Clinical and Economic Assessment of Patients with Acute Coronary Syndrome Managed with Percutaneous Coronary Intervention and Treated with Prasugrel or Clopidogrel using Academic Center Databases (H7T-US-B020)

First published: 12/03/2015

Last updated: 22/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS8687

Study ID

11418

DARWIN EU® study

No

Study countries

United States

Study description

To compare major adverse cardiac event (MACE) outcomes (the composite occurrence of all-cause death, MI, stroke, or unplanned coronary revascularization) within 90 days of index PCI in patients with ACS treated with prasugrel or clopidogrel.

Study status

Finalised

Research institutions and networks

Institutions

Icahn School of Medicine at Mount Sinai

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Institution

Mount Sinai Medical Center New York City, NY USA, Aurora Health Care Milwaukee, WI USA, Christiana Care Health Services Wilmington, DE USA, Cleveland Clinic Cleveland, OH USA, Duke University Durhan, NC USA, Intermountain Heart

Institute Murray, UT USA, University of Pittsburgh PIttsburgh, PA USA, Minneapolis Heart Institute Minneapolis, IN

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Roxana Mehran

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/07/2014

Actual: 01/07/2014

Study start date

Planned: 06/08/2014

Actual: 29/09/2014

Data analysis start date
Planned: 27/02/2015

Actual: 28/02/2015

Date of interim report, if expected
Planned: 01/03/2015

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

Actual: 30/06/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

PROMETHEUS_B020_SAP_Final.pdf (468.5 KB)

H7T-US-B020 Observational Protocol_2.0.pdf (926.66 KB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

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:

Primary Objective: To compare major adverse cardiac event (MACE) outcomes (the composite occurrence of all-cause death, MI, stroke, or unplanned coronary revascularization) within 90 days of index PCI in patients with ACS treated with prasugrel or clopidogrel.

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

Percutaneous coronary intervention

Population studied

Short description of the study population

Acute Coronary Syndrome (STEMI, NSTEMI, UA) patients at least 18 years of age at time of index Percutaneous Coronary Intervention (PCI) managed by PCI with stent implantation during the index hospitalization between 01 January 2010 and 30 June 2013 and treated with prasugrel or clopidogrel during index hospitalization either prior to, or during the peri-procedural period.

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

Renal impaired

Hepatic impaired

Estimated number of subjects

8606

Study design details

Outcomes

Composite and individual components of MACE endpoint (all-cause death,MI, stroke, and unplanned revascularization) at 90 Days. Outcomes for patients regarding demographics, clinical, and angiographic profiles and composite and individual components of MACE at 30, 180, and 365 days following index PCI and difference in rates for bleeding (inpatient and outpatient), stent thrombosis, economic resource utilization (length of stay, rehospitalization rates for MI and bleeding, and applicable costs for hospitalization.

Data analysis plan

The primary endpoint of interest is the first occurrence of MACE within 90 days from date of index PCI. Event-free patients will be censored at 90 days or last contact, whichever comes first. Crude unadjusted 90-day rates of MACE will be calculated for each group using the Kaplan-Meier method, also including index hospital events. Crude rates will be compared between groups using the logrank test. To evaluate the adjusted associations between treatment group (therapy initiation with prasugrel versus clopidogrel) and the primary MACE outcome, hazard ratios will be calculated using Cox proportional hazards regression that are stratified by the propensity to receive either prasugrel or clopidogrel. In addition to age, and gender, this model will include all baseline covariates demonstrating significant differences ($p<0.05$) between groups. From this logistic regression model, each observation will be assigned a predicted probability for prasugrel treatment.

Documents

Study results

PROMETHEUS Clinical Study Report_Final.pdf (1.82 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

Mount Sinai Medical Center United States, Aurora Health Care United States, Christiana Care Health Services United States, Cleveland Clinic United States, Intermountain Heart Institute United States

Data sources (types)

Disease registry

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