Coronary Artery Plaque Characterisation with Non-invasive Multi-Slice Computed Tomography and Invasive Intravascular Ultrasound and Optical Coherence Tomography in Patients with Acute Coronary Syndromes Without ST-segment Elevation

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The objective of this study is to compare coronary artery plaque characteristics between non-invasive MSCT, and invasive IVUS and OCT in patients presenting with ACS without ST-elevation (non-ST elevation myocardial infarction (NSTEMI)).

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

Summary

ID

NL-OMON36442

Source
ToetsingOnline

Brief title
Non-invasive and invasive plaque characterisation

Condition

- Coronary artery disorders

Synonym
atherosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: acute coronary syndromes, computed tomography, coronary artery plaque, intravascular ultrasound

Outcome measures

Primary outcome

The accuracy of coronary plaque characterization with MSCT as compared to IVUS

and OCT will be investigated. In addition, the correlation between plaque

characteristics and clinical characteristics (gender and diabetes) will be

explored.

Secondary outcome

not applicable

Study description

Background summary

Multi-slice computed tomography (MSCT) enables non-invasive coronary plaque characterization. Potentially, non-invasive MSCT may improve risk stratification. Intravascular ultrasound (IVUS) and optical coherence tomography (OCT) allow invasive and more accurate characterization of coronary atherosclerotic plaques as compared to MSCT, and accordingly may enhance our understanding on plaque imaging with MSCT. A high correlation between coronary plaque composition was observed between MSCT and IVUS. Nevertheless, the data on comparison of coronary plaque characteristics between non-invasive MSCT and OCT in particular in patients presenting with acute coronary syndromes (ACS) are scarce.

Study objective

The objective of this study is to compare coronary artery plaque characteristics between non-invasive MSCT, and invasive IVUS and OCT in patients presenting with ACS without ST-elevation (non-ST elevation myocardial infarction (NSTEMI)).

Study design

Single-center, prospective, observational study.

Intervention

The participants will undergo extra examinations. 1) A MSCT examination preliminary of the percutaneous coronary intervention; and 2) during the percutaneous coronary intervention a IVUS and OCT examination.

Study burden and risks

Based on currently available clinical evidence, risks related to the devices used in this study are comparable to standard equipment used. Dual source MSCT is performed in routine clinical practice and is considered as safe, non-invasive investigation, although it involves administration of contrast medium, and the use of radiation. Accordingly, only patients with good kidney function and with no prior history of allergy to contrast agents will be included in the study. The MSCT study protocols with the least possible radiation exposure will be applied, so that exposure favourably compares to other non-invasive clinical investigations (such as myocardial perfusion scintigraphy).

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

- Chest pain suggestive for myocardial ischemia for at least 30 minutes;
- Electrocardiogram (ECG) with ST-segment shifts (ST-segment depression >1 mm in at least two contiguous leads or transient ST-segment elevation > 1mm with duration of < 30 min in at least two contiguous leads) and/or T-wave changes (T-wave inversion > 1.5 mm in at least three contiguous leads);
- Positive hs Troponin T > 14 ng/L or positive Troponin T <0.01 µg/L
- Clinical indication for invasive coronary angiography followed by PCI of the ischemia-related target lesion;
- Informed consent.

Exclusion criteria

- Persistent ST-elevation of >1 mm in 2 or more leads;
- Need for emergency invasive coronary angiography and PCI;
- Need for emergency coronary artery bypass grafting;
- Presence of cardiogenic shock;
- Estimated glomerular filtration rate (eGFR) < 50 ml/min;
- Known allergy to iodine contrast agents;
- Cardiac rhythms other than sinus rhythm;
- Inability to lay supine;
- Inability tot sustain a breath-hold for 15 seconds;
- Inability to provide informed consent.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-06-2011
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	15-04-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-12-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL33521.042.10