

# 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

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### Study ID

13443

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### DARWIN EU® study

No

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### Study countries

☐ United States

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## 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).

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## Study status

Ongoing

# Research institutions and networks

## Institutions

Optum

☐ Germany

**First published:** 03/01/2012

**Last updated:** 07/02/2014

Institution

Outdated

Other

ENCePP partner

# Contact details

## Study institution contact

Cliff Molife Molife\_cliff@lilly.com

Study contact

[Molife\\_cliff@lilly.com](mailto: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

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## Study start date

Planned: 01/03/2014

Actual: 01/04/2014

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## Data analysis start date

Planned: 01/05/2014

Actual: 01/06/2014

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## Date of interim report, if expected

Planned: 01/09/2015

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## 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

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**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

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**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)
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## 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.

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## 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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

Data characterisation

**Data characterisation conducted**

No