Comparison Of Clinical Outcomes, Resource Utilisation, And Costs In Patients Hospitalized For ACS Managed With PCI And Receiving Prasugrel Or Ticagrelor (H7T-US-B019)

First published: 11/06/2015

Last updated: 11/06/2015

Study Finalised

Administrative details

EU PAS number

EUPAS9938

Study ID

9939

DARWIN EU® study

No

Study countries

United States

Study description

This study is an observational retrospective database analysis designed to compare 30-day net adverse clinical event (NACE) rates in ACS patients who were managed with PCI. The major hypothesis of this studyis that, after adjustment for baseline differences, prasugrel will be non-inferior to ticagrelor through 30 days in ACS-PCI patients in regards to NACE.

Study status

Finalised

Research institutions and networks

Institutions

IM Health Incorporated

First published: 01/02/2024

Last updated: 01/02/2024

Institution

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: 23/03/2013

Actual: 23/03/2013

Study start date
Planned: 15/10/2013

Actual: 15/10/2013

Data analysis start date
Planned: 17/10/2013

Actual: 17/10/2013

Date of interim report, if expected
Planned: 04/11/2013

Actual: 04/11/2013

Date of final study report
Planned: 10/02/2014

Actual: 10/02/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company, Daiichi Sankyo Inc

Study protocol

H7T-US-B019 Prasugrel Study Protocol.pdf (445.18 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:

To compare 30-day net adverse clinical events (NACE) rates in ACS patients managed with PCI and treated with prasugrel vs. ticagrelor through 30 days, including the index hospitalisation.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AC22) prasugrel

prasugrel

Medical condition to be studied

Acute coronary syndrome

Population studied

Short description of the study population

ACS patients managed with PCI and treated with prasugrel vs. ticagrelor through 30 days, including the index hospitalization.

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

18414

Study design details

Outcomes

Net adverse clinical events (NACE), defined as the composite of all-cause death, any CV event, severe bleeding during index hospitalisation or rehospitalisation for bleeding, Components of the composite primary outcome measure (bleeding, mortality, TIA, stroke, or rehospitalisation for MI, UA, CHF, revascularisation, or stent thrombosis), dyspnea, bradyarrhythmia, economic outcomes (resource utilisation, costs), and treatment patterns(concomitant medications, PCI procedure, CABG surgery) at 30 and 90 days post discharge from the index hospitalisation

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Data analysis plan

Propensity score matching based on baseline demographic, clinical, procedural and payer characteristics will be used to adjust for potential confounding. All baseline variables will be described before and after matching. Primary and secondary categorical outcomes will be assessed as dependent variables using McNemar’s test. A one-sided p-value will be computed to test if the upper confidence limit of the event rate comparison between prasugrel and ticagrelor is <1.2 (20% non-inferiority margin based on relative risk). Cohort differences in matched continuous outcome variables will be analyzed as dependent variables using a generalized linear model (GLM) with gamma, Poisson and/or negative binomial distribution. Generalized Estimating Equations will be used to account for correlation between matched pairs. Sensitivity analyses will be employed as appropriate to assess the robustness of results to the potential for unmeasured confounding and other statistical assumptions.

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

IMS Patient-Centric Data Warehouse 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