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

PURI
https://redirect.ema.europa.eu/resource/45784

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 institution 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 data collection

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

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

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
400000

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

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