

Periventricular white matter lesions in small vessel disease related cognitive decline

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1) to investigate cognitive functioning in lacunar infarct patients with and without periventricular white matter lesions; 2) to identify predictors for cognitive dysfunction in lacunar infarct patients.

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

Summary

ID

NL-OMON39446

Source

ToetsingOnline

Brief title

Small vessel disease and cognitive function

Condition

- Central nervous system vascular disorders
- Cognitive and attention disorders and disturbances
- Vascular injuries

Synonym

lacunar infarct, silent lesions

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Weijerhorst

Intervention

Keyword: cognitive functioning, small vessel disease, white matter lesions

Outcome measures

Primary outcome

Cognitive function based on several (neuro)psychological domains: information processing speed, attention/concentration, executive functioning, memory and language. Raw test scores will be used for analyses.

Presence/ progression WMLs.

Secondary outcome

Brain Microbleeds.

Other cerebral abnormalities observed by MRI: atrophy and other cerebral abnormalities.

Study description

Background summary

Rationale: around a quarter of the yearly 24 to 25 thousand new patients with a brain infarct suffers from a so-called lacunar stroke: a small, deeply located brain infarct caused by a local abnormality in the small arteries (cerebral small vessel disease, SVD). Previous research found cognitive impairment in these patients. However, the exact cause of this SVD-mediated cognitive decline is not clear. Also, factors influencing and predicting the course of cognitive functioning have not yet been identified. Recent studies suggest that endothelial dysfunction may play a role.

Study objective

- 1) to investigate cognitive functioning in lacunar infarct patients with and without periventricular white matter lesions;
- 2) to identify predictors for cognitive dysfunction in lacunar infarct

patients.

Study design

Prospective, observational, follow-up cohort study.

Study burden and risks

Patients undergo non-invasive magnetic resonance imaging (MRI) of the brain and a neuropsychological assessment.

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

- First lacunar infarct, diagnosed clinically as well as radiologically.
- Age of 18 years and older.

Exclusion criteria

- Brain infarct or other cerebral pathology in recent history.
- Potential source of cardio-embolism or carotic stenosis (large vessel disease)
- Severe comorbidity (specified as not being able to perform Activities of Daily Living (ADL independently)), including dementia.
- Limited life-expectancy
- History of inflammatory disease
- Contra indications for MRI
 - o Heart valve prosthesis
 - o Pacemaker
 - o Intracerebral clips (aneurysm)
 - o Intra-ocular metal pieces
 - o Cochlear implant
 - o Claustrophobia
- When the patient does not appreciate to receive the results of the study, in particular if abnormalities are found during MRI or neuropsychological assessment, which are of great importance for the patients health.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 04-08-2009

Enrollment: 150

Type: Actual

Ethics review

Approved WMO	
Date:	15-07-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	18-09-2013
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO	
Date:	19-05-2014
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC 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	NL26933.068.09

Study results

Date completed:	28-06-2016
Actual enrolment:	83