Dynamic Information Flow based on EEG and Diffusion MRI in Epilepsy: An explorative study

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Exploration and possibly chaniging of the VBMEG method to analyse dynamic changes in the connectivity network in epilepsy patients. This study is a prerequisite to apply the VBMEG method to a larger dataset to possibly identify a quantitative...

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

Summary

ID

NL-OMON48456

Source
ToetsingOnline

Brief title
VBMEG in epilepsy.

Condition

- Neurological disorders NEC

Synonym
Epilepsy

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Epilepsie Instellingen Nederland
Source(s) of monetary or material Support: Eigen KNF onderzoeksreserve - RVE Research SEIN

Intervention

Keyword: Connectivity analysis, dMRI, Electroencephalogram, Transcranial magnetic stimulation

Outcome measures

Primary outcome

The network connectivity of the brain will be analysed using the VBMEG method.

This method works by estimating the EEG activity of the cortical sources and

the dynamic causal interactions between these. We will explore this methode and

possibly change to investigate whether we can identify dynamic changes in the

network connectivity in both focal and generalised epilepsy patients.

Futhermore we will study whether anti-epileptic medication causes identifiable

changes in the network connectivity.

Secondary outcome

- Dose of anti-epileptic drugs on the day of the first and second TMS-EEG

measurement

- Differences in VBMEG results between visual versus TMS stimulation

- Intolerance for research methods (TMS,EEG,EMG,MRI)

Study description

Background summary

Epilepsy is a complex neurological disorder characterised by recurrent seizures. It is the most common serious neurological disorder worldwide, but there are still no reliable biomarkers. Recently renewed interest for the coupling of transcranial magnetic stimulation (TMS) with EEG (TMS-EEG) has grown among researchers to use it as an additional tool for epilepsy diagnostics and therapy evaluation. Recent studies have shown that epileptiform discharges are connected with changes in the dynamics of the brain and possible

alterations in connectivity between inter-connected areas of the brain. The "Variational Bayesian Multimodal Encephalography" methode provides a way to analyse the dynamic information flow between cortical sources, this can provide information about among other things the seizure, the interictal state and change in the brain network connectivity. TMS in combination with electroencephalogram (EEG) is a non-invasive method. TMS induces an electrical field in the brain, causing a depolarization and generation of action potentials. TMS-evoked EEG responses can be used to analyse the brain's excibatility and the brain network connectivity. Visual stimulation evoked EEG responses might serve as an alternative method to study changes in brain connectivity.

Study objective

Exploration and possibly chaniging of the VBMEG method to analyse dynamic changes in the connectivity network in epilepsy patients. This study is a prerequisite to apply the VBMEG method to a larger dataset to possibly identify a quantitative biomarker in epilepsy patients.

This might eventually serve three goals:
1. Serving as a biomarker which can be used to define the phenotype of the disease.
2. Objective evaluation of the effectiveness of the treatment
3. Regain more insight in the pathophysiology of the epileptic brain

Een side objective is an exploration if visual stimulation, as being part of routine EEG recordings, might serve as an alternative stimulation method to study VBMEG changes in brain connectivity.

Study design

We aim to design an explorative study to investigate the differences in the brain network connectivity in epileptic patients and healthy people, secondly to investigate the influence of medication on the brain network connectivity. Participation will consist of two session with an EEG registration with TMS and photic stimulation for the TLE participants.The first measurement will be a week before the admission to the EMU or observational unit. The second measurement will be when the medication is tapered. This will be either just before or directly after their stay on to the EMU. Both the healthy participants and GGE participants will only schedule one appointment. Lastly, a MRI-scan will be made of all participants.

Study burden and risks

Participation for the TLE participants will consists of a total of 2 EEG registrations. The first TMS-EEG measurement shall be performed during an extra

appointment, scheduled prior the admission to the EMU/observation unit. The second measurement shall be performed just before or directly after the regular EMU stay for EEG-videoregistration. The admission to the EMU unit shall not be lengthened due to participation in this study. Each session will have a total duration of 120 minutes and will consist of explanation of the study, filling out questionnairs, the TMS-EEG stimulation protocol and lastly photic stimulation protocol. For both the GGE participants and healthy controls, participation will only consist of one EEG registration with TMS and photic stimulation. Furthermore, all participants will schedule an appointment to make a MRI-scan.

TMS is non-invasive. TMS stimulation itself can be experiene as a small shock with an accompanying muscle twitch. Furthermore, there is a small chance of dizzyness and headache. The sitmulaiton protocol will be given with continuous patient feedback to determine comfort, tolerability and effects of the stimulation trials.The risk that it triggers a seizure in people with epilepsy is reported to be max. 2.6%. In healthy subjects, TMS-related seizures have been reported in seven cases in literature to our knowledge, and doubt was expressed as to whether the events were seizures as no EEG was available at the moment of occurence.The EMU or observation unit, where the TMS-EEG registration will be performed, is a setting designed for optimal safety of patients in case of seizure events. The goal of an EEG-videoregistration is the registration of seizures, this is also the reason for the tapering of the medication which increases the chance of capturing a seizure during the patients' admission. The TMS evoked seizure may give valuable clinical information that influences the decision-making process for that
patient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- A form of genetic generalised epilepsy (2 subjects), who do not use any anti-epileptic drugs (AED)
- Aged over 18 years, AND, - Temporal lobe epilepsy (2 subjects), considered for epileptic surgery, whose AEDs will be tapered as part of usual diagnostic procedure
- Admitted to the Epilepsy Monitoring Unit (EMU)
- Aged over 18 years

Exclusion criteria

- Pregnancy
- Mentally incapacitated
- Evidence of major radiological evidence of asymmetry between hemispheres
- Any major neurological condition other than epilepsy
- Any major psychiatric condition
- Individuals with a cochlear implant or a deep brain stimulator
- Metal and/or metal fragments in the head

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2019
Enrollment:	6
Type:	Anticipated

Medical products/devices used

Generic name:	Transcranial Magnetic Stimulator
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	29-07-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL69087.058.19