Non-Invasively recorded high frequency oscillations as biomarkers in focal epilepsy

Published: 18-03-2015
Last updated: 21-04-2024

Primary objective of this study is to improve identification of epileptic HFOs in EEG and MEG, by comparing them to HFOs in corticography. Secondary objectives are to study the predictive value of non-invasively recorded HFOs for disease activity...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Seizures (incl subtypes)
Study type	Observational non invasive

Summary

ID

NL-OMON44429

Source
ToetsingOnline

Brief title
MEG-EEG HFO Study

Condition

- Seizures (incl subtypes)

Synonym
convulsion, epileptic fit, Epileptic seizure

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMW veni,Epilepsiefonds

Intervention

Keyword: Focal epilepsy, High frequency oscillations (HFOs), MEG, Scalp EEG

Outcome measures

Primary outcome

- The number of patients with HFOs with each technique (corticography, scalp

EEG, MEG)

- The number of HFOs per minute with each technique

- The brain aeas showing HFOs with each technique

Secondary outcome

- The number of seizures before and after surgery

- The results of cognitive tests before and after surgery

Study description

Background summary

High frequency oscillations (HFOs) are proposed as biomarker for epileptogenicity, but HFOs are currently used in intracranial electroencephalography (iEEG). Very recent studies show that HFOs can also be measured non-invasively using scalp EEG and magnetoencephalography (MEG). This discovery needs more research before we can draw conclusions on HFOs.
Non-invasive HFO analysis will improve early identification of a focal epilepsy generator, and might be used for monitoring of disease activity.
Hypothesis: HFOs recorded non-invasively with MEG and scalp EEG are biomarkers of ictogenesis and disease activity like iEEG HFOs.

Study objective

Primary objective of this study is to improve identification of epileptic HFOs in EEG and MEG, by comparing them to HFOs in corticography. Secondary objectives are to study the predictive value of non-invasively recorded HFOs for disease activity and cognitive functions.

Study design

Prospective observational cohort study

Study burden and risks

In this study, patient will undergo pre and post operative simultaneous EEG-MEG recordings and pre- or intraoperative corticography. However, the corticography is done in all patients regardless of our research. The only extra burden for our patients would therefore be the simultaneous scalp EEG-MEG recording (two times).

Risks
MEG and EEG are both safe recording techniques of brain signals, there is no risk involved in undergoing an MEG-EEG.

Burden
-Patients would have to travel to the VU medical center in Amsterdam for the MEG-EEG recording, because there is no MEG available in the UMCU.
-MEG-EEG recording can be uncomfortable because patients need to lie practically motionless while the machine is recording brain signals. We expect this to be too demanding for children under six. We will also exclude older patients for whom this is expected or appears to be too much.

Benefit
A benefit of undergoing MEG-EEG is that patients get an extra test in their pre and post surgical work-up.

Patients can not count on above mentioned benefit, but considering the very low risk and small burden, we think it is ethically justified to perform this study.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100

Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

-Patients have refractory focal epilepsy (not responding to treatment with anti-epileptic drugs) and are candidates for epilepsy surgery in the University Medical Center Utrecht with pre or intra operative corticography (measuring brains signals during surgery).
- Adults and children over six
- EEG and MEG compatible

Exclusion criteria

-Patients who undergo epilepsy surgery outside the UMCU, or without pre or intra operative corticography
-Patients with metal implants (not MEG compatible)
-Patients under six and other patients unable to lie down or sit motionless for at least 15 minutes (not MEG compatible)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-08-2015
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	18-03-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	03-06-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-06-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	25-04-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL50715.041.14