Genetic Clopidogrel response testing to finetune the antithrombotic regimen in (D)OAC Treated patients undergoing PCI

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This study has been transitioned to CTIS with ID 2024-512350-17-01 check the CTIS register for the current data. The aim of this study is to evaluate the feasibility and safety of CYP2C19-genotype-guided p2y12 inhibitor selection in patients who are...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON52157

Source
ToetsingOnline

Brief title
COATS

Condition

- Coronary artery disorders

Synonym
coronary sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Astra Zeneca,Bedrijf: Astra Zeneca

Intervention

Keyword: Genetic testing, p2y12inhibitor selection, PCI

Outcome measures

Primary outcome

Primary safety endpoint:

Major and CRNM bleeding at 12 months, compared to an objective performance goal (OPG) derived from a meta-analysis of five contemporary (D)OAC + PCI studies, estimated at 14.1%.

Primary efficacy endpoint:

Composite of all cause mortality, myocardial infarction, stroke and stent thrombosis at 12 months, compared to an OPG of 10.1% for (D)OAC + P2Y12 treated patients.

Secondary outcome

Secondary safety endpoints:

Net clinical benefit, ISTH-defined major, CRNM, and minor bleeding and any ISTH-defined bleeding, intracranial and fatal bleeding, and bleeding as per the Bleeding Academic Research Consortium (BARC) and Thrombosis in Myocardial Infarction (TIMI) definitions.

Secondary efficacy endpoints:

Stroke, ischaemic stroke, haemorrhagic stroke, systemic embolic events, myocardial infarction, definite stent thrombosis, probable stent thrombosis, all-cause death, cardiovascular death, and cardiovascular or unexplained death.

Angina frequency and stability, physical limitations, treatment satisfaction

and quality-of-life

Study description

Background summary

Patients on oral anticoagulation drugs who undergo a percutaneous coronary intervention (PCI) temporarily need concomitant antiplatelet therapy. The risk of bleeding in this context is a concern. Genotype-guided p2y12-inhibitor selection is gaining ground in clinical practice to help guide safe antiplatelet drug selection. It is unclear whether CYP2C19 genotyping is safe and could improve antithrombotic strategy selection for patients who are indicated for treatment with a (non-)vitamin K antagonist ((D)OAC) and require a percutaneous coronary intervention (PCI).

Study objective

This study has been transitioned to CTIS with ID 2024-512350-17-01 check the CTIS register for the current data.

The aim of this study is to evaluate the feasibility and safety of CYP2C19-genotype-guided p2y12 inhibitor selection in patients who are indicated for (D)OAC and require PCI. Both safety and efficacy outcomes will be captured. Also a cost-benefit analysis, assessment of quality-of-life and predictors of bleeding and ischemic outcomes will be studied.

Study design

This study is a prospective, multicenter cohort study

Study burden and risks

At the time of PCI, genotyping will be done either by standard laboratory-based research or point-of-care testing by oropharyngeal swab. Blood samples (if necessary) are drawn from venepuncture or from the arterial access sheath which was used for PCI. There are no major risks or benefits for individual patients included in this study. The study results of the different patient groups will provide insight in the antithrombotic strategy selection for patients who are indicated for treatment with a (non-)vitamin K antagonist ((D)OAC) and require a percutaneous coronary intervention (PCI).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Patients >= 18 years of age
• Patients indicated for indefinite (D)OAC
• Patients undergoing successful PCI for stable or unstable (ACS) coronary artery disease
• Patients with written informed consent as approved by the ethics committee

Exclusion criteria

• Contraindication to aspirin • Contraindication to ticagrelor or clopidogrel • Under the age of 18 years • Planned cardiac surgery • Life expectancy < 1 year • Unable or unwilling to provide informed consent • Pregnancy • Suboptimal

result of stenting as defined by the operator • Need for continued triple antithrombotic therapy per treating physician • Any other condition putting patient at excessive risk for bleeding with ticagrelor • Use of gp2b3a inhibitor • Treatment with a strong CYP3A4 inhibitor or inducer • History of definite stent thrombosis

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-04-2023
Enrollment:	520
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Brilique
Generic name:	Ticagrelor
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Plavix
Generic name:	Clopidogrel
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	26-04-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-10-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-07-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-01-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EU-CTR	CTIS2024-512350-17-01
EudraCT	EUCTR2022-001093-55-NL
CCMO	NL77315.078.22