Dual-AntiPlatelet Therapy strategies FOR elective PCI in a REAL-world setting

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To assess whether the in-laboratory strategy is non-inferior to the preloading strategy in patients planned for diagnostic CAG with optional ad-hoc PCI.

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

Summary

ID

NL-OMON51842

Source
ToetsingOnline

Brief title
DAPT for REAL

Condition

- Coronary artery disorders

Synonym
Coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Clopidogrel, Diagnostic coronary angiography, Pretreatment

Outcome measures

Primary outcome

The difference in occurrence of the composite endpoint 'Net Adverse Clinical Events' (NACE; all-cause death, myocardial infarction, definite/probable stent thrombosis, stroke and BARC type 2, -3 or -5 bleeding) assessed at 30 days.

Secondary outcome

To assess the difference in :

- Bleeding Academic Research Consortium (BARC) -2, -3 and -5 bleeding in-hospital and at 30 days

- The composite endpoint 'Patient Oriented Clinical Events' (POCE; all-cause death, stroke, myocardial infarction, repeat revascularization) in-hospital and at 30 days

- Individual endpoints of the composite endpoints POCE / NACE in-hospital and at 30 days

Study description

Background summary

In the contemporary national and international practice, two medication strategies are used for patients that are referred for diagnostic coronary angiography with optional ad-hoc PCI treatment. The first strategy includes a pretreatment period of several (3-5) days in which all patients are treated with a low dose of clopidogrel prior to the procedure (preloading strategy). Patients treated according to the second strategy, receive a clopidogrel loading dose in the catheterization laboratory but only after the indication for ad-hoc PCI is made (in-laboratory loading). The two locations of the recently merged Amsterdam University Medical Center (AUMC) both use a different medication strategy in this patient group. With this prospective observational registry we want to investigate whether the 'in-laboratory' strategy is non-inferior to the 'preloading' strategy. If clopidogrel preloading could be

omitted in patients referred for diagnostic CAG, then it would lead to a reduction in unnecessary medication intake, less inconvenience for patients and lower healthcare costs. This prospective registry will determine the future policy of the AMC for patients referred for diagnostic CAG.

Study objective

To assess whether the in-laboratory strategy is non-inferior to the preloading strategy in patients planned for diagnostic CAG with optional ad-hoc PCI.

Study design

A prospective registry.

Intervention

The first group will receive a 600mg loading dose of clopidogrel directly before start of PCI (in-laboratory group), while the second group will receive clopidogrel 75mg once daily 3 days before diagnostic coronary angiography with optional ad-hoc PCI (preloading group).

Study burden and risks

Follow-up data at 30 days will be collected by (telephone) questionnaire. The risks associated with participation to this registry can be considered negligible and the burden can be considered minimal, because this study evaluates outcomes in common practice loading strategies that are already used in the AUMC.

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

- Adult men and women aged at least 18 years
- Scheduled for diagnostic CAG due to suspected obstructive coronary artery disease

Exclusion criteria

- Inability to give informed consent (e.g., language barrier)
- Presence of contra-indications for the use of clopidogrel
- Patients using clopidogrel for other reasons than the scheduled diagnostic CAG
- Patients using P2Y12 inhibitors other than clopidogrel
- Patients using VKA
- Patients using DOAC/NOAC

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2022
Enrollment:	1462
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	01-08-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-08-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-01-2024
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam

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Approved WMO Date:	22-01-2024
Application type:	Amendment
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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
EudraCT	EUCTR2021-006072-16-NL
CCMO	NL79315.018.22