Serial plaque changes predicting cardiovascular events

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Evaluate the natural history of coronary artery disease and evaluate whether mid- to long-term plaque progression and changes measured with CCTA imaging can effectively predict CV events.

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

Summary

ID

NL-OMON54890

Source
ToetsingOnline

Brief title
SPECTRE

Condition

- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
atherosclerosis arteriosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Top Medical,Unrestricted research grant Top Medical

Intervention

Keyword: CCTA, CVD, plaque

Outcome measures

Primary outcome

The main parameter to study will be the mean plaque progression measured with follow-up CCTA imaging comparing between patients with and without MACE.

Secondary outcome

The secondary study parameters to be studied will be the following:

* Number of high risk plaque features, i.e.:

o positive remodelling (RI>1.1)

o low attenuation plaque (* 30 HU)

o spotty calcification

o napkin ring sign

* Relative mean plaque progression

* Difference in non-calcified plaque volume between baseline and follow-up CCTA (delta non-calcified plaque volume)

* Difference in calcified plaque volume between baseline and follow-up CCTA (delta calcified plaque volume)

* Coronary calcium score

* Plasma biomarker expression

Study description

Background summary

With the increasing burden of coronary artery disease (CAD), we are still unable to identify patients at highest risk for recurrent events. With the arrival of high-cost novel therapeutics, identifying these high-risk patients is crucial. Recent studies have suggested that plaque progression over time is an important predictor of cardiovascular (CV) events.

Study objective

Evaluate the natural history of coronary artery disease and evaluate whether mid- to long-term plaque progression and changes measured with CCTA imaging can effectively predict CV events.

Study design

Multicenter, observational, cross-sectional study

Study burden and risks

Participating subjects in this study receive no direct clinical benefits from participation in this study. The burden and risk of participating in this study is estimated to be low. The study requires one visit (90 minutes). Blood withdrawal for clinical laboratory assessment will be 18 ml. Patients will be exposed to a limited radiation burden related to CCTA imaging of 6 mSv. Furthermore, there is a small risk of contrast nefropathy.

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

- Aged 50 years and older
- Underwent CCTA imaging for clinical indications between 2008 and 2014
- Able to provide written informed consent

Exclusion criteria

- Renal insufficiency, defined as eGFR < 30 ml/min
- Atrial fibrillation
- Any other treatment or clinically relevant condition that could interfere with the conduct or interpretation of the study in the opinion of the investigator
- Inability or unwillingness to comply with the protocol requirements, or deemed by investigator to be unfit for the study.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-11-2020
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	22-06-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-07-2021
Application type:	Amendment
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	NL73195.029.20