Comparative Effectiveness of Ticagrelor vs. Prasugrel in Patients With Acute Coronary Syndrome Undergoing Percutaneous Coronary Intervention

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000551

EU PAS number

EUPAS1000000551

Study ID

1000000551

DARWIN EU® study

No

Study countries

- [ ] Korea, Republic of
- [ ] United States

Study description

This study aims to compare ticagrelor and prasugrel, P2Y12 antiplatelet agents commonly used in patients with acute coronary syndrome (ACS) undergoing percutaneous coronary intervention (PCI). By conducting a direct, head-to-head comparison, this research will provide valuable insights into their associations with various ischemic and hemorrhagic outcomes. The findings are expected to inform and guide clinical decision-making, helping to optimize treatment strategies for patients with ACS.

Study status

Ongoing

Research institutions and networks

Institutions

Yonsei University

First published: 01/02/2024

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Institution

UMass Chan Medical School

Networks

Observational Health Data Sciences and Informatics (OHDSI) Network

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Network

Contact details

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 01/03/2025

Actual: 01/03/2025

Study start date
Planned: 14/04/2025

Actual: 14/04/2025

Data analysis start date
Planned: 14/04/2025

Actual: 14/04/2025

Date of final study report
Planned: 31/12/2025

Study protocol

TicaPra_Research Protocol_20250411.pdf(375.01 KB)

Github repository (study package & protocol)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This is a retrospective cohort study, comparing the incidence rates of effectiveness and safety outcomes. Data sources will be electronic health record (EHR) data & claims data in Observational Medical Outcomes Partnership Common Data Model (OMOP-CDM) format.

Main study objective:

This study is a cohort study which aims to:
I. Determine and compare the incidence rate of net adverse clinical events (NACE), a composite outcome including cardiovascular deaths, ischemic and hemorrhagic events of ticagrelor and prasugrel in ACS patients undergoing PCI.
II. Determine and compare the incidence rate of major adverse cardiovascular events (MACE) and individual outcomes, including all-cause mortality, cardiovascular mortality, ischemic events, and hemorrhagic events of ticagrelor and prasugrel in ACS patients undergoing PCI.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

BRILIQUE

Name of medicine, other

Study drug International non-proprietary name (INN) or common name

TICAGRELOR

PRASUGREL

Anatomical Therapeutic Chemical (ATC) code

(B01AC24) ticagrelor

ticagrelor

(B01AC22) prasugrel

prasugrel

Medical condition to be studied

Acute coronary syndrome

Population studied

Short description of the study population

The study population includes patients aged 18 or higher diagnosed with ACS undergoing PCI, administered with either ticagrelor or prasugrel. The index date is defined as the date of PCI, with the minimum date 2009-07-10 (the day of FDA approval of prasugrel). Patients with previous history of other major ischemic or hemorrhagic events, including stroke and gastrointestinal (GI) bleeding are excluded. Specific rules defining the index date are described below.

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Study design details

Setting

Index rule defining the index date:

• First procedure occurrence of PCI

• With age greater or equal to 18 at the index date.

• With continuous observation of at least 90 days before the event index date.

• At least 1 occurrence of a condition occurrence of ACS between 7 days before and 0 days after index start date

• At least 1 occurrence of a drug exposure to the drug of interest between 7 days before and 0 days after index start date
Inclusion rules based on the index date:
• With no exposure to the comparator/target drug between 30 days before and 0 days after index start date
• With no condition occurrence of ischemic stroke or hemorrhagic stroke before and 0 days after index start date
• With no condition occurrence of GI bleeding before and 0 days after index start date
Exit rules defining the cohort end date (on-treatment):
• Event will persist until the end of a continuous drug exposure of interest.
• Allowance for 14-day gaps between exposure records of the drug of interest.
• No additional period of surveillance after the end of the era of persistent exposure
• Censored with an exposure of clopidogrel, cangrelor or the drug of the other group

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Comparators

The target group consists of patients who were initiated with ticagrelor and who meet the criteria above. The comparator group consists of patients who were initiated with prasugrel and who meet the criteria above.

Outcomes

The primary outcome of this study is NACE, which is defined as a composite outcome of cardiovascular mortality, acute myocardial infarction (AMI), stroke (ischemic and hemorrhagic), and GI bleeding.

Among the components, cardiovascular mortality is operationally defined as

death occurrence with a condition occurrence of sudden cardiac death, AMI, stroke (ischemic or hemorrhagic), or hospitalization from heart failure.

For secondary outcomes, MACE is defined as a composite outcome of cardiovascular mortality, AMI, and stroke. An ischemic event is defined as a composite outcome of AMI and ischemic stroke. A hemorrhagic event is defined as a composite outcome of hemorrhagic stroke and GI bleeding. Each inidvidual components of the composite outcomes, as well as all cause mortality will also be evaluated.

Data analysis plan

Propensity score (PS) adjustment methods will be used to adjust for potential confounding biases originating from differences in baseline covariates. Absolute standardized mean differences (aSMD) before and after PS adjustment will be calculated to estimate the difference in patient characteristics in the two groups and how they are adjusted. Based on PS distribution, quantification of empirical equipoise will be achieved.

Incidence rates will be estimated for each group. Cox proportional hazards models will be used to estimate the hazard ratios (HR) and 95% confidence intervals (CI). Furthermore, negative control outcomes will be used for empirical calibration and minimization of potential unmeasured confounding biases.

Data management

Data sources

Data source(s), other

Yonsei University Healthcare System EHR

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

CDM version

5.4

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

No

Data characterisation moment

after extract-transform-load to a common data model

Procedures

Procedure of data extraction

Full study package Github repository link

Procedure of results generation

Full study package Github repository link