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

First published: 24/04/2025

Last updated: 05/06/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000551

Study ID

1000000551

DARWIN EU® study

No

Study countries

- ☐ Australia
- ☐ 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).

Given ongoing uncertainty from prior trials, mixed guideline recommendations, and the limitations of previous observational research, additional rigorous real-world evidence is needed to clarify optimal treatment strategies for ACS.

By conducting a direct, head-to-head comparison, this research will provide valuable insights into their comparative effectiveness and safety.

Study status

Ongoing

Research institutions and networks

Institutions

Yonsei University

First published: 01/02/2024

Last updated: 01/02/2024

Institution

UMass Chan Medical School

UT Southwestern

University of New Mexico

VUMC

Penn State Health

UNSW Sydney

Networks

Observational Health Data Sciences and Informatics (OHDSI) Network

First published: 01/02/2024

Last updated: 01/02/2024

Network

Contact details

Study institution contact

Chang Hoon Han paul9567@yuhs.ac

Study contact

paul9567@yuhs.ac

Primary lead investigator

Chang Hoon Han 0000-0002-8092-5884

Primary lead investigator

ORCID number:

0000-0002-8092-5884

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)

TicaPra_Research Protocol_20250605_final.pdf(483.15 KB)

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 hazard of major adverse cardiovascular events (MACE)
II. Determine and compare the incidence rate of net adverse clinical events (NACE) 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

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

As primary analysis, intention-to-treat design will be applied to derive 1-year outcomes.

As sensitivity analysis, intention-to-treat design will be applied to derive 1-month outcomes.

Index rule defining the index date:

• First procedure occurrence of PCI (Table 1)

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

• With continuous observation of at least 365 days before the event index date.

• At least 1 occurrence of a condition occurrence of ACS (Table 2) 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 1

day before and 1 day after index start date
Inclusion rules based on the index date:
• With no exposure to the drug of the other group or cangrelor (Table 10) between 180 days before and 0 days after index start date
• With no exposure to warfarin or direct oral anticoagulants (DOAC) (Table 6) between 180 days before and 0 days after index start date
• With no condition occurrence of ischemic stroke (Table 3) or hemorrhagic stroke (Table 4) before and 0 days after index start date
• With no condition occurrence of GI bleeding (Table 5) before and 0 days after index start date

On-treatment design will also be applied for a sensitivity analysis. In this case, the cohort exit rule described below will be applied for time at risk end.

Exit rules defining the cohort end date:
• 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 (Table 9), cangrelor or the drug of the other group

---

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 MACE, which is defined as a composite outcome of all-cause mortality, acute myocardial infarction (AMI), stroke (ischemic and hemorrhagic).

For secondary outcomes, NACE is defined as a composite outcome of all-cause mortality, AMI, stroke, and GI bleeding. 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 and cardiovascular mortality will also be evaluated.

Among the secondary outcomes, 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.

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.

Cumulative incidence 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 and quantify systematic error.

Data management

Data sources

Data source(s), other

Yonsei University Healthcare System EHR

HIRA (Health insurance review & assessment)

TriNetX (UMass Chan Medical School)

UTSW (UT Southwestern)

Merative MDCR (University of New Mexico)

VA (Veterns Affairs)

PSH (Penn State Health)

ePBRN (UNSW Sydney)

Data sources (types)

Administrative healthcare records (e.g., claims)

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