Association between endothelial glycocalyx volume and cardiovascular risk scores

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The principal aim of this study is to examine whether glycocalyx volume, as estimated by SDF-imaging, is associated with cardiovascular risk as estimated by conventional risk scores.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vascular disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON37440

Source
ToetsingOnline

Brief title
Endothelial glycocalyx and cardiovascular risk

Condition

- Vascular disorders NEC

Synonym
Atherosclerosis; cardiovascular disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: AMC flex AIO grant to BJH van den Born

Intervention

Keyword: Cardiovascular risk profile, Endothelium, Glycocalyx

Outcome measures

Primary outcome

Association between estimated glycocalyx volume and cardiovascular risk as estimated by conventional risk scores.

Secondary outcome

- Variation of estimated glycocalyx volume in the entire study population.

- Variation of estimated glycocalyx volume in subgroups of patients divided by predicted cardiovascular risk.

Study description

Background summary

Further improvement in cardiovascular disease management in individuals calls for novel strategies to detect early atherosclerotic changes, before overt cardiovascular disease exists.
The endothelial glycocalyx ,recently emerged as an important regulator of vascular homeostasis and perturbation of this structure, has been associated with cardiovascular disease. The endothelial glycocalyx may therefore be a potential target for treatment as well as for the identification of individuals at increased risk for cardiovascular disease. Thus far however, non-invasive measurement of glycocalyx volume was not possible. Therefore, glycocalyx properties have only been investigated in small selected patient groups. Estimation of endothelial glycocalyx volume by Sideview Dark-Field (SDF) imaging of the sublingual microcirculation may be a promising technique. Large-population data are however not yet available. In this study, we aim to asses the association of glycocalyx volume as estimated by SDF-imaging with conventional cardiovascular risk scores. We hypothesize that the estimated glycocalyx volume is diminished in subjects with higher cardiovascular risk scores.

Study objective

The principal aim of this study is to examine whether glycocalyx volume, as estimated by SDF-imaging, is associated with cardiovascular risk as estimated by conventional risk scores.

Study design

This is a cohort study. Patients will attend one visit in which they will be subjected to a questionnaire and sublingual visualization of the microcirculation using the SDF-camera. The questionnaire will be used to assess the cardiovascular risk profile of individuals. In addition to general information such as date of birth, gender and ethnicity, information will be gathered on the medical history, medication use, intoxication and family history. The questionnaire will be completed in approximately 15 minutes. Laboratory data and data on the physical examination performed by the treating physician will be adopted from the patients charts after the study visit. Finally, the sublingual microcirculation will be visualized by SDF-imaging. The SDF-camera may be handled by the patients. This measurement will take 5 minutes.

Study burden and risks

The nature of the burden consists of an SDF measurement , a non-painful, non-invasive 5 minute procedure using small camera surrounded by a circle of led lights which can be applied to the sublingual microcirculation. In addition, a questionnaire will be completed which will take approximately 15 minutes. There are no invasive procedures to this study and therefore there is no risk associated with participation.
We consider the burden for participants not to be higher than any regular visit to the outpatient department. They will only be asked to stay an additional 20 minutes in the hospital. There is no benefit for individual participants.

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

- At least 18 years of age
- Able to provide written informed consent

Exclusion criteria

- Chronic inflammatory disease
- Malignancy
- Pregnancy

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-05-2012
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO

Date:	09-03-2012
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	NL38826.018.12