Ultra snelle hersengolven bij mensen met epilepsie

No registrations found.

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

Summary

ID

NL-OMON27112

Source
NTR

Health condition

epilepsy, seizures, focal epilepsy, epilepsie, aanvallen

Sponsors and support

Primary sponsor: University MEdical Center Utrecht
Source(s) of monetary or material Support: Dutch Epilepsy Foundation and NWO Zon MW veni grant

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Number of seizures before and after surgery and cognitive outcome

Study description

Background summary

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.

Study objective

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

Study design

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.

Intervention

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.

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Eligibility criteria

Inclusion criteria

Patients with refractory epilepsy

six years and older

Exclusion criteria

metal implants

no MEG compatibility

having had depth electrodes (sEEG)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2015
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-12-2014
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	NL4936
NTR-old	NTR5038
Other	METC : 15-038

Study results

Summary results

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