Measuring the Activated Clotting Time in patients receiving unfractionated heparin prior to coronary angiography and intervention. A single-centre validation study comparing different blood sampling sites

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This study aims at establishing the influence of sampling site on the variability of ACT measurement at the end ofcoronary angiography or PCI.

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

Summary

ID

NL-OMON44549

Source
ToetsingOnline

Brief title
Validation of ACT measurements

Condition

- Coronary artery disorders

Synonym
coronary artery disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: activated clotting time, coronary angiography, heparin

Outcome measures

Primary outcome

Variability in ACT measurements at different blood sampling sites at the end of

coronary angiography or intervention in

patients receiving pre-procedural UFH.

Secondary outcome

N.A.

Study description

Background summary

The current era of coronary angiography and intervention in a progressively aging and frail population- bids for a feasible and clear protocol regarding the adiministration of UFH and measuring its level of anticoagulation. The activated clotting time (ACT) reflects UFH activity and has been used for decades to monitor or adjust heparin dosage.1 However, no definite guidelines regarding ACT measurements exist. The ACT measurements could be obtained from venous as well as arterial blood samples. Theoretically, sampling blood from heparin-coated access
sites (i.e. arterial sheath, diagnostic or guiding catheter) might influence ACT measurement and result in an incorrect representation of coagulation level. It goes within saying that underestimation or overestimation of coagulation level might jeopardize adequate coronary treatment and patient well-being.

Study objective

This study aims at establishing the influence of sampling site on the variability of ACT measurement at the end of

coronary angiography or PCI.

Study design

Prospective, single-center observational study

Study burden and risks

The burden of participation solely consists of obtaining extra blood from the three sample sites (i.e. approximately 10cc
of blood). Therefore, there are no risks in participation, but benefit is also small since the treatment does not differ from
routine practice.

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

Consecutive patients scheduled for diagnostic coronary angiography or elective percutaneous coronary intervention (PCI) are screened for entry into this study. Patient are eligible for this study when it is expected that the scheduled procedure will be accomplished with a single bolus of heparin, i.e. patient undergoing a procedure with expected duration of > 1 hour will not be included in this study.

Exclusion criteria

- Use of novel oral anticoagulants or vitamin K antagonists
- Chronic use of non-steroid anti-inflammatory drugs with the exception of aspirin
- Known renal insufficiency (e.g. serum creatinine level of more than 265 *mol/L (i.e. more than 3.5 mg/L))
- Liver function disorders with coagulopathies (PT >1.5N, INR >2.0 and/or thrombocyte count < 100 x 109/L)
- Suspicion of unstable coronary artery disease with chest pain in rest, ECG changes, elevated cardiac markers, or hemodynamic instability at the time of the procedure
- Unability to read and understand the Dutch language
- Previous participation in this study

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2018
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO Date:	23-11-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL63160.094.17