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

No registrations found.

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

Summary

ID

NL-OMON23506

Source
Nationaal Trial Register

Brief title
BBBinPSE

Health condition

Primary acute stroke (including both cerebral infarction and hemorrhage)

Sponsors and support

Primary sponsor: Academic hospital Maastricht (azM)
Source(s) of monetary or material Support: ZonMW, Epilepsiefonds

Intervention

Outcome measures

Primary outcome

The differences in blood-brain barrier integrity of patients who will or will not develop epilepsy after stroke.

Secondary outcome

The pathophysiological changes in the brain after stroke, and how these changes are related to the development of epilepsy after stroke.

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.

This study will include 80 post-stroke patients with a high chance to develop epilepsy, according to the SeLECT score for ischemic stroke patients and the CAVE score for patients who had cerebral hemorrhage. These patients will be recruited from the Neurology department of Maastricht University Medical Center (MUMC+) during their first intake at the Stroke Unit.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. Patients will undergo venipuncture to measure the micro RNA levels in the blood, which might function as a biomarker for epilepsy. Additionally, 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.

The aim of this study is 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 objective

1. 3T MRI can identify potential 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.
2. Pathophysiological changes after stroke can be elucidated by looking at the relationship between blood-brain barrier permeability and other microstructural and microvascular properties of the brain in PSE patients.
3. The relation between blood-brain barrier integrity and alterations in structural and functional network formation in the brain can evaluate network reorganization after tissue damage due to stroke.

Study design

±6 days and 6 weeks, with follow-up every three months for up to one year after stroke

Intervention

- 2x 3T MRI scan
- Blood sampling via venipuncture
- Neurological evaluation up to one year

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Diagnosed with a primary acute stroke (including both cerebral infarction and hemorrhage)
• A SeLECT score ≥ 5 or a CAVE score ≥ 2
• Age of ≥ 18 years

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Contradictions for a gadolinium-based contrast agent (known allergy or insufficient kidney function determined by an eGFR ≤ 30 mL/min)

• Contradictions for MRI scanning (e.g. metal implants, cardiac pacemaker, claustrophobia, pregnancy)
• Previous history of stroke, 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 non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2020
Enrollment:	80
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	16-10-2020
Application type:	First submission

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
NTR-new	NL8976
Other	METC azM/UM : METC20069

Study results