The value of simultaneous TMS-EEG recordings for diagnostic purposes in epilepsy patients

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Seizures (incl subtypes)
Study type	Observational non invasive

Summary

ID

NL-OMON43343

Source
ToetsingOnline

Brief title
TMS-EEG for epilepsy diagnosis

Condition

- Seizures (incl subtypes)

Synonym
falling sickness; seizure disorder

Research involving
Human

Sponsors and support

Primary sponsor: Epilepsiecentrum Kempenhaeghe
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: electroencephalography, epilepsy, excitability, transcranial magnetic stimulation

Outcome measures

Primary outcome

The primary study parameter is that changes in excitability of the brain studied with MEPs evoked by TMS, are reflected in the EEG either as evoked discharges or as increased rsFC.

Secondary outcome

A secondary endpoint is the rejection of the null-hypothesis that the excitability of the brain is not increased in the condition without the use of AEDs compared to the condition that the patient is on the steady-state maintenance doses of AEDs as prescribed.

Study description

Background summary

Transcranial magnetic stimulation (TMS) is a non-invasive method that can be used to stimulate the human brain. Due to recent developments, it is now possible to record TMS and EEG simultaneously. In this way, the changes in brain activity induced by TMS can be recorded with EEG. It has been shown that TMS in relation with the measurement of Motor Evoked Potentials (MEPs) reflects the changes in excitability of the brain. MEPs, however, are highly variable in between and within subjects. The simultaneously recorded EEG might be an alternative to measure the excitability of the brain. Furthermore, it has been shown that TMS while recording simultaneously EEG (TMS-EEG) is a new research field to measure directly drug effects on brain excitability.

Study objective

A primary goal is to relate EEG based rsFC to changes in excitability of the brain. Since the excitability recorded with the MEPs reflect antiepileptic drug effects [1,2] it is assumed that these changes will be more pronounced after

withdrawal of anti-epileptic drugs (AEDs). Secondary objectives: The secondary goal is to assess TMS-EEG recordings systematically with regard to abnormal discharges and the diagnostic value of these discharges.

Study design

To study the excitability of the brain in relation to medication for patients with focal epilepsy (n=103). The AEDs as prescribed will be tapered according to standard clinical procedures during their pre-surgical video-EEG examination. TMS-EEG will be applied before withdrawal of AEDs, while the patient is on the usual maintenance of AEDs, before the start of the video-EEG session and after withdrawal of AEDs, at the end of the session. For each of the conditions it will be investigated whether the EEG reflects abnormal discharges and whether these findings are of diagnostic and/or localizing value and whether rsFC has changed after withdrawal of AEDs. For comparison, the excitability of the brain as measured in each condition, before and after withdrawal of AEDs by Motor Threshold (rMT) measurements (which is the gold standard) will be related to the changes in rsFC.

Study burden and risks

TMS is a widely used non-invasive brain stimulation technique, based on the principle of electromagnetic induction. In the current study, healthy participants and patients will be stimulated with a protocol that falls within the safety guidelines, i.e. high-frequency stimulation is not used [3]. It is not expected that epileptic seizures are induced in healthy volunteers and there is a slight chance that seizures are induced in epilepsy patients. However, when patients with a lowered cortical excitability threshold (e.g., as a consequence of anti-epileptic drug treatment) are stimulated, the risk of inducing habitual spells or even a seizure might be increased. Such a case will be managed by the neurologist/clinical neurophysiologist and in epilepsy specialised care takers according to the protocols in place at Kempenhaeghe.

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

* Patients and healthy volunteers need to be 18 years or older and should be able to perceive magnetic stimulation, i.e. do not fulfil any of the exclusion criteria as mentioned in section 4.3.
* The patients included should be candidate for a video-EEG recording as part of their pre-surgical investigations.
* The decision for withdrawal of AEDs is a clinical decision, which is not influenced by the protocol requirements of this study.
* The patients included all are selected to have a pre-surgical simultaneous EEG and fMRI investigation.

Exclusion criteria

* Serious head trauma or brain surgery
* Large or ferromagnetic metal parts in the head (except for a dental wire)
* Implanted cardiac pacemaker or neurostimulator
* Pregnancy
* Skin diseases at intended electrode sites (EMG, EEG, TMS)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO Date:	03-08-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL57098.091.16