Glycocalyx in epilepsy.

Gepubliceerd: 11-11-2015 Laatst bijgewerkt: 19-03-2025

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

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

Samenvatting

ID

NL-OMON26910

Bron
Nationaal Trial Register

Verkorte titel
Glycolepsy.

Aandoening

Temporal lobe epilepsy. Cerebral glycocalyx. Microcirculation.

Ondersteuning

Primaire sponsor: Maastricht University Medical Center, Maastricht, the Netherlands
Overige ondersteuning: Fund = initiatior = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	11-11-2015
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-11-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47782
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

Will follow