Glycocalyx measurements in premature atherosclerosis

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Our objective is to measure systemic glycocalyx volume in patients with premature atherosclerotic disease before the age of 40 years and to compare this with a age and sex matched healthy control group.

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

Summary

ID

NL-OMON30991

Source
ToetsingOnline

Brief title
Glycocalyx measurements in premature atherosclerosis

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: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Hartstichting

Intervention

Keyword: Atherosclerosis, Glycocalyx, Premature

Outcome measures

Primary outcome

Changes in the volume of the intravascular glycocalyx between the different

subjectgroups.

Secondary outcome

Not applicable.

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 there are also genetic factors that play an important role. Furthermore, there is a big impact on the yet unaffected family members which would like to know their liability to develop atherosclerosis. The detection of early vascular alterations could provide this answer. One of these early vascular alterations might be the changes of the vascular glycocalyx. If indeed this methodes functions within this hospital and appears to be succesfull, this might render us the oppertunity to study nonaffected family members aswell. We therefore hypothezise that subjects with premature atherosclerosis have a diminished glycocalyx volume as compared to healthy control subjects. For this purpose we will investigate the glycocalyx volume in subjects with premature atherosclerosis and healthy control subjects.

Study objective

Our objective is to measure systemic glycocalyx volume in patients with premature atherosclerotic disease before the age of 40 years and to compare this with a age and sex matched healthy control group.

Study design

The study will be an observational case control study.

Intervention

Not applicable.

Study burden and risks

The research consists of a single 2.5 hours lasting visit to the azM. Subjects have to be fasted, meaning that they can't eat, drink or smoke in the 12 hours before the research. Drinking of water is also prohibited. Preceding to the research, a short interview is taken concerning medication use and clinical history. Furthermore, a short physical examination will be done, in which length, weight and bloodpressure will be determined.
Next, a venflon catheter will be inserted in both arms. A total of 17 blood samples will be taken (3 x 1 ml, 12 x 7 ml, 1 x 15 ml and 1 x 40 ml). Also, Dextran 1 (10 ml), fluorescently labelled erythrocytes and dextran 40 (140ml) will be infused. As mentioned earlier, there is a small chance to a serious allergic reaction to Dextran 40 (1:2.000) This can be diminished after a bolus infusion of Dextran 1 to 1:70.000. Futhermore subject's skin and urine might take on a yellow-orange discolouration as a reaction to sodiumfluorescein, for maximum 24 hours. Furthermore because of this subjects are advised to stay out of the sun for 24 hours.

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 35 and 55 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 35 and 55 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:	Interventional
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):	15-10-2007
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	08-10-2007
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	NL17929.068.07