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

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To investigate whether it is possible to induce epileptiform activity with TMS. We expect to see abnormal discharges on TMS-EEG and we expect that these findings are of diagnostic value and will help to localize the epilepsy.

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

Summary

ID

NL-OMON36884

Source
ToetsingOnline

Brief title
Diagnostic value of TMS-EEG

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: Ministerie van OC&W

Intervention

Keyword: Electroencephalography (EEG), Epilepsy, Transcranial magnetic stimulation (TMS)

Outcome measures

Primary outcome

To investigate whether it is possible to induce epileptiform activity with TMS.

We expect to see abnormal discharges on TMS-EEG and we expect that these

findings are of diagnostic value and will help to localize the epilepsy.

Secondary outcome

To obtain a measure for the added diagnostic value, expressed as the number

needed to test with TMS for one additional confirmation of the diagnosis of

epilepsy.

Study description

Background summary

Epilepsy is one of the most common neurological diseases. The diagnosis of epilepsy is currently based on clinical history together with EEG recordings. However, EEG it is not very sensitive in the sense that it does not always include epileptiform activity. Therefore, patients with unclassified spells often undergo multiple EEG registrations before a diagnosis and treatment plan can be made. It would be beneficial to have a method to provoke the occurrence of epileptiform activity.
Transcranial magnetic stimulation (TMS) is a non-invasive method that can be used to stimulate parts of 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.

Study objective

To investigate whether it is possible to induce epileptiform activity with TMS.
We expect to see abnormal discharges on TMS-EEG and we expect that these findings are of diagnostic value and will help to localize the epilepsy.

Study design

Single pulse TMS will be performed starting at an intensity of the resting motor threshold. Stimulation will be delivered at the standard electrode positions; F7(8), F3(4), T3(4), C3(4), T5(6), P3(4). After eight stimuli at each position, the EEG responses are analyzed. If no response is seen, the stimulation will be proceeded at higher intensities, in 30% increments, until a response is visible or until the maximum output level of the TMS equipment is reached.

Study burden and risks

Participants will not directly benefit from their participation in the study, except for a compensatory (financial) incentive. TMS is a widely used non-invasive brain stimulation technique, based on the principle of electromagnetic induction. During stimulation, the participant will likely hear the clicks of the TMS pulses and experience stimulation of nerves and muscles of the head. The most common side effect is a light transient headache (2-4% occurrence). A severe headache is uncommon (0.3-0.5% occurrence). In TMS studies of patient populations (e.g. epilepsy) or those exceeding the standard protocols (e.g. in intensity or frequency) epileptic seizures have been reported in rare cases, most of these induced seizures can be attributed to high-frequency stimulation. 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. A seizure that occurs coincidentally during the measurement cannot be excluded. Although it is not expected, in case of the (accidental) occurrence of an epileptic seizure a neurologist/clinical neurophysiologist will always attend the TMS experiment. So specialized care can be given.
All subjects are screened for their relevant medical history and other TMS safety aspects (e.g. metal parts in the head). In summary, because the risk and burden associated with participation can be considered negligible-to-minimal, we do not expect serious adverse events during the project.

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

Older than 18 years.

Exclusion criteria

With regard to transcranial brain stimulation
• 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
With regard to other experimental techniques
• Skin diseases at intended electrode sites (EMG, EEG)

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:	Recruiting
Start date (anticipated):	01-07-2013
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	13-06-2013
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	NL42306.091.12