Effectiveness and safety of low dose rivaroxaban plus aspirin in patients with Chronic Coronary Syndrome and high ischemic risk. (Dutch CCS Registry)

First published: 02/06/2023

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Study Ongoing

Administrative details

EU PAS number

EUPAS105067

Study ID

105068

DARWIN EU® study

No

Study countries

Netherlands

Study description

A registry to describe the impact in terms of effectiveness and safety of the combination treatment of rivaroxaban 2.5 mg twice daily with aspirin on clinical outcomes and practices in a real-life Dutch patient population that are at high risk of ischemic events

Study status

Ongoing

Research institutions and networks

Institutions

Isala

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Institution

OLVG Amsterdam, Zuyderland Medical Centre Heerlen, Rijnstate Arnhem, Haaglanden Medical Centre Den Haag, Isala Zwolle & Meppel, Jeroen Bosch Hospital Den Bosch, Medisch Spectrum Twente Enschede, St Antonius Nieuwegein, Elisabeth Tweesteden hospital Tilburg, HAGA Den Haag Viecuri Venlo

Contact details

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Study contact

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Primary lead investigator

R.S. Hermanides

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 21/08/2020

Actual: 21/08/2020

Study start date

Actual: 21/12/2021

Date of final study report

Planned: 31/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

Clinicaltrials.gov: NCT04753372

URL:https://clinicaltrials.gov/ct2/show/NCT04753372?term=Dutch+CCS+registry&cond=C

Registration number Dutch Ethical Committee: AW21.028/W20.215

/NWMO20.09.037

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

The main objective of the study is to describe the impact in terms of effectiveness and safety of the combination treatment of rivaroxaban 2.5 mg twice daily in combination with Acetyl Salicylic Acid on clinical outcomes and practices in a real-life Dutch patient population that are at high risk of ischemic events.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

National, multicentre, prospective, single-arm, observational study

Study drug and medical condition

Medicinal product name

XARELTO

Anatomical Therapeutic Chemical (ATC) code

(B01AC06) acetylsalicylic acid

acetylsalicylic acid

Medical condition to be studied

Coronary artery disease

Peripheral arterial occlusive disease

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

1.000

Study design details

Outcomes

The primary effectiveness endpoint is a composite of: - Major Adverse Cardiac Events (MACE including ischemic stroke, cardiovascular mortality and myocardial infarction) - Clinically driven coronary, peripheral, or carotid revascularization - Stent thrombosis during one-year follow-up The primary safety endpoint is Major Bleeding during one-year follow-up. Occurrence (and date) stroke, myocardial infarction, cardiovascular death, coronary revascularization procedures (PCI, CABG), peripheral revascularization procedures, carotid revascularization procedures, peripheral revascularization procedures, minor bleeding complications (according to ISTH) All bleeding events including minor bleedings according to ISTH definitions will be reported

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Data analysis plan

The statistical analyses will be explorative and descriptive. The study is not aimed to test pre-defined hypotheses. Analyses of the clinical outcomes will be performed using the full-analysis-set (FAS) population, including all patients that received at least one dose of the study drug.

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

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