Post-discharge Clinical and Economic Outcomes Among Patients with ACS Managed with PCI and treated with Prasugrel versus Ticagrelor (H7T-MC-B023)

First published: 15/06/2015

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Study Finalised

Administrative details

EU PAS number

EUPAS9949

Study ID

9950

DARWIN EU® study

No

Study countries

☐ United States

Study description

Retrospective cohort study using the Prometix Lx claims database to compare clinical and economic outcomes and treatment patterns among patients treated with prasugrel and those treated with ticagrelor. The primary study population will be patients with ACS managed with PCI who have no prior TIA or stroke (that is, indicated population for treatment with prasugrel). The primary study objective is to compareNACE up to one year post-discharge from an index hospitalisation. The main study hypothesis will be to show that prasugrel is associated with non-inferior outcomes at 1 year compared to ticagrelor. Secondaryendpoints include clinical and economic outcomes and treatment patterns through 30 days, 6 months, and 1 year post index hospitalization discharge. Data will be assessed before and after adjustment for baseline risk differences via propensity score matching. The overall ACS-PCI population, as well as a subgroup of the primary population aged <75 years or >75 years with diabetes or prior MI, will be assessed.

Study status

Finalised

Research institutions and networks

Institutions

Evidera

United Kingdom

First published: 20/11/2013

Last updated: 07/03/2024

Institution | Laboratory/Research/Testing facility | Non-Pharmaceutical company

ENCePP partner

Contact details

Study institution contact

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Study contact

Molife_cliff@lilly.com

Primary lead investigator

Cliff Molife

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 12/12/2013

Actual: 12/12/2013

Study start date

Planned: 01/05/2014

Actual: 02/06/2014

Data analysis start date

Planned: 15/05/2014

Actual: 08/06/2014

Date of interim report, if expected
Planned: 01/01/2015

Actual: 27/02/2015

Date of final study report
Planned: 31/03/2015

Actual: 31/05/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

H7T-MC-B023 Prasugrel Study Protocol.pdf(522.44 KB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The primary objective is to compare net adverse clinical events (NACE) up to 1 year post-discharge from an index ACS-PCI hospitalisation in patients treated with prasugrel versus ticagrelor. The main hypothesis is that, after adjustment for baseline differences, outcomes associated with prasugrel will be non-inferior to those with ticagrelor through 1 year for ACS-PCI patients in regards to NACE.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AC22) prasugrel

prasugrel

(B01AC24) ticagrelor

ticagrelor

Medical condition to be studied

Acute coronary syndrome

Population studied

Short description of the study population

Study conducted between 31 July 2008 and 01 Aug 2013 includes patients from ProMetis Lx® Database with no history of TIA or stroke will have evidence of a fill for prasugrel or ticagrelor within 30 days post-discharge from an index ACS-PCI hospitalization and any physician visit within 90 days after hospital discharge.

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

17406

Study design details

Outcomes

Net adverse clinical events (NACE) up to one year post-discharge from an index hospitalisation. Resource utilisation (medical and pharmacy utilisation) and other clinical outcomes (NACE components including bleeding rehospitalisations), healthcare charges, and treatment patterns (including adherence and persistence) at 30 days, 6 months, and one year post-discharge from the index hospitalisation.

Data analysis plan

Baseline and outcomes data will be analysed before and after propensity matching. Unmatched cohorts will be compared with an appropriate 2-tailed statistic for continuous or categorical variables. Treatment groups will be matched based on baseline demographic, clinical, procedural, and payer characteristics. A one-sided test will then be computed to see if the clinical event rate difference between treatment groups is significantly <1.2 (20% non-inferiority margin). Cox regression will be used to compare clinical outcomes, with patients censored at the end of the index treatment exposure time (that is, 7 days after discontinuation or switching of the index medication). Per patient per month economic measures and incidence rates will be assessed to account for the variable follow-up. Economic outcomes and treatment patterns will be analysed after matching using descriptive statistics and appropriate regression models (for example, generalized linear model and logistic regression).

Data management

Data source(s), other

Prometis Lx Database United States

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

No