Ultra snelle hersengolven bij mensen met epilepsie

Gepubliceerd: 17-12-2014 Laatst bijgewerkt: 18-08-2022

We hypothesize that HFOs recorded non-invasively with MEG and scalp EEG are biomarkers of disease activity like iEEG HFOs

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

Samenvatting

ID

NL-OMON27112

Bron
NTR

Aandoening

epilepsy, seizures, focal epilepsy, epilepsie, aanvallen

Ondersteuning

Primaire sponsor: University MEdical Center Utrecht
Overige ondersteuning: Dutch Epilepsy Foundation and NWO Zon MW veni grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The occurrence of HFOs in EEG, MEG and ECoG.
The main study endpoints are the number of patients showing HFOs with each technique, the number of HFOs per channel and the brain areas that show HFOs.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Background: A new biomarker is needed to establish prognosis in focal epilepsy. High frequency oscillations (HFOs) seem a good candidate biomarker, but HFOs are currently used in intracranial electroencephalography (iEEG). When measured with subdural grids, this is called corticography. HFOs can also be measured non-invasively using scalp EEG and magnetoencephalography (MEG). This is a very recent discovery which needs more research before we can draw conclusions on HFOs. Non-invasive HFO analysis will improve early identification of a focal epilepsy generator, and will be available in all patients.

Hypothesis: HFOs recorded non-invasively with MEG and scalp EEG are biomarkers of ictogenesis and disease activity like iEEG HFOs.

Objective:

Primary objective of this study is to improve identification of epileptic HFOs in EEG and MEG, by using combined MEG-EEG recordings and to compare these with HFOs in corticography. Secondary objective is to study the relation of non-invasively recorded HFOs with the number of seizures and cognitive test results before and after surgery.

Study design:

Prospective observational study

Study population:

Patients with drug-resistant focal epilepsy who will undergo epilepsy surgery with intraoperative corticography in the UMCU and will get a clinical MEG registration, and patients with drug-resistant focal epilepsy who will undergo epilepsy surgery with pre-operative corticography in the UMCU, regardless whether they get a clinical MEG registration or not. All patients are six years of age or older. In total we will include 30 patients.

Intervention (if applicable):

Not applicable

Main study parameters/endpoints:

The parameter we study is HFOs. We will compare the number and distribution of HFOs recorded with different techniques (corticography and simultaneous MEG and scalp EEG), look at how the extent of brain tissue generating HFOs correlates to seizure frequency, and investigate if there is a correlation between the number of HFOs remaining after surgery and the number of postoperative seizures and cognitive functioning, and compare these measures between the different techniques.

Doel van het onderzoek

We hypothesize that HFOs recorded non-invasively with MEG and scalp EEG are biomarkers of disease activity like iEEG HFOs

Onderzoeksopzet

EEG and MEG will take place before surgery, right after inclusion. Surgery will follow within 2 week- 3 months and followed by MEG and EEG in 6 weeks to 6 months.

Surgical outcome and cognitive outcome are determined 1 year after surgery.

Onderzoeksproduct en/of interventie

EEG, MEG and ECoG before and after resection.

EEG and ECoG are part of the standard clinical work-up.

Pre-operative MEG is part of standard clinical work-up for some patients.

Patients will undergo extra post-operative MEG and sometimes pre-operative MEG together with simultaneous EEG.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with refractory epilepsy

six years and older

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

metal implants

no MEG compatibility

having had depth electrodes (sEEG)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2015
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-12-2014
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	NL4936

Register	ID
NTR-old	NTR5038
Ander register	METC : 15-038

Resultaten

Samenvatting resultaten

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