Proteomics and genomics combined with CT to predict CVD

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To evaluate the predictive value of a combined risk score of proteomics, polygenic risk score and baseline CCTA imaging for ASCVD risk.

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

Summary

ID

NL-OMON53785

Source
ToetsingOnline

Brief title
PREDICT-CVD

Condition

- Coronary artery disorders

Synonym
atherosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: AMC Foundation

Intervention

Keyword: cardiovascular disease

Outcome measures

Primary outcome

The main parameter to study will be the total coronary plaque volume

progression.

Secondary outcome

• Presence of obstructive stenosis (and number of vessels)

• Progression in number of significant (>50%) and severe (>70%) stenoses

• Absolute total plaque volume progression (mm3)

• Calcified plaque volume progression (mm3)

• Non-calcified plaque volume progression (mm3)

• Low-attenuation plaque volume progression (mm3)

• Change in Pericoronary Adipose Tissue CT-Attenuation (HU)

• CAD-RADS progression (yes/no)

• Progression in number of high-risk plaque characteristics (yes/no).

Study description

Background summary

Identification of patients at greatest atherosclerotic cardiovascular disease (ASCVD) risk remains a major challenge in both primary prevention and secondary prevention. With the introduction of high-throughput targeted proteomics, polygenic risk scoring and improved coronary computed tomography angiography (CCTA), combined with the advances in machine learning technologies, ample opportunities for improved ASCVD risk prediction have arisen.

Study objective

To evaluate the predictive value of a combined risk score of proteomics, polygenic risk score and baseline CCTA imaging for ASCVD risk.

Study design

Single center, observational, cohort study

Study burden and risks

The results of this study can contribute to the improved ASCVD risk stratification in primary prevention to identify patients at high risk of ASCVD.

Participating subjects in this study receive no direct clinical benefits from clinical CCTA imaging. However, the expected risk for participants is low. The most important risk in this study is radiation exposure. However, the maximum exposure related to CCTA imaging is 2.8 mSv. This a low radiation exposure and is comparable to the yearly dose of background radiation in the Netherlands. Furthermore, ionized contrast agents will be used during CCTA, which can be nephrotoxic and may elicit allergic reactions. In addition, incidental extra-coronary findings, such as pulmonary malignancies, can be a potential benefit from CCTA imaging since early detection of these findings may enable early treatment. Cardiac findings, except for left main stenosis, will be blinded until follow-up is completed.

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 subjects between 50 and 75 years old.
- Subjects at intermediate to high risk for ASCVD
- Asymptomatic subjects without cardiac chest pain
- Evidence of atherosclerosis on baseline CCTA

Exclusion criteria

- Renal insufficiency, defined as eGFR < 30 ml/min
- History of cardiovascular events (myocardial infarction, peripheral artery disease and ischemic stroke)
- Use of lipid lowering therapy other than statin, ezetimibe or bempedoic acid monotherapy
- Change in lipid lowering therapy in the last 6 months
- Use of more than two antihypertensive agents
- No coronary atherosclerosis at baseline imaging
- Active malignancy requiring treatment
- 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:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-01-2023
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	21-09-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-03-2023
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	NL81913.018.22