Glycocalyx in epilepsy.

No registrations found.

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

Summary

ID

NL-OMON26910

Source
Nationaal Trial Register

Brief title
Glycolepsy.

Health condition

Temporal lobe epilepsy. Cerebral glycocalyx. Microcirculation.

Sponsors and support

Primary sponsor: Maastricht University Medical Center, Maastricht, the Netherlands
Source(s) of monetary or material Support: Fund = initiatior = sponsor

Intervention

Outcome measures

Primary outcome

To establish glycocalyx properties of temporal lobe epilepsy (TLE) patients.

Secondary outcome

- To establish differences in glycocalyx properties of glycocalyx between TLE patients and controls.

- To establish the correlation between sublingual glycocalyx measurements and cortical glycocalyx measurements in TLE patients and controls.

- To establish differences in glycocalyx properties between TLE patients with hippocampal sclerosis and those without hippocampal sclerosis.

- To establish differences in glycocalyx between TLE patients with a history of febrile seizures and/or traumatic brain injury and those without a history of febrile seizures and/or traumatic brain injury.

- To establish the correlation of glycocalyx properties in TLE patients to epilepsy-specific factors such as type of seizures and seizure frequency.

- To establish the effect of anesthesia on sublingual glycocalyx measurements in all patients.

- To establish the examination of viability of small cortical arteries in an in-vitro setting using an arteriography.

- To establish the examination of the neurovascular unit of small cortical arteries in an in-vitro setting using an arteriograph and electrical field stimulation.

- To establish the examination of the glycocalyx of small cortical arteries in an in-vitro setting using an arteriograph and 2-photon microscopy and to correlate this to the in-vivo results.

Study description

Background summary

Rationale:

Pathophysiology of temporal lobe epilepsy (TLE) has not been elucidated yet. Endothelial dysfunction may play a role. The inner part of the endothelium is lined by glycocalyx. It is the first barrier between vessel lumen and the brain, and is affected in cerebrovascular disease. We hypothesize that in epilepsy patients, the glycocalyx is affected as well.

Objective:
Main objective: to explore cerebral glycocalyx characteristics in epilepsy patients. Other objectives: to correlate sublingual glycocalyx characteristics to directly measured cerebral glycocalyx characteristics; to establish the effect of anaesthetics on glycocalyx characteristics, to correlate glycocalyx characteristics to hippocampal sclerosis, seizure severity, and history of febrile seizures (FS) or traumatic brain injury (TBI).

Study design:
Observational case-control study.

Study population:
Adult TLE-patients suffering from medically refractory seizures who are candidates for resective brain surgery, and adult controls that are undergoing resective brain surgery for oncological indications.

Intervention (if applicable):
Sublingual and cerebral glycocalyx measurements. On admission to the hospital one day prior to surgery the first sublingual glycocalyx measurements will be performed. This sublingual measurement is repeated in the operating theatre after induction of anaesthesia, and immediately prior to resection of the temporal lobe. Cerebral glycocalyx measurements are performed twice: once cortically prior to temporal corticectomy, and once hippocampally prior to hippocampectomy Thus, glycocalyx thickness is measured five times in all patients. Hippocampus glycocalyx will not be measured in the control patients.

Main study parameters/endpoints:
Successful measurement of glycocalyx, expressed in
perfused boundary region (PBR, in ìm) and Dperf (in ìm), in epilepsy patients and controls.

Study objective

Epilepsy is associated with thinner glycocalyx in cerebral microcirculation, but not with systemic microvascular differences (sublingually).

Study design

Interim analysis yearly and/or after 5 included candidates in both arms.

Intervention

Measurement of sublingual and cerebral (cortical and hippocampal) glycocalyx in temporal lobe epilepsy patients and patients with intracranial tumor. Measurement is performed using a SDF camera.

Contacts

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Eligibility criteria

Inclusion criteria

Epilepsy patients

- adults between 18 and 60 years

- patient diagnosed with pharmacoresistant epilepsy, temporal lobe epilepsy, focus in non-eloquent area.

Control patients

- adults between 18 and 60 years

- patient diagnosed with cerebral oncological pathology that requires resective brain surgery.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: child (<18y) or elderly (>60y), pregnancy, diabetes mellitus, familiar

(combined) hyperlipidemia, history of stroke or other cardiovascular diseases, use of cardiovascular medication, silent signs of cerebral small vessel disease on brain MRI. Control patients in whom a history of seizures is reported.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-11-2015
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-11-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47782
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5441
NTR-old	NTR5568
CCMO	NL51594.068.14
OMON	NL-OMON47782

Study results

Summary results
Will follow