A multicentre observational, prospective cohort study including patients with acute coronary syndromes undergoing percutaneous coronary intervention who receive cangrelor i.v. transitioning to either clopidogrel, prasugrel or ticagrelor per os (ARCANGELO)

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Study Finalised

Administrative details

EU PAS number

EUPAS36393

Study ID

43794

DARWIN EU® study

No

Study countries

Italy

Study status

Finalised

Research institutions and networks

Institutions

San Camillo Forlanini

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Leonardo De Luca

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 31/07/2020

Actual: 06/08/2020

Study start date
Planned: 31/10/2020

Actual: 23/10/2020

Date of interim report, if expected
Planned: 30/04/2021

Actual: 20/04/2021

Date of final study report
Planned: 31/01/2023

Actual: 20/12/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Chiesi Farmaceutici

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

To assess the safety of cangrelor in a real-world setting, when administered in patients with acute coronary syndromes undergoing PCI. The safety of cangrelor will be based on the incidence of any haemorrhage at 30 days post-PCI.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

KENGREXAL

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

CANGRELOR TETRASODIUM

CLOPIDOGREL

PRASUGREL

TICAGRELOR

Anatomical Therapeutic Chemical (ATC) code

(B01) ANTITHROMBOTIC AGENTS

ANTITHROMBOTIC AGENTS

(B01AC04) clopidogrel

clopidogrel

(B01AC22) prasugrel

prasugrel

(B01AC24) ticagrelor

ticagrelor

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)

Estimated number of subjects

1000

Study design details

Outcomes

- Any haemorrhage within 30 days post-PCI
- Moderate to severe haemorrhages according to BARC (type 3-5)
- Mild haemorrhages according to BARC (type 1-2)
- Major adverse cardiac events (MACE)
- Use of oral platelet P2Y12 receptor antagonists
- Use of glycoprotein IIb/IIIa (GPIIb/IIIa) inhibitors
- Details of PCI
- Use of cangrelor
- Transfusions
- Adverse events/reactions

Data analysis plan

The results of analyses on primary safety and secondary safety variables, efficacy variables, and all the other remaining variables will be presented by descriptive statistics (frequency count and percentage for categorical variables, number of observations, mean, standard deviation, median, quartiles, minimum and maximum for continuous variables).

Data management

Data sources

Data sources (types)

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

No