implementation of magnetoencephalography (MEG) for the diagnosis of epilepsy

Published: 06-08-2013
Last updated: 24-04-2024

The mean objective of this research project is the implementation in daily clinical practice of MEG as the examination of the first choice for the diagnosis of patients with suspicion of epilepsy. Furthermore, the current project links directly to...

Ethical review	Approved WMO
Status	Pending
Health condition type	Neurological disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON38612

Source
ToetsingOnline

Brief title
MEG for diagnosis

Condition

- Neurological disorders NEC

Synonym
epilepsy, falling sickness

Research involving
Human

Sponsors and support

Primary sponsor: Epilepsiecentrum Kempenhaeghe
Source(s) of monetary or material Support: Zorginnovatiefonds zorgverzekeraars

Intervention

Keyword: diagnosis, epilepsy, MEG

Outcome measures

Primary outcome

The primary outcome parameter is the clinical diagnosis at the end of the trajectory, after completion of the standard EEG and MEG recordings, which is considered as gold standard. .

Secondary outcome

The secondary outcomes will be (1) the patient experiences regarding each diagnostic procedure, (2) the relevant cost-factors taking into account the disease and interventions under investigation (EEG, EEsd, MEG), and (3) the societal costs due to the consumption of health care and other goods

Study description

Background summary

The success and effectiveness of the treatment of epilepsy is highly dependent on the specific type of epilepsy. Currently, the diagnosis of epilepsy is a lengthy and stressful process for the patient. Initially epilepsy is diagnosed on basis of clinical symptoms during seizures. A standard EEG can confirm the diagnosis. However, in over 50% of the cases routinely applied EEG recording (routine EEG) does not lead to an accurate diagnosis of patients with epilepsy. If a routine EEG is inconclusive a EEG after sleep deprivation (EEGsd) or 24-hour EEG recording (24h-EEG) recording is performed. It has been argued based on a number of recent studies that MEG is more sensitive to epileptic discharges and, therefore, may present a more efficient alternative. Furthermore, MEG is argued to be less burdensome for the patient and more cost-effective than EEG.

Study objective

The mean objective of this research project is the implementation in daily

clinical practice of MEG as the examination of the first choice for the diagnosis of patients with suspicion of epilepsy. Furthermore, the current project links directly to the objective of sustained implementation of innovative technology, which is patient friendly and (cost-)effective.

Study design

In a comparative trial all patients who are referred for a routine EEG will be offered an extra MEG recording. After the routine EEG, additional EEG (EEGsd or 24h-EEG) and MEG recordings, patients are requested to indicate their experiences on a visual analogue scale (VAS) on three different topics (stress level, patient friendliness and quality of life). Furthermore, to measure the use of health care resources, including all activities related to epilepsy, we gather data for each patient at baseline, at the moment of inclusion in the study, at the end of the trajectory and one year follow-up, including all health care resources used.

Study burden and risks

MEG is a non-invasive technique that enables recording of epileptiform discharges over the whole head, without placement of electrodes, while the patient is in a supine position during the recordings. The burden for the patient is an additional examination which only can be performed at VU Medical Center in Amsterdam. Furthermore, additionally compared to standard procedures are the questionnaires regarding the experiences (VAS) that have to be completed after each examination (EEG, EEGsd or 24h-EEG, MEG) and the questionnaires regarding the cost-effectiveness that have to be completed at the final consultation with a follow-up after 12, 24, 38 weeks.

Contacts

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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

- suspicion of epilepsy
- 6 years or older
- able to co-operate

Exclusion criteria

- a pacemaker or intracranial metal
- younger than six year
- patients who cannot meet the mild physical or psychological criteria for prolonged MEG scanning

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2013
Enrollment:	350
Type:	Anticipated

Ethics review

Approved WMO

Date:	06-08-2013
Application type:	First submission
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	NL43357.029.13