The long-term effects of Small Vessel Disease

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Primary ObjectiveOur primary objective is to investigate the effect of SVD-progression on the long-term clinical outcome. Secondary Objectives- To identify causes and risk factors related to an unfavourable clinical outcome over time- To identify...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Structural brain disorders
Study type	Observational invasive

Summary

ID

NL-OMON48199

Source
ToetsingOnline

Brief title
The long-term effects of Small Vessel Disease

Condition

- Structural brain disorders
- Cognitive and attention disorders and disturbances
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Cerebral vasculopathy - White matter hyperintensities

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cerebral angiopathy, Cerebral vasculopathy, Small Vessel Disease, White matter hyperintensities

Outcome measures

Primary outcome

The SVD neuroimaging markers, incidence of vascular events, dementia and

parkinsonism.

Secondary outcome

- Change in cognitive function

- Severity of BBB dysfunction, based on quantitative pharmacokinetic parameter

values

Study description

Background summary

Small vessel disease (SVD) is a slowly progressive vasculopathy of the small perforating cerebral vessels and is now considered to be the most important vascular contributor to stroke and cognitive decline, ultimately leading to dementia and loss of functional independence. It has been assumed that SVD is a more dynamic and heterogeneous disease than previously thought, showing inter-individual variability in progression as well as regression on MRI over time. Yet, the mechanisms underlying progression as well the long-term effects of SVD progression are still poorly understood. We therefore propose to perform another follow-up study, including novel advanced perfusion imaging (assessing BBB-function and brain perfusion), and neuropsychological examinations among survivors of our RUN DMC study with already known moderate to severe SVD. We will hereby be collecting 13-14 years of follow up data of SVD including imaging and neuropsychological assessments, which is as far as we know the longest follow-up of SVD-patients in literature. By doing so, we aim to gain more insights in the long-term (> 13 years after diagnosis) clinical effects of SVD, assess the clinical outcome of temporal dynamics of SVD, and identify potential causes (such as BBB dysfunction) and risk factors that may play an important role in the progression of the disease.

Study objective

Primary Objective
Our primary objective is to investigate the effect of SVD-progression on the long-term clinical outcome.

Secondary Objectives
- To identify causes and risk factors related to an unfavourable clinical outcome over time
- To identify causes and risk factors related to the temporal dynamics of SVD
- To assess the correlation between SVD-severity and BBB dysfunction

Study design

The RUN DMC study is a prospective cohort study, initiated to investigate risk factors and clinical consequences of SVD.

Study burden and risks

The participants, previously diagnosed as SVD, will be asked to undergo the following procedures: standardized MRI protocol, vena puncture to collect blood and neuropsychological examinations. Some participants will additionally receive gadolinium-based contrast agent to assess the BBB impairment; in case of adverse effects, they will be treated reasonably and professionally.

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

Participants alive of the RUN DMC cohort (cohort of patients with small vessel disease)
• In such a condition allowing to visit the research centre
• Written informed consent

Exclusion criteria

- (Psychiatric) disease interfering with cognitive testing or follow-up
- Contra-indications to MR Imaging

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):	24-09-2019
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	01-07-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-07-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL69678.091.19