Treatment Patterns and Bleeding Risks Comparison in Patients Treated with Clopidogrel or Prasugrel during the Index Hospitalisation in Sweden (H7T-MC-B010)

First published: 26/02/2014

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Study | Finalised

Administrative details

EU PAS number

EUPAS5934

Study ID

20448

DARWIN EU® study

No

Study countries

Sweden

Study description

This is a retrospective analysis using data collected within the SCAAR registry. This noninterventional cohort study aimed to compare bleeding risks in prasugrel-treated and only-clopidogreltreated patients in the ACS-PCI population. The study also provided information regarding bleeding risks in the study population (including patients not diagnosed with ACS) as well as prasugrel treatment patterns during the index hospitalisation in Sweden. Patients were prospectively enrolled into the SCAAR over a 3-year study period and observed only during the index hospitalisation following enrollment.

Study status

Finalised

Research institutions and networks

Institutions

SCAAR

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Asiimwe Alex

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 13/12/2010

Actual: 13/12/2010

Study start date
Planned: 01/05/2010

Actual: 01/05/2010

Date of final study report
Planned: 15/10/2013

Actual: 15/10/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company and Daiichi Sankyo, Inc.

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

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

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

 To compare the incidence rates of SCAAR-defined major or minor bleeding between only-prasugrel-treated plus prasugrel/clopidogrel-treated patients and only-clopidogrel-treated patients with ACS undergoing PCI (the indicated population for prasugrel) during the index hospitalisation.See report for details

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

PRASUGREL

Medicinal product name, other

Clopidegrel

Medical condition to be studied

Acute coronary syndrome

Population studied

Short description of the study population

Patients enrolled in the SCAAR (Swedeheart) who were at least 18 years of age at study entry and were prasugrel- or clopidogrel-treated patients undergoing percutaneous coronary intervention (PCI) with or without acute coronary syndrome (ACS) during the index hospitalisation.

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

Other

Special population of interest, other

Patients with acute coronary syndrome

Estimated number of subjects

34363

Study design details

Outcomes

Bleeding

Data analysis plan

For information related to data analysis, please refer to the study report attached

Documents

Study results

B010 Synopsis_15 Oct 2013.pdf (1.52 MB)

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

SCAAR Sweden

Data sources (types)

Disease registry

Other

Data sources (types), other

Prospective patient-based data collection

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