Monitoring the effect of oral anticoagulants during cardiac catheterisation

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1) to investigate if patients on chronic NOAC treatment are sufficiently anticoagulated without additional UFH during CAG/PCI, and 2) if this sufficient anticoagulation can be confirmed pre-procedure by a point-of-care test, and3) to investigate if...

Ethical review	Approved WMO
Status	Completed
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON50931

Source
ToetsingOnline

Brief title
POPular MEASURE trial

Condition

- Coronary artery disorders

Synonym
coronary artery disease, percutaneous coronary intervention

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: St. Antonius Ziekenhuis

Intervention

Keyword: anticoagulation, cardiac catheterisation, heparin, NOAC

Outcome measures

Primary outcome

Laboratory measurements

1) APTT, PT

2) Fibrinogen, D-dimer, fibrinopeptide A and B, trombin generation test,

soluble fibrin

3) factor XIIa and kallikrein; XIa, IXa, Xa- in complex with inhibitors and

prothrombin fragment 1+2

4) Anti-Xa

5) Soluble platelet release markers including P-selectin, GpVI, CD40L etc.

6) T-TAS

Point-of-care tests

1) ClotPro IN, HI, RVV, ECA, and NA-tests

2) TEG: global haemostasis assay

3) Activated Clotting Time (ACT)

Secondary outcome

Clinical events related to bleeding or thrombosis at discharge, and after 30

days

Study description

Background summary

During coronary angiography and/or percutaneous coronary intervention (PCI) additional anticoagulation with unfractionated heparin (UFH) is recommended by international guidelines to prevent catheter thrombosis and thrombotic complications.1,2 In patients using chronic vitamin K antagonist (VKA) treatment, the use of peri-procedural UFH, however, is associated with an increased risk of access site complications after PCI (mainly bleeding), without benefit in thrombotic complications.3 Bleeding after PCI has been shown to be related to both short- and long-term mortality4, and thus should be prevented by minimizing antithrombotic therapy where possible. Therefore, for patients using VKA with an INR > 2.5 no additional UFH is recommended.1 For NOACs it is yet unknown if UFH can be omitted, and thus current guidelines still recommend additional UFH for patients using NOAC.1

Study objective

1) to investigate if patients on chronic NOAC treatment are sufficiently anticoagulated without additional UFH during CAG/PCI, and
2) if this sufficient anticoagulation can be confirmed pre-procedure by a point-of-care test, and
3) to investigate if patients treated with chronic NOAC with additional periprocedural UFH are hypocoaguable during CAG/PCI

To be in the end able to omit periprocedural heparin, to reduce procedure related bleeding complications

Study design

Randomized controlled trial

Intervention

Group 1 (reference cohort)
40 patients without chronic NOAC treatment undergoing elective CAG or PCI with peri-procedural UFH

Group 2 (NOAC cohort)
80 patients with chronic NOAC treatment undergoing elective CAG/PCI
1:1 randomized to:
Arm 2a: continuation of NOAC with additional peri-procedural UFH
Arm 2b: continuation of NOAC without additional UFH

Study burden and risks

Blood draws will be taken from a routinely placed IV catheter that also would

be placed during a procedure without study participation. The timing of blood draws will be within the standard admission duration of 4 hours after PCI. So with blood sampling there will be no extra burden for the patients apart from the blood that will be drawn.
Patients participating in group 1 will not have possible benefit since they serve as reference group. Also their risk is very limited, since only blood will be drawn.
Patients participating in group 2 would usually be treated following the guideline recommendations with NOAC plus UFH, if not participating in this study.
Patients randomized to group 2a will be treated according to this guideline, so there will not be a possible benefit or risk compared to usual treatment, apart from that extra blood will be drawn.
Patients randomized to group 2b might have a slight risk of insufficient anticoagulation since UFH will be withhold compared to the standard treatment. However, clinical end point data from VKA, and laboratory data with NOACs seem to indicate that this is safer and equally effective (see study protocol chapter 1 and Table 1). Also, as in all study patients, extra blood will be drawn compared to standard treatment.

Contacts

Public
Sint Antonius Ziekenhuis

Koekoekslaan 1
Nieuwegein 3435CM
NL
Scientific
Sint Antonius Ziekenhuis

Koekoekslaan 1
Nieuwegein 3435CM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patient must meet all of the following criteria:
- Male or female >= 18 years
- Undergoing non-emergent CAG or PCI
- Loaded with P2Y12 inhibitors before PCI
- Patients with signed informed consent

Exclusion criteria

Patients who fulfill the above mentioned inclusion criteria but who manifest any of the following exclusion criteria will not be eligible for the study: - Patients with hematologic, renal (estimated glomerular filtration <30 ml/min/1.73m2), hepatic (liver enzymes >2 times the upper limit of normal), inflammatory (CRP >2 times the upper limit of normal) or neoplastic disorders - Patients using nonsteroidal anti-inflammatory drugs, corticosteroids, or hormone replacement therapy

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	01-02-2022
Enrollment:	120
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Heparin 5000 IU/ml
Generic name:	Heparin 5000 IU/ml
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	04-03-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	16-03-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	16-01-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	EUCTR2020-005298-29-NL
CCMO	NL75820.100.20