Treatment Patterns and Bleeding Risks Comparison in Patients Treated with Clopidogrel and Prasugrel during the Index Hospitalisation in Germany (H7T-MC-B008)

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Study | Finalised

Administrative details

EU PAS number

EUPAS5924

Study ID

20442

DARWIN EU® study

No

Study countries

Germany

Study description

This is a prospective non internvetional cohort study aiming to assess prasugrel treatment patterns (especially as they relate to the timing of loading dose of prasugrel treatment) and to compare bleeding risks(including bleeding risks associated with the timing of loading dose and the overall bleeding risks) between prasugrel and clopedgrel treated patients during index hospitalisation in the ALKK-PCI registry in Germany. Consecutive patienst will be prospectively enrolled into the registry over a three year period, starting 3-4 months after the launch of prasugrel in Germany. Information collected in this registry will be used to address CHMP’s requirements of comparing bleeding risks between prasugrel- treated patients and of describing the treatment patterns of prasugrel.

Study status

Finalised

Research institutions and networks

Institutions

ALKK-ATCs

Contact details

Study institution contact

Asiimwe Alex alex.asiimwe@lilly.com

Study contact

alex.asiimwe@lilly.com

Primary lead investigator

Asiimwe Alex

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/10/2009

Actual: 14/10/2009

Study start date

Planned: 01/10/2009

Actual: 01/10/2009

Date of final study report

Planned: 14/01/2013

Actual: 16/08/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company and Daiichi Sankyo, Inc.

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To compare the incidence rates (cumulative incidence) of any non-CABG related bleeding (requiring any blood transfusion of whole blood or red blood cell

concentrates RBCs) and/or intracranial hemorrhage (ICH) between prasugrel and clopidogrel patients treated for ACS-PCI (the indicated population for prasugrel) during the index hospitalisation.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Effient, Clopidegrel

Medical condition to be studied

Acute coronary syndrome

Population studied

Short description of the study population

Patients who underwent an invasive cardiac diagnostic procedure in hospitals participating in the ALKK-PCI registry.
Patients aged at least 18 years of age at study entry, had acute coronary syndrome (ACS) or treatment with prasugrel (with or without ACS), and prescribed clopidogrel or prasugrel during the index hospitalisation were included.

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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

11201

Study design details

Outcomes

Bleeding events

Data analysis plan

Descriptive summary measures were presented in tabular form for all relevant variables in the defined analysis populations and treatment groups. In addition to the total group, the calculations were done for the strata of patients with ST-segment elevation MI (STEMI), ACS without ST-segment elevation (NSTEMI or unstable angina UA), and patients without ACS if relevant. For binary variables, percentages and absolute counts of available cases and the category of interest

are shown. For categorical variables with more than two categories the frequency of each category is shown. Metrically scaled variables are presented in suitably categorized form. The distribution of the key variables of age and body weight were additionally characterized by mean, SD, median, quartiles, min and max. The propensity scores for the choice 'prasugrel treatment' were estimated from logistic regression models for the ACS population. More details on the analysis, please refer to report

Documents

Study results

B008 03 Synopsis_Part1.pdf (731.48 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

ALKK-PCI registry Germany

Data sources (types)

Disease registry

Other

Data sources (types), other

Prospective patient-based data collection

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

Unknown