Neuronal correlates of post-stroke epilepsy and the associated cognitive impairment

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Aim of the study is to determine the neuronal correlates of post-stroke epilepsy and cognitive dysfunction, in PSE and non-PSE stroke patients, and healthy controls.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23401

Bron
NTR

Verkorte titel
PoSECI-7T

Aandoening

stroke, post-stroke epilepsy, cognitive deterioration.

Beroerte, epilepsie na beroerte, cognitieve achteruitgang.

Ondersteuning

Primaire sponsor: Prof.Dr. Robert v Oostenbrugge, Department of Neurology, Maastricht University Medical Centre+ (MUMC+)
Overige ondersteuning: Eerste geldstroom

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- BBB permeability as determined by DCE-MRI to assess the leakiness of the cerebral vasculature by dynamically measuring the rate of contrast agent transfer from blood into the interstitial space (leakage rate; units: mL / (min 100 g tissue)). We will compare BBB permeability in PSE patients with non-PSE.
- Resting state functional MRI: connectivity measures, locally as well as whole brain network analysis (using graph theoretical measures) as well as DTI connectivity measures, locally (mean diffusivity/fractional anisotropy) and anatomical features (measured by standard T2, SWI and FLAIR sequences: gliosis, iron deposits microbleeds, dilated perivascular spaces, and cortical and subcortical ischemic lesions).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale and Objective: Up till now, neuronal correlates of post-stroke epilepsy and the comorbid cognitive dysfunction in patients are largely unknown. Therefore, the aim of this study is to unravel imaging biomarkers of post-stroke epilepsy. We will assess blood brain barrier (BBB) properties and brain network formation in patients with and without post-stroke epilepsy (PSE).

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Study design: This is an observational cross-sectional study. We will use high field neuroimaging (7T MRI) to assess BBB properties (using the DCE technique), as well as brain remodeling (using DTI and rs-fMRI techniques).

Study population: We will include 20 adult patients suffering from post-stroke epilepsy from our outpatient departments (MUMC and Kempenhaeghe) and 20 stroke patients without epilepsy from our neurological outpatient department of the Maastricht University Medical Center (MUMC), as well as 20 healthy controls. These three groups will be matched regarding age, sex and stroke subtype (approximate size and location).

Main study parameters/endpoints: Differences in blood-brain barrier permeability, differences in structural and functional connectivity. The results will be correlated with outcomes of stroke and cognition. For stroke the outcomes will be correlated with the National Institutes of Health Stroke Scale (NIHSS) ; for cognition scale for speed of central information processing will be used.

Nature and extent of the burden and risks associated with participation, benefit and group

relatedness: Patients will undergo cognitive testing and 7T MRI imaging including gadolinium contrast enhancement. 7T imaging is safe, an adverse reaction to the intravenous contrast agent is a rare complication, which is very well treatable.

Doel van het onderzoek

Aim of the study is to determine the neuronal correlates of post-stroke epilepsy and cognitive dysfunction, in PSE and non-PSE stroke patients, and healthy controls.

Onderzoeksopzet

We aim to include patients in this study in a 2 year period.

Onderzoeksproduct en/of interventie

none

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- patients suffering from post-stroke epilepsy after cortical stroke defined as one or more unprovoked epileptic seizures occurring more than one week after the stroke, according to International League Against Epilepsy criteria(22), with the onset of clinical stroke symptoms less 2 years prior to inclusion.

-Patients suffering from cortical stroke, with the onset of acute stroke symptoms between 4 months and 2 years prior to inclusion.

-Age 40-70 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject (PSE or control) who meets any of the following criteria will be excluded from participation in this study:

-primary intracerebral hemorrhage

-hemorrhagic transformation of stroke of any clinical significance

-previous history of epilepsy

-history of another cerebral disorder (neurodegenerative diseases, tumours)

-inability to provide informed consent

- any contraindication for MRI: metallic foreign body, pacemaker, claustrophobia, pregnancy, tattoos, permanent make-up.

- known contrast allergy to gadolinium, insufficient kidney function (eGFR<=30).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd

Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2017
Aantal proefpersonen:	72
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-12-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6470
NTR-old	NTR6648
Ander register	METC azM/UM : METC162054

Resultaten