of low-dose ASA, -Relative risk of Intracranial bleeding associated with use of other medications -Relative risk of Upper gastrointestinal bleeding associated with use of other medications -Relative risk of Lower gastrointestinal bleeding associated with use of other medications

Data analysis plan

Incidence, time to event, relative risk (overall and in age and sex-specific, duration and dose response.

Documents

Study results

18116_EU PAS_Abstract_redacted.pdf (267.16 KB)

Study report

18116_CSR _EU PAS_Redacted.pdf (6.33 MB)

Study publications

Cea Soriano L, Gaist D, Soriano-Gabarró M, García Rodríguez LA. Incidence of in…

Cea Soriano L, Gaist D, Soriano-Gabarró M, Bromley S, Garcia Rodriguez LA. Low-…

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)

THIN® (The Health Improvement Network®)

Data sources (types)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

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