Zoom@SVDs

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29334

Source
NTR

Health condition

Small vessel disease, SVDs, VCI, lacunar infarcts

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: European Union’s Horizon 2020 research and innovation programme under grant agreement No 666881, SVDs@target

Intervention

Outcome measures

Primary outcome

Primary Objective:

To assess which measures of microvascular function on 7T MRI are affected in patients with symptomatic SVDs, relative to controls

Secondary outcome

Secondary Objective(s):

To establish how microvascular function relates to:

• parenchymal lesion presence 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 description

Background summary

Zoom@SVDs is a longitudinal observational study with 7T MRI in 60 patients with sporadic SVDs and 30 healthy controls and in 15 patients with CADASIL. Primary objective is to determine which novel 7T markers of microvascular malfunction most clearly differentiate patients with SVDs from healthy controls. Secondary objectives are to explore the relation between microvascular function and parenchymal lesion presence at baseline and lesion progression after 24 months and to relate microvascular function to BP and BP variability (BPv) and to cognitive dysfunction.

Study objective

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 design

Baseline will be divided over two days.

Follow-up will be preformed after 24 months.

Intervention

Observational study.

Participants will undergo: an interview with full medical history and examination. Cognitive testing, a 3T MRI scan and a 7T MRI scan. Participants will be issued with a BP machine with telemonitoring capabilities and instructed to perform home BP monitoring with the device over seven days.

Contacts

Public
Neurology, Brain Center Rudolf Magnus UMC Utrecht

GJ Biessels
Utrecht
The Netherlands
0887556866
Scientific
Neurology, Brain Center Rudolf Magnus UMC Utrecht

GJ Biessels
Utrecht
The Netherlands
0887556866

Eligibility criteria

Inclusion criteria

• Symptomatic sporadic SVD defined as

o History of clinical lacunar stroke in the last 5 years with a corresponding recent small subcortical infarct visible on MRI scan or CT scan* compatible with the clinical syndrome.

*On MRI, recent infarct is defined as a DWI lesion on the acute MRI scan. On CT, recent infarct is defined as a novel infarct on CT within 3 weeks after the event that was not visible on the admission CT.

o or cognitive impairment defined as visiting a memory clinic with cognitive complaints, and a CDR score of ≥0.5, and capacity to consent, and with confluent WMH on MRI (defined as a Fazekas WMH score ≥ 2)16

• Age 18 years or older

• Written informed consent

Exclusion criteria

• Inclusion criteria are not met

• Evidence for a monogenic for of SVDs

• Unwillingness or inability to give written consent

• Pregnant or breastfeeding women, women of childbearing age not taking contraception.

• Contraindications to MRI (pacemaker, aneurysm clip, cochlear implant etc.)

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

• In case of inclusion for clinical lacunar stroke other causes of stroke such as

o ≥50% luminal stenosis (NASCET) in large arteries supplying the infarct area

o major-risk cardioembolic source of embolism (permanent or paroxysmal atrial fibrillation, sustained atrial flutter, intracardiac thrombus, prosthetic cardiac valve, atrial myxoma or other cardiac tumours, mitral stenosis, recent (<4 weeks) myocardial infarction, left ventricular ejection fraction less than 30%, valvular vegetations, or infective endocarditis)

o other specific causes of stroke (e.g. arteritis, dissection, migraine/ vasospasm, drug misuse)

• Life expectancy <2 years

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-01-2016
Enrollment:	90
Type:	Unknown

Ethics review

Positive opinion

Date:	10-03-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47570
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6126
NTR-old	NTR6265
CCMO	NL58737.041.16
OMON	NL-OMON47570

Study results