

Imaging of the permeability of the blood brain barrier with use off contrast enhanced magnetic resonance in people with a first even lacunar stroke

Published: 10-12-2007

Last updated: 10-05-2024

Determine if there is a difference in permeability of the blood brain barrier between the twodifferent types of cerebral small vessel disease.

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

Summary

ID

NL-OMON30940

Source

ToetsingOnline

Brief title

Imaging the permeability of the blood brain barrier

Condition

- Central nervous system vascular disorders
- Vascular injuries

Synonym

lacunar stroke, stroke due to small vessel disease

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht

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

Intervention

Keyword: blood brain barrier, lacunar stroke, permeability

Outcome measures

Primary outcome

The extent of leakage of contrast across the blood brain barrier.

Secondary outcome

None

Study description

Background summary

A lacunar infarct is a small brain infarct located deeply in the brain which is caused by local pathology in one of the small, perforating arteries (so called cerebral small vessel disease). The two distinguished forms of small vessel disease can be differentiated during life; patients with one single lacunar infarct have atheromatosis, whereas patients with multiple infarct especially when accompanied by extensive white matter disease do have arteriolosclerosis. Recent studies showed evidence for involvement of endothelial dysfunction due to arteriolosclerosis. This dysfunction might result in an increased permeability of the blood brain barrier. This permeability can be investigated in vivo using magnetic resonance imaging by estimating the degree of leakage of contrast across the blood brain barrier. We hypothesized that leakage of contrast across the blood brain barrier especially seen in patients with a first ever lacunar stroke and concomitant ischemic white matter lesions.

Study objective

Determine if there is a difference in permeability of the blood brain barrier between the two different types of cerebral small vessel disease.

Study design

Observational, experimental imaging study

Study burden and risks

Participants will be intravenously injected with a small amount of a paramagnetic contrast agent and magnetic resonance images of their brains will be made. The discomfort of these procedures is minimal. Theoretically, one might react allergic to the contrast medium, although this chance is minimal. A recently recognized risk of MR contrast agents is the development of nefrogenic systemic fibrosis which only develops in patients with an impaired kidney function. However, participants are not at risk for this complication as an impaired kidney function is an exclusion criteria for this study.

Contacts

Public

Academisch Ziekenhuis Maastricht

Postbus 5800
6202 AZ Maastricht
Nederland

Scientific

Academisch Ziekenhuis Maastricht

Postbus 5800
6202 AZ Maastricht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- known with a lacunar infarct
- age 18 years and older

Exclusion criteria

- presence of severe co-morbidity
- presence of cognitive defects
- diabetes mellitus
- claustrofobia
- known contra-indications for MR including the presence of known kidney disease or the presence of an increased serum creatinin

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-12-2007

Enrollment: 20

Type: Anticipated

Ethics review

Approved WMO

Date: 10-12-2007

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	NL18823.068.07