Treatment patterns in acute myocardial infarction patients initiated with prasugrel or clopidogrel during the index hospitalisation with one year follow-up (H7T-FR-B016)

First published: 05/03/2014

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Study Finalised

Administrative details

EU PAS number

EUPAS5972

Study ID

20451

DARWIN EU® study

No

Study countries

France

Study description

This study is a retrospective, nonintervention cohort study whose main objective is to provide information on the routine use of prasugrel and clopidogrel (as a reference) in France during the index hospitalization and during one-year follow-up in patients hospitalized with acute Myocardial Infarction (MI).

Study status

Finalised

Research institutions and networks

Institutions

FAST MI

Contact details

Study institution contact

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Study contact

alex.asiimwe@lilly.com

Primary lead investigator

Alex Asiimwe

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/10/2010

Actual: 01/10/2010

Study start date
Planned: 01/10/2010

Actual: 01/10/2010

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 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:

To describe prasugrel and clopidogrel routine use, and clinical outcomes. For more details, refer to the study report attached.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

PLAVIX

Medicinal product name, other

Effient

Medical condition to be studied

Acute coronary syndrome

Population studied

Short description of the study population

Patients 18 years of age or older who were diagnosed with acute myocardial infarction (MI) and managed in any of 213 cardiology units of French hospitals. Patients who were included in this report were required to be in the FAST-MI registry for 12 months after index hospitalisation.

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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

Acute myocardial infarction patients

Estimated number of subjects

2.644

Study design details

Outcomes

Bleeding

Data analysis plan

Continuous variables are presented with the sample size, mean, standard deviation, median, 1st and 3rd quartiles, and number of missing responses. Categorical variables are presented with count, percentage, and number of missing. All the analyses were descriptive without adjustments.For descriptive analyses, missing responses were counted and excluded from the analysis for each variable separately. No data imputation techniques were planned.For more details, refer to study report

Documents

Study results

FAST-MI (B016) Registry Summ 1-yr Report FINAL.pdf (1.29 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

FAST MI, France

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