The endothelial glycocalyx in premature cardiovascular disease

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To investigate the relation between premature cardiovascular disease and glycocalyx perturbation

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

Summary

ID

NL-OMON33709

Source
ToetsingOnline

Brief title
PreA

Condition

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

Synonym
coronary artery disease, coronary atherosclerosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: glycocalyx, premature cardiovascular disease

Outcome measures

Primary outcome

Assessment of the glycocalyx by Sidestream Dark Field Imaging (SDF) before and

after NTG

Secondary outcome

Assesment of risk factors through blood samples (diabetes/cholesterol levels)

Assesment of PWV

Study description

Background summary

Further improvement in cardiovascular disease management in high-risk individuals calls for novel strategies to detect early atherosclerotic changes, before overt cardiovascular disease exists. This would lead to the selection and treatment of individuals at risk in an early phase. Family members of subjects with premature cardiovascular disease are such a high risk group, although it is still not possible to asses individual risk, apart from risk factor scores. The endothelial glycocalyx, is a component of the vasculature and has been associated with surrogate endpoints of early cardiovascular disease. This inner layer of the vessel wall exerts potent anti-atherogenic effects in vivo. To enlighten the protective role of the glycocalyx on the vascular endothelium more knowledge is needed in several disease states. We therefore, hypothesize that glycocalyx volume is diminished in subjects with premature atherosclerosis and in part also in yet unidentified, seemingly unaffected first degree relatives.

Study objective

To investigate the relation between premature cardiovascular disease and glycocalyx perturbation

Study design

Observational study

Study burden and risks

The nature of the burden consists of an approximately 12 hour fasting period previous to a one hours visit to our clinical trial unit. The patients will visit the hospital on one occasion. During this visit, the patients will be asked to fill out a short questionnaire and undergo a short physical examination. Furthermore, SDF measurement (non-invasive imaging of the sublingual microcirculation), PWV measurement and venapuncture (blood withdrawal of 11.5 ml) will be done. Patients will be asked to postpone medication in take until after the test-visit and refrain from smoking 24 hours before the start of the visit.

The benefit of this investigation lies in the fact that this method provides the use of a unique technique to investigate early atherosclerotic vascular changes. If our expectations are confirmed, this might renders us a tool which will be able to identify seemingly unaffected subjects in an early stage at risk for cardiovascular disease. The identification of these subjects makes it possible to treat them early on in their disease and hopefully thereby prevent overt atherosclerotic disease. Furthermore, this is the first large scale study on human glycocalyx measurement, since we use a novel technique. Since the systemic measurement of the glycocalyx, previously used, is rather invasive and time consuming, this is not the ideal method to use on a large scale. Recently, we were able to develop an accurate, non invasive technique, to measure glycocalyx thickness, which enables us to investigate the glycocalyx in large population samples.

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

Men with a first cardiovascular event under de age of 41, woman under the age of 46.
Furthermore a positive family history for CVD

Exclusion criteria

A positive history for hypertension, diabetes mellitus or other malignant or chronic inflammatory disease.
Pregnancy or lactating women

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2008
Enrollment:	420
Type:	Anticipated

Ethics review

Approved WMO

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	NL24376.018.08