Blood-brain barrier leakage as a predictive factor for post-stroke epilepsy

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON52151

Source
ToetsingOnline

Brief title
BBBinPSE

Condition

- Other condition
- Central nervous system vascular disorders

Synonym
epilepsy after stroke, Post-stroke epilepsy

Health condition

Epilepsie

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW,Epilepsiefonds

Intervention

Keyword: Blood-brain barrier, MRI, Post-stroke epilepsy, Predictive factor

Outcome measures

Primary outcome

To identify potential imaging biomarkers for early identification of patients at risk for PSE, by investigating blood-brain barrier leakage in acute phase and during first stage of rehabilitation.

To elucidate the relationship between blood-brain barrier permeability and other microstructural (connectivity, integrity) and microvascular properties (perfusion, diffusivity, blood flow, blood volume) of the brain in PSE patients. Data acquisition at two time points makes it possible to monitor the pathophysiological changes between the primary effects and early recovery.

Secondary outcome

To determine the relation between blood-brain barrier integrity and alterations in structural and functional network formation in the brain. Serial MRI measurements allow for the evaluation of spontaneous network reorganization after tissue damage.

Study description

Background summary

Post-stroke epilepsy (PSE) is a major complication after stroke, which remains difficult to predict. Management of PSE can be challenging, as underlying mechanisms and optimal treatment are undetermined. Blood-brain barrier (BBB) dysfunction has been associated with the development of PSE, though the exact course and consequence of increased BBB permeability in epileptogenesis are unclear. Using new MRI techniques BBB permeability, as well as other microstructural and microvascular properties of the brain tissue, can be assessed non-invasively in patients with and without PSE.

Study objective

This study aims to identify potential imaging biomarkers for early identification of patients at risk for PSE, and to elucidate the relationship between BBB permeability and other pathophysiological properties in PSE patients in acute phase and during first stage of rehabilitation.

Study design

To characterize the spatiotemporal dynamics and effects of BBB permeability in relation to the development of PSE in stroke patients, 3T MRI will be performed shortly after stroke (within ±6 days) and after 6 weeks. A standardized neurological evaluation will be performed, taking into account neurological characteristics (National Institutes of Health Stroke Scale) and the functional status (modified Rankin scale). The patients will be followed-up every three months for one year in total, with special attention being paid to development of epilepsy and the patients functional status.

Study burden and risks

Patients will undergo two MRI scans of approximately 60 minutes including gadolinium-based contrast administration. Risks concerning contrast agent administration will be negligible, as patients with an impaired renal function (eGFR<30mL/min) are excluded from the study. Patients will not benefit directly from participation in this study. However, to learn more about the development of post-stroke epilepsy, and to improve the treatment of (possible) PSE patients, it is necessary to examine stroke patients who are at high risk for developing epilepsy. All included patients will have large stroke lesions, with mostly a large deficit in physical but also in cognitive functioning. The patients often will have very specific deficits, like aphasia or anosognosia (the inability to recognize your own illness/deficit). In case the patient is legally incompetent, due to their injuries as a result of stroke, a legal representative will be involved in the study.

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

A SeLECT score 0-9 or a CAVE score 0-4
Age of >= 18 years

Exclusion criteria

Contra-indications for a gadolinium based contrast agent (known allergy or insufficient kidney function determined by an eGFR <= 30 mL/min)
Contra-indications for MRI scanning (e.g. metal implants, cardiac pacemaker, claustrophobia, pregnancy)
Previous history of epileptic seizures or other cerebral disorders (e.g. neurodegenerative diseases or head/brain tumors)

Re-infarction during follow-up
Potential epileptogenic co-morbidities (e.g. alcohol or drugs abuse, cerebral venous thrombosis, history of brain surgery)
Absence of written informed consent (by a legal representative)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-05-2021
Enrollment:	72
Type:	Actual

Ethics review

Approved WMO

Date:	18-12-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	29-07-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL74935.068.20
Other	NL8976