Wearable MEG - Using novel technology to improve surgery outcome in epilepsy patients

Published: 23-07-2019
Last updated: 12-04-2024

To demonstrate that novel MEG sensors can be used successfully in clinical practice, and to demonstrate their effectiveness as a powerful diagnostic tool in epilepsy.

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

Summary

ID

NL-OMON48086

Source
ToetsingOnline

Brief title
OPMs for epilepsy

Condition

- Seizures (incl subtypes)
- Nervous system, skull and spine therapeutic procedures

Synonym
epilepsy, seizure

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Epilepsiefonds

Intervention

Keyword: Epileptic seizures, Magnetoencephalography, Optically Pumped Magnetometers, Presurgical evaluation

Outcome measures

Primary outcome

Primary outcome is a demonstration of the effectiveness of OPMs as a powerful diagnostic tool in epilepsy. The parameter we study is epileptiform activity (spikes, spike-waves). We will compare the even-rate (number of spikes/minute) and the strength (in terms of signal-to-noise ratio) between the different techniques.

Secondary outcome

Demonstration of the ability to successfully record MEG signals during a seizure.

Study description

Background summary

For patients with focal refractory epilepsy, seizure freedom can be achieved through epilepsy surgery by removal of the epileptogenic zone (EZ). This requires the delineation of the EZ during the pre-surgical workup using non-invasive techniques such as Magneto/Electro-encephalography (MEG/EEG), or invasive recordings using intracranial electrodes (dEEG). The success of the pre-surgical workup, and thereby surgery, should be improved since seizure freedom is achieved in only two-thirds of the patients.
Newly developed MEG sensors, so-called Optically Pumped Magnetometers (OPMs), provide an unprecedented opportunity for epilepsy. These sensors are smaller, lighter, and cheaper, yet have a sensitivity that is comparable to that of cryogen-based Superconducting Quantum Interference Devices (SQUIDs). Importantly, they can be placed directly on the scalp, thereby improving the sensitivity to, and localisation accuracy of, epileptiform activity. Moreover, with a wearable OPM-based array, one could record during seizures. Together, this will not only improve diagnosis, but also the pre-surgical workup, thereby

improving the chances of successful surgery and seizure freedom.

Study objective

To demonstrate that novel MEG sensors can be used successfully in clinical practice, and to demonstrate their effectiveness as a powerful diagnostic tool in epilepsy.

Study design

This is primarily a feasibility study. We will employ a multiple case approach, whereby each patient*s OPM recordings will be compared with their clinically recorded (SQUID-based) MEG recording and their previously recorded scalp EEG or clinically recorded dEEG.

Study burden and risks

Specific study population:
Patients with focal, drug-resistant epilepsy who undergo epilepsy surgery with pre-operative workup that includes MEG and scalp EEG or dEEG. We need to study this particular patient population to be able to compare the performance, and show the benefits, of the novel sensors in epilepsy patients in a clinical situation.
The inclusion of three patients under the age of 18 is required to demonstrate that by using on-scalp sensors instead of the standard, adult-sized, helmet the sensitivity to epileptiform activity increases.

Study procedures:
The SQUID-based MEG recording and dEEG have already been performed as part of routine clinical care. Similarly, the simultaneous MEG / scalp EEG recording has already been performed as part of another research project. The extra burden for patients in this study would be an extra recording using the OPM sensors. The recording protocol is identical to the one they have already undergone for the routine clinical MEG scan, with the exception that they now wear a modified EEG cap with the OPMs attached.

Risks:
MEG is a save, non-invasive, recording technique of brain signals. The use of OPMs has negligible risks. There is a risk of a seizure during scanning but this should not expose the patient to any greater risk of injury than what would be experienced in their everyday lives.

Burden:
Patients will have to travel to the VU University Medical Center in Amsterdam. The recording will take place in a magnetically shielded room (which is about the size of a large freight elevator), which may cause claustrophobia. They

will wear a modified EEG cap with the OPMs attached. The recording will take a maximum of 2 hours, with breaks every 10-15 minutes. As is standard procedure for the clinical MEG recording, patients will be sleep-deprived to increase the chances that epileptiform activity occurs. One patient will be asked to undergo an extended (maximal 8 hours) recording in order to capture ictal activity, with breaks every 10-15 minutes and longer breaks of 30 minutes every 2 hours (during which the patient can leave the scanner).

Benefits:
The OPM recordings will be evaluated for epileptiform activity. If epileptiform activity is seen at locations not previously seen in the existing MEG data and/or dEEG/EEG data, then this information will be reported to the treating neurologist.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1118
Amsterdam 1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1118
Amsterdam 1081 HV
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 epilepsy and are candidates for epilepsy surgery
- We include adults (VUmc) or children of six years of age or older (UMCU).
Adults:
- Patients have already undergone a clinical SQUID-based MEG and dEEG at VUmc
- 3 patients: confirmed focal source on dEEG of mesial temporal origin
- 1 patient: frequent seizures (~daily);Children:
- Six years of age or older
- Patients have already undergone a clinical SQUID-based MEG with simultaneous scalp-EEG at VUmc
- Confirmed focal source of epileptiform activity in clinical MEG or EEG

Exclusion criteria

- Have already undergone surgery for their current epilepsy
- The patients have already undergone a clinical SQUID-based MEG. Those patients who had claustrophobic or anxiety experiences from being enclosed in the magnetically shielded room will be excluded.
- Patients with many artefacts, related to either movement or metal implants (not MEG compatible), on their clinical SQUID-based MEG

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):	03-12-2020

Enrollment:	7
Type:	Actual

Ethics review

Approved WMO Date:	23-07-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL68259.029.18