Expanding the pheno- and genotype of premature atherosclerosis.

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to identify novel molecular pathways resulting in premature atherosclerosis (PAS) in families where the traditional risk factors are not present / near absent.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON44418

Source
ToetsingOnline

Brief title
EXPAT study

Condition

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

Synonym
premature atherosclerosis, young cardiovascular disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medische Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiovascular disease, Premature atherosclerosis

Outcome measures

Primary outcome

To unravel the cause(s) of the PAS phenotype in patients with (near) absence of

traditional risk factors.

Secondary outcome

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Study description

Background summary

Cardiovascular Disease (CVD) is a leading cause of mortality and morbidity worldwide. A number of CVD risk factors such as smoking, hypertension, diabetes, obesity and dyslipidemias have been well established and are currently used in CVD risk prediction tools. In addition to these factors, several studies have confirmed that a family history of CVD is an independent risk factor, which suggests that other genetic factors (with no direct effect on the traditional risk factors) are of clinical relevance. However, the genetic basis for CVD is still not completely understood, and identification of these genes is of great interest, not only for our understanding of CVD, but also for the development of potential therapeutic strategies. These novel genes are most likely to be identified in families where a *non-explained* premature form of atherosclerosis is observed.

Study objective

to identify novel molecular pathways resulting in premature atherosclerosis (PAS) in families where the traditional risk factors are not present / near absent.

Study design

case-control study, cross-sectional.

Study burden and risks

The burden for all participants is a venous puncture. The risks associated with this procedure are hematomas or bleeding.
In a selected population we will perform DNA analysis (genome sequencing, and or epigenetic profiling. We will report genetic data to the patient and his/her GP in accordance to the regulations set forward by the AMC
A CT scan is performed in family members without clinical manifestations of CVD. The exposure to radiation is 4.1 mSv for 1 CT scan in this study.
The individual patient might gain direct *health* benefit from participating in this study by obtaining a full CVD risk profile, which might result in a medical advise to either change the life style or start with CVD risk lowering medication (according to EAS/ESC guidelines).

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

males with cardiovascular event before age of 50.
females with cardiovascular event before age of 55.
family members of patients with premature atherosclerosis.

Exclusion criteria

males with cardiovascular event before age of 50 caused by known cardiovascular risk factors.
females with cardiovascular event before age of 55 caused by known cardiovascular risk factors.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	150
Type:	Anticipated

Ethics review

Approved WMO

Date:	22-01-2018
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	NL63297.018.17