# Microvasculopathy in Cerebral Small Vessel Disease

Published: 28-06-2007 Last updated: 08-05-2024

Aim of the study is to study systemic microvascular changes in patients with cerebral small vessel disease compared with patients with large vessel atherosclerosis.

Ethical review	Approved WMO
Status	Pending
Health condition type	Central nervous system vascular disorders
Study type	Observational invasive

# **Summary**

### ID

NL-OMON30895

**Source** ToetsingOnline

**Brief title** Cerebral small vessel disease

## Condition

· Central nervous system vascular disorders

#### Synonym

Cerebral small vessel disease / Ischemic stroke

#### **Research involving** Human

## **Sponsors and support**

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

### Intervention

Keyword: Cerebral small vessel disease, Glycocalyx, Microvasculopathy

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### **Outcome measures**

#### **Primary outcome**

The main study endpoint is the difference in endothelial microvascular

glycocalyx thickness between patients with cerebral small vessel disease and

patients with large vessel atherosclerosis.

#### Secondary outcome

The presence of blood parameters related to glycocalyx destruction in patients

with cerebral small vessel disease.

The presence of microalbuminuria in both research groups.

The presence of pathological changes in microvessels found in skin biopsy.

# **Study description**

#### **Background summary**

Cerebral small vessel disease (CSVD) causes about 30% of all ischemic strokes, but little is known about its pathophysiology. In contrast to large vessel atherosclerosis there is far less known about the best prevention and therapy of CSVD. We hypothesize that CSVD is a generalized vascular disorder, and is associated with destruction of the endothelial glycocalyx.

### **Study objective**

Aim of the study is to study systemic microvascular changes in patients with cerebral small vessel disease compared with patients with large vessel atherosclerosis.

### Study design

Pilot study

#### Study burden and risks

The patients will be asked to visit the hospital once, for the following

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investigations: venous blood sample, a urine sample, and a punch biopsy of the skin to determine the quality of the microvasculature. The endothelial glycocalyx will be imaged by orthogonal polarisation spectral imaging and retinal angiography. All investigational techniques are nearly without any risk or side effect. The total time of one visit will be approximately 2-3 hours.

# Contacts

**Public** Academisch Medisch Centrum

Postbus 22660 1100 DD Amsterdam Nederland **Scientific** Academisch Medisch Centrum

Postbus 22660 1100 DD Amsterdam Nederland

# **Trial sites**

## **Listed location countries**

Netherlands

# **Eligibility criteria**

Age Adults (18-64 years) Elderly (65 years and older)

## **Inclusion criteria**

Inclusion criteria cerebral large vessel disease group TIA or stroke patients with one of the following: -clinically demonstrated loss of sensibility -clinically demonstrated loss of motor function; and including one or more of the following: -hemianopsia

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-aphasia -neglect;and a carotid stenosis of more than 70% at the ipsilateral side.

Inclusion criteria cerebral small vessel disease group Patients with a clinically established lacunar syndrome (see appendix A) and lacunar infarcts and/or leukoaraiosis on CT.

# **Exclusion criteria**

Exclusion criteria for both groups are: -Age of less than 18 years -Incapacitated subjects -A Modified Rankin Scale (MRS) >3 -Diabetes Mellitus type I and II -Smoking -lodine allergy -Hyperthyroidism Exclusion criteria cerebral large vessel disease group -Lacunar infarcts and/or leukoaraiosis on CT -Indication of a cardiac source of intracranial embolism; Exclusion criteria cerebral small vessel disease group -Carotid stenosis of more than 30% -Intermittent claudication -Angina pectoris -Myocardial infarction -Radiologically demonstrated cortical infarction

# 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:	Pending
Start date (anticipated):	01-06-2007
Enrollment:	16
Туре:	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 CCMO ID NL17848.018.07