Three methodological aspects in TMS-EEG: Noise masking, pulse intensity and need for accurate coil positioning

Published: 17-05-2011
Last updated: 28-04-2024

The primary goal of this study is to develop a protocol for future studies in patients after a first seizure. We investigate 3 methodological aspects. - What is the effect on the auditory evoked potential of different types of noise masking?- What...

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

Summary

ID

NL-OMON38385

Source
ToetsingOnline

Brief title
TMS-EEG: Three methodological aspects

Condition

- Seizures (incl subtypes)

Synonym
epilepsy, seizures

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: Ministerie van OC&W,PIDON project (Pieken in de Delta Oost Nederland)

Intervention

Keyword: EEG, electroencephalography, TMS, transcranial magnetic stimulation

Outcome measures

Primary outcome

Our main endpoints are the presence and characteristics of the auditory evoked potential, the TMS-MEP and TMS-EEG response.

Auditory evoked potential

o Amplitude (microV)

o Latency (msec)

MEP

o Amplitude (mV)

o Latency (msec)

o Motor Threshold (Tesla)

TMS-EEG response

o Amplitude of peaks (microV)

o Latencies of peaks (msec)

Secondary outcome

TMS-EEG response: Additional signal analysis methods, including wavelet analysis of early and late TMS-EEG responses and the spatiotemporal characteristics of the TMS-EEG response.

In the epilepsy patients, we will record the number of epileptic abnormalities

in the EEG before and after the TMS experiment.

Study description

Background summary

The diagnostic process in epilepsy is often time-consuming due to the limited sensitivity and the nature of standard EEG recordings. TMS-EEG is a candidate tool to significantly improve the diagnostic efficiency in epilepsy. In this second study we perform measurements in healthy subjects and epilepsy patients to investigate three methodological aspects.

Study objective

The primary goal of this study is to develop a protocol for future studies in patients after a first seizure. We investigate 3 methodological aspects.

- What is the effect on the auditory evoked potential of different types of noise masking?
- What TMS intensity do we need to evoke TMS-EEG responses?
- How accurate do we need to position the TMS coil to evoke reproducible TMS-EEG responses?

Secondary objectives are to:
- Investigate what the effect of noise masking is on the motor threshold
- Investigate whether single-pulse TMS has any effect on the presence of epileptic abnormalities in spontaneous EEG recordings
- Investigate whether epilepsy patients show abnormal TMS-EEG responses
o Investigate which brain area shows abnormal TMS-EEG responses
o Investigate whether the abnormal TMS-EEG responses are reproducible
o Investigate whether the need for accurate positioning of the coil is different for abnormal TMS-EEG responses
o Investigate whether the needed TMS intensity to evoke TMS-EEG responses is different for abnormal TMS-EEG responses

Study design

This study is an interventional study that will run from May 2011 - April 2013.

Before subjects will be included, they will ifll out the screening questionnaire for TMS candidates and the Dutch handedness questionnaire.

The healthy subjects will undergo 3 TMS sessions during 1 day. During the administration of TMS pulses, EMG and EEG measurements take place. Single pulse TMS is applied to the motor cortex in the left hemisphere. We assess 8 different ways of noise masking, 7 different intensities and 8 locations surrounding a specific target.

The epilepsy patient will undergo 1 TMS session during day 1. If they show abnormal responses, they will undergo 3 more TMS sessions during a second day. During the administration of TMS pulses, EMG and EEG measurements take place. TMS is applied to 6 different brain areas. In addition, we assess 7 different intensitites and 8 locations surrounding a specific target.

Intervention

TMS (transcranial magnetic stimulation).
The TMS equipment has a maximum output of 1.5 Tesla. The puls duration is 400 microsec. Pulses are given with a frequency of ~0.25 Hz (single pulse TMS).

First, the hot spot and motor threshold of the abductor digiti minimi muscle (ADM) are determined on both sides. In healthy subjects, we stimulate the hot spot in the left hemisphere, while applying 8 different types of noise masking. After that, we stimulate at 7 different intensities and at 8 locations surrounding the hot spot.

In patients, we stimulate 6 different brain areas (hot spot left/right, Brodmann area 19 left/right, epileptic focus ipsilateral/contralateral). If they show abnormal responses, patients return for a second day of measurements. On that day we stimulate at 7 different intensities and at 8 locations surrounding a specific target.

Study burden and risks

Applying the EEG cap and EMG electrodes takes 15 minutes, locating the hot spot and determining the motor threshold takes 20 minutes, and calibrating the equipment takes 10 minutes, these actions take place prior to the first TMS session. The single-pulse TMS experiment consists of 3 or 4 sessions of varying length (40 - 65 minutes). During the TMS experiments, the subject will be seated in a comfortable chair. The EEG and EMG measurements and listening to the noise sounds will only produce minor discomfort and do not have associated risks. Single-pulse TMS is generally well tolerated. Possible side-effects and risks are described in section 9.4.

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

age between 18 and 60;patients: focal epilepsy

Exclusion criteria

hearing problems
(possible) pregnancy
metal objects in brain/skull
cochleair implang, implanted brain electrode or pacemaker
severe medical condition
take medications that lower the threshold for seizure
spinal surgery, drains in spinal cord or ventricles
use illegal drugs

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-05-2011
Enrollment:	31
Type:	Actual

Ethics review

Approved WMO Date:	17-05-2011
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	09-10-2012
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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	NL36317.044.11
Other	TC 2821