Single pulse TMS: variability and reproducability of MEP and EEG responses in healthy subjects.

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

Summary

ID

NL-OMON34432

Source
ToetsingOnline

Brief title
TMS response in healthy subjects

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, MEP, TMS, transcranial magnetic stimulation

Outcome measures

Primary outcome

Our main endpoints are the variability and reproducibility of the MEP and EEG responses during the day, so we will present mean values, standard deviations and amounts of change in the following TMS responses:

MEP

o Amplitude (mV)

o Latency (msec)

o Motor threshold (Tesla)

EEG response

o Amplitude of peaks (microV)

o Latencies of peaks (msec)

Secondary outcome

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

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 study, we will perform initial measurements in healthy volunteers to evaluate the presence of a circadian rhythm in TMS-EEG responses. Clearly, the presence or absence of a circadian rhythm is relevant for subsequent measurements in patients, as this may interfere with variations due to epilepsy.

Study objective

The primary objective of this study is to evaluate if there exists a circadian variability of the MEP and EEG response to single pulse TMS in healthy subjects.

Secondary objectives are to:
- investigate the accuracy of coil placement and the overall reproducibility of the MEP and EEG measurements performed with our equipment.
- explore additional signal analysis techniques for characterizing the EEG response.
- evaluate the TMS-EEG protocol for future studies in epilepsy patients.
- collect TMS-MEP and TMS-EEG data in healthy subjects to use as control data for future studies in epilepsy patients.

Study design

This study is an interventional study that will run from July - September 2010.

Before subjects will be included, they will fill out the screening questionnaire for TMS candidates and the Dutch Handedness Questionnaire to determine if they are right-handed. All subjects will receive an MRI of the head prior to the TMS experiments.

At the day of the TMS experiments, subjects will undergo five sessions of single pulse TMS between 8 AM and 19 PM. During the administration of TMS pulses, MEP and EEG measurements take place. Single pulse TMS is applied to 3 different parts of the brain, in both hemispheres. Five subjects will be asked to return for an additional session, one week after their whole day of TMS experiments. This session will be used to examine the reproducibility of our measurements. There will be no invasive procedures. None of the procedures is part of a medical treatment.

Intervention

TMS (transcranial magnetic stimulation).
The TMS equipment has a maximum output of 1.5 Tesla. The puls duration is 400 microsec. 50 Single TMS pulses will be given to 6 different brain areas (3 in each hemisphere), while the EMG and EEG are registrated. There are 5 TMS sessions, at 8:00 AM, 10:30 AM, 13:00 PM, 15:30 PM and 18:00 PM.

First, the hot spot and motor threshold of the right abductor digiti minimi (ADM) are determined. Then, the 3 brain areas in the left hemisphere are stimulated on 110% of motor threshold. Measurements are then repeated in the right hemisphere. Pulses are given with a frequency of ~0.25 Hz (single pulse TMS).

Study burden and risks

The MRI scan of the head takes ~ 20 minutes. The single pulse TMS experiment consists of 5 experimental sessions of ~ 50 minutes during 1 day. Applying the EEG cap and EMG electrodes takes 30 minutes and takes place prior to the first TMS session. During the TMS experiments, the subject will be seated in a comfortable chair. The MRI, EEG and EMG measurements 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 in the protocol.

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
right handed

Exclusion criteria

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

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-11-2010
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	27-09-2010
Application type:	First submission
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	NL32504.044.10