One Year Post-discharge Clinical and Economic Outcomes among Patients with ACS Managed with PCI and Treated with Prasugrel versus Clopidogrel (H7T-MC-B022)

First published: 15/06/2015

Last updated: 12/05/2016

Study Ongoing

Administrative details

EU PAS number

EUPAS9953

Study ID

13443

DARWIN EU® study

No

Study countries

☐ United States

Study description

Retrospective cohort study using the Optum Research Claims Database to compare clinical and economic outcomes and treatment patterns among patients treated with prasugrel and those treated with clopidogrel. The primary study population will be patients with ACS managed with PCI who have no prior TIA or stroke (that is, the indicated population for treatment with prasugrel). Primary study objective is to compare major adverse cardiac events (MACE) up to one year and secondary endpoints will include clinical and economic outcomes and treatment patterns through 1 year post index hospitalisation discharge. Data will be assessed before and after adjustment for baseline risk differences via propensity score matching. The subgroup of the primary population aged <75years or >75 years with diabetes or prior MI, will also be assessed (that is, the population recommended for treatment with prasugrel per USPI).

Study status

Ongoing

Research institutions and networks

Institutions

Optum

Germany

First published: 03/01/2012

Last updated: 07/02/2014

Institution | Other | ENCePP partner

Contact details

Study institution contact

Cliff Molife Molife_cliff@lilly.com

Study contact

Molife_cliff@lilly.com

Primary lead investigator

Cliff Molife

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/10/2013

Actual: 31/10/2013

Study start date

Planned: 01/03/2014

Actual: 01/04/2014

Data analysis start date

Planned: 01/05/2014

Actual: 01/06/2014

Date of interim report, if expected

Planned: 01/09/2015

Date of final study report

Planned: 01/10/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

H7T-MC-B022 Prasugrel Study Protocol.pdf(548.96 KB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

The primary study objective is to compare major adverse cardiovascular events (MACE) up to 1 year post-discharge from an index ACS-PCI hospitalization in patients treated with prasugrel versus clopidogrel. The main hypothesis is that, after adjustment for baseline differences, prasugrel will be associated with a significantly lower risk of MACE than clopidogrel up to one year post-discharge.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AC22) prasugrel

prasugrel

(B01AC04) clopidogrel

clopidogrel

Medical condition to be studied

Acute coronary syndrome

Population studied

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)

Estimated number of subjects

26079

Study design details

Outcomes

Major adverse cardiovascular events (MACE) up to 1 year post discharge from an index ACS-PCI hospitalization. Resource utilization (medical and pharmacy utilization) and other clinical outcomes (MACE components, bleeding rehospitalizations), healthcare charges, and treatment patterns (including adherence and persistence) at one year post discharge from the index hospitalization.

Data analysis plan

Baseline and outcomes data will be analyzed before and after propensity matching. Treatment groups will be matched based on baseline demographic, clinical, procedural, and payer characteristics. Multivariable cox regression will be used to compare adjusted clinical outcomes. Unmatched cohorts will be compared with the appropriate 2-tailed statistic for continuous or categorical variables. Patients will be censored at the end of index treatment exposure time (that is, 7 days after discontinuation or switching of the index medication). Pre- and post-match Kaplan Meier curves will be constructed and log-rank tests used

to compare unadjusted rates through 1 year. Per patient per month economic measures and incidence rates will be assessed to account for the variable follow-up period. Economic outcomes and treatment patterns will also be analyzed after matching using descriptive statistics and appropriate regression models (for example, generalized linear model and logistic regression).

Documents

Study, other information

H7T-MC-B022 Study Termination Letter.pdf(78.65 KB)

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

Optum Research 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