

Glycocalyx in cerebral small vessel disease

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Measuring the thickness of the microvascular glycocalyx, and make a comparement between lacunar stroke patients and healthy controls. We also compare glycocalyx between patients with and without concomitant silent signs of cSVD on brain MRI.

| | |
|------------------------------|---|
| Ethical review | Approved WMO |
| Status | Recruitment stopped |
| Health condition type | Central nervous system vascular disorders |
| Study type | Observational invasive |

Summary

ID

NL-OMON36152

Source

ToetsingOnline

Brief title

Glycocalyx in cerebral small vessel disease

Condition

- Central nervous system vascular disorders
- Vascular disorders NEC

Synonym

cerebral small vessel disease

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cerebral small vessel disease, glycocalyx, lacunar infarcts, white matter lesions

Outcome measures

Primary outcome

Registration of baseline characteristics (age, gender, weight, length, medication, cardiovascular risk profile, brain MRI)

Venous blood sampling for measuring of glucose, cholesterol, kreatinin, and CRP.

Measurement of the sublingual glycocalyx, non-invasively using sidestream dark field imaging.

We will compare glycocalyx thickness between patients and controls, and between patients with and without silent lesions.

Predictors of glycocalyx thickness will be analysed using regression analyses.

Secondary outcome

nvt

Study description

Background summary

A lacunar infarct is caused by an arteriopathy of small perforating brain arteries, which is called cerebral small vessel disease (cSVD). cSVD can cause a symptomatic lacunar stroke, but it can also cause "silent" lacunar infarcts, white matter lesions and microbleeds. It is hypothesized that endothelial dysfunction plays an important role in the pathogenesis of cSVD. Glycocalyx is a thin layer at the inside of the endothelium in blood vessels. Over the past decade, inside has been gained into the role of the glycoclayx in vascular hemostasis. The glycocalyx acts as a protectionlayer between the endothelium and flowing blood. Disturbance of the glycocalyx could be a cause of endothelial dysfunction. Thus it could be that the glycocalyx is a factor in

the pathogenesis of cSVD.

Glycocalyx can not be measured in cerebral small vessels. However, there is some evidence that cSVD parallels a systemic small vessel endotheliopathy. The systemic microvascular glycocalyx can be measured in a quite simple way and non-invasively: sublingual.

We hypothesize that the sublingual measured systemic microvascular glycocalyx is thinner in patients with cSVD.

Study objective

Measuring the thickness of the microvascular glycocalyx, and make a comparement between lacunar stroke patients and healthy controls.

We also compare glycocalyx between patients with and without concomitant silent signs of cSVD on brain MRI.

Study design

observational case-control study

Study burden and risks

All participants will give informed consent.

Participants will come after an overnight fast. The whole procedure including the measurement of glycocalyx will take 30 minutes. A venous blood sample will be taken, which has only minimal risk. The measurement of glycocalyx is non-invasively and without any risk.

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

patients: first-ever lacunar stroke in the last 2 years, age 50-85 years

healthy controls: age 50-85 years, without major co-morbidity

Exclusion criteria

patients: carotid stenosis, cardioembolic source, diabetes, coronary heart disease, major co-morbidity

healthy controls: hypertension, diabetes, cardiovascular disease (TIA/stroke/coronary heart disease), use of cardiovascular medicine, silent signs of cSVD on (former) brain MRI

Study design

Design

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

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 01-03-2012
Enrollment: 60
Type: Actual

Ethics review

Approved WMO
Date: 29-08-2011
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 | NL36504.068.11 |