

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

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**Study ID**

43794

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**DARWIN EU® study**

No

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## Study countries

 Italy

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## 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

[leo.deluca@libero.it](mailto:leo.deluca@libero.it)

### 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

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## **Study start date**

Planned: 31/10/2020

Actual: 23/10/2020

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## **Date of interim report, if expected**

Planned: 30/04/2021

Actual: 20/04/2021

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## **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

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## 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

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Primary data collection

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**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

**Medicinal product name**

KENGREXAL

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

CANGRELOR TETRASODIUM

CLOPIDOGREL

PRASUGREL

TICAGRELOR

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**Anatomical Therapeutic Chemical (ATC) code**

(B01) ANTITHROMBOTIC AGENTS

ANTITHROMBOTIC AGENTS

(B01AC04) clopidogrel

clopidogrel

(B01AC22) prasugrel

prasugrel

(B01AC24) ticagrelor

ticagrelor

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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**

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
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### **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

## 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 sources (types)

Other

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### 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

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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