Zoom@SVDs

Gepubliceerd: 10-03-2017 Laatst bijgewerkt: 15-05-2024

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Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29334

Bron
NTR

Aandoening

Small vessel disease, SVDs, VCI, lacunar infarcts

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: European Union’s Horizon 2020 research and innovation programme under grant agreement No 666881, SVDs@target

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Baseline will be divided over two days.

Follow-up will be preformed after 24 months.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-01-2016
Aantal proefpersonen:	90
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	10-03-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47570
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten