Non-invasive glycocalyx measurements in premature atherosclerosis

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

Summary

ID

NL-OMON33763

Source
ToetsingOnline

Brief title
Non-invasive glycocalyx measurements in PA

Condition

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

Synonym
Atherosclerosis, vascular abnormalities

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Nederlandse Hartstichting

Intervention

Keyword: Atherosclerosis, Glycocalyx, Premature

Outcome measures

Primary outcome

Change in glycocalyx volume, before and after sublingual nitroglycerine

administration between the different study groups

Secondary outcome

To compair the glycocalyx volume of the different study groups we measure this

year, with last year's measurements.

Study description

Background summary

The pathophysiology of premature atherosclerosis is poorly understood. Patients often display few risk factors, but the clinical manifestations are evident. If atherosclerosis is expressed at a very young age, it is likely that besides the classical risk factors genetic factors play an important role. Therefore, it is of relevance to develop a methode, which can identify subjects at risk at an early stage. The detection of early vascular alterations is therefore of major importance, especially in unaffected subjects of families with premature atherosclerosis. A dimished glycocalyx volume is thought to represent early vascular injury and therefore seems the ideel target for investigation.
From our previous research, we showed that subjects with premature atherosclerosis had a smaller glycocalyx volume as compared to healthy subjects. Unfortunately, we used an invasieve technic to establish glycocalyx volume. If we can develop a new non-invasive method (OPS imaging) to measure glycocalyx volume, this would lead to the development of a better tool, to detect early vascular alterations. This could lead to a method that is applicable in large scale patient populations.
For this purpose we will investigate the glycocalyx volume in subjects with premature atherosclerosis and healthy control subjects.

Study objective

Our primary objective is to measurec glycocalyx volume with OPS imaging, before

and after sublingual nitroglycerine-spray administration, in patients with premature atherosclerotic disease before the age of 40 years and a positiev family history for cardiovascular disease and to compare this with a age and sex matched healthy control group.

Study design

The study will be an observational case control study.

Study burden and risks

The research consists of a single 30 minutes lasting visit to the azM. Subjects will come fasted, meaning that they can't eat, drink or smoke in the 12 hours before the research. Drinking of water is permitted. The ivestigation will start with a short questionairre concerning medication use and clinical history. After that, two non-invasive sublingual OPS glycocalyx imaging measurements will be made, before and after sublingual nitroglycerine-spray administration. De risks of applying his drug is minimal, patients could suffer from a headache, which can be antagonated by a cop of coffee.

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

Cases: - a cardiac, cerebral or peripheral vascular disease before the age of 40 - a positive family history for cardiovascular disease, defined as a first degree family member with a cardiovascular event before the age of 55 for men and 60 for women. Furthermore, they should be between the age of 36 and 56 years old. Controls: -Controls will be defined as healthy in case they have no cardiovascular history, such as no cardiac, cerebrovascular or peripheral artery disease and no complaints of angina, claudication or TIA and no family history for cardiovascular disease. Furthermore, they should be between the age of 36 and 56 years old.

Exclusion criteria

Cases: - a positive history for hypertension or diabetes mellitus - pregnancy or lactating women - subjects below the age of 18 - unable to give informed consent Controls: Diseases mentioned at the inclusioncriteria.

Study design

Design

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

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	15-08-2009
Enrollment:	40
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	01-04-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL26075.068.08
Other	Nog niet bekend.