Zoom@SVDs: Zooming in at microvascular malfunction in Small Vessel Diseases with 7T MRI

Published: 05-10-2016 Last updated: 15-05-2024

Primary Objective: To assess which measures of microvascular function on 7T MRI are affected in patients with symptomatic SVDs, relative to controlsSecondary Objective(s): To establish how microvascular function relates to:• parenchymal lesion...

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

Summary

ID

NL-OMON47570

Source ToetsingOnline

Brief title Zoom@SVDs

Condition

- Central nervous system vascular disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym cerebral small vessel disease

Research involving Human

Sponsors and support

Primary sponsor: Neurologie Source(s) of monetary or material Support: European Union S Horizon 2020 research

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and innovation programme under grant agreement No 666881;SVDs@target

Intervention

Keyword: 7Tesla MRI, dementia, Small vessel disease, stroke

Outcome measures

Primary outcome

Measures of microvascular function at 7T MRI:

- Difference in mean velocity and pulsatility index of perforator flow between

patients with SVDs and healthy controls.

- Difference in time course of the BOLD-fMRI signal to a visual stimulus in

different cortical layers between patients with SVDs and healthy controls.

- Difference in Cerebrovascular reactivity (CVR) to a hypercapnic stimulus

between patients with SVDs and healthy controls.

Secondary outcome

Relationship between measures of microvascular function at 7T MRI and:

- Severity (total burden) and location of conventional markers of SVD on 3T MRI

at baseline and progression of these lesions after 2 years.

- Cognitive functioning at baseline and decline in cognitive function after 2

years

- blood pressure (BP) and BP variability

Study description

Background summary

Cerebral small vessel diseases (SVDs) are a major cause of stroke and dementia, and yet there is no targeted treatment. Progress in understanding the

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mechanisms that drive SVDs and SVDs-related brain damage has been elusive, until now. Zoom@SVDs is part of a coordinated programme to elucidate key mechanisms common to different SVDs, and determine how these mechanisms contribute to individual SVDs (SVDs@Target Project, funded by the European Horizon 2020 Scheme).

Current approaches to study and diagnose SVD focus on lesion-detection with MRI. However, SVD-lesions represent an end-stage and are insufficiently specific to understand disease processes. It would be a major advance if SVDs in humans could also be examined in terms of microvascular function. High field strength imaging with 7TMRI now offers this possibility. In Zoom@SVDs we will use 7T MRI to assess which aspects of microvascular function are affected in patients with symptomatic SVDs and how microvascular function relates to other markers of SVD-related brain injury and cognition.

Study objective

Primary Objective: To assess which measures of microvascular function on 7T MRI are affected in patients with symptomatic SVDs, relative to controls Secondary Objective(s): To establish how microvascular function relates to:

• parenchymal lesion presence (3T MRI) at baseline and lesion progression after 24 months

- cognitive function at baseline and cognitive decline after 24 months
- blood pressure (BP) and BP variability

Study design

Observational case-control study with two years follow-up

Study burden and risks

The burden associated with participation is that the subject will come to the UMCU for two visits at baseline and one after two years. At these visits the subjects are interviewed and undergo a short physical examination. There is a cognitive assessment at baseline and again after 2 years, a 7T MRI scan of the brain at baseline, and a 3T MRI scan at baseline and follow-up. Between the first and the second baseline visit, there will be blood pressure recordings, three times per day, for one week. There is a venipuncture at baseline. There is no direct personal benefit for the patients or controls who participate. The benefit of the project is that it will deliver a new perspective on a common, but incompletely understood disease. There are no known health risks of the proposed procedures. A venipuncture can give some discomfort.

Contacts

Public Selecteer

Heidelberglaan 100 Utrecht 3584 CX NL **Scientific** Selecteer

Heidelberglaan 100 Utrecht 3584 CX NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

participants must meet all of the following criteria: -For the patients only: symptomatic SVD defined as history of clinical lacunar stroke or cognitive impairment due to SVD -age over 18 -ability to provide informed consent

Exclusion criteria

-Other major neurological or psychiatric conditions affecting the brain and interfering with the study design (e.g. multiple sclerosis, epilepsy, Parkinson*s disease)

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-For the controls only: history of symptomatic SVD or pronounced silent SVD on MRI -Contraindications for MRI

Study design

Design

| Study type: | Observational invasive |
|---------------------|---------------------------------|
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| | |

Primary purpose: Basic science

Recruitment

| NL | |
|---------------------------|---------------------|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 20-03-2017 |
| Enrollment: | 90 |
| Туре: | Actual |

Ethics review

| Approved WMO | |
|--------------------|------------------|
| Date: | 05-10-2016 |
| Application type: | First submission |
| Review commission: | METC NedMec |
| Approved WMO | |
| Date: | 13-12-2017 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO | |
| Date: | 29-08-2019 |
| Application type: | Amendment |
| Review commission: | METC NedMec |

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 29334 Source: NTR Title:

In other registers

| Register | |
|----------|--|
|----------|--|

| Register | ID |
|----------|----------------|
| ССМО | NL58737.041.16 |
| OMON | NL-OMON29334 |