TMS response in healthy subjects.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23183

Source
NTR

Brief title
TMS01

Health condition

epilepsy
diagnosis
TMS
transcranial magnetic stimulation
epilepsie
diagnose
TMS
transcraniele magnetische stimulatie

Sponsors and support

Primary sponsor: Clinical Neurophysiology, Medisch Spectrum Twente & University of Twente
Source(s) of monetary or material Support: Sponsor
PIDON

Intervention

Outcome measures

Primary outcome

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 outcome

1. Investigate the accuracy of coil placement and the overall reproducibility of the MEP and EEG measurements performed with our equipment;

2. Explore additional signal analysis techniques for characterizing the EEG response;

3. Evaluate the TMS-EEG protocol for future studies in epilepsy patients;

4. Collect TMS-MEP and TMS-EEG data in healthy subjects to use as control data for future studies in epilepsy patients.

Study description

Background summary

Rationale:

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 normal variation and the presence of a circadian rhythm in TMS-EEG responses.

Objective:

The main objective is to explore and quantify the variability and reproducibility of MEP and EEG responses after single pulse TMS in healthy subjects.

Study design:

Interventional study.

Study population:

20 Healthy, right-handed volunteers, age between 18 and 60 years, who do not take pro-epileptogenic medication or drugs and without a personal history of epilepsy.

Intervention:

Five single pulse TMS sessions during 1 day.

Main study parameters/endpoints:

Variability and reproducibility of MEP (Motor Evoked Potential: amplitude, latency) and EEG response (electroencephalography response: amplitude, latency, frequency content) for 3 different brain areas.

Study objective

Before we focus our research on TMS-EEG experiments in epilepsy patients, we first aim to learn more about the characteristics and intra-subject variability of the TMS-EEG and MEP response in healthy subjects.

In addition, we will evaluate if TMS-EEG and MEP responses show a circadian rhythm. Although this was explored in a previous study [Koski 2005], no definite conclusions were drawn, possibly due to significant variability in the measurements due to inaccurate (re-)positioning of the magnetic coil. We expect to confirm or reject the presence of a circadian rhythm of the motor threshold. 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 design

Subjects will receive an MRI of the head prior to the TMS experiment. During the day of the experiment, the subject will undergo 5 TMS sessions during the day (8:00 AM - 10:30AM - 13:00 PM - 15:30PM - 18:00 PM). Five subjects will return 1 week after the day of the experiments for an additional TMS session.

Intervention

Our Transcranial Magnetic Stimulation equipment has a maximum output of 1,5 Tesla. Pulse duration is 400 microsec. 50 single TMS pulses will be given to 6 different brain areas (3 on

each hemisphere) while the EMG and EEG are recorded.

First, the hot spot and motor threshold of the right extensor digiti minimi (EDM) will be determined. Then, we stimulate the 3 brain areas on the left hemisphere with 110% of motor threshold. Measurements are then repeated for the right hemisphere. Pulses will be given with a frequency of ~0.25 Hz (single pulse TMS).

Contacts

Public
Postbus 217
Esther Braack, ter
Carre CA-3714
Enschede 7500 AE
The Netherlands
+31 (0)53 4895310
Scientific
Postbus 217
Esther Braack, ter
Carre CA-3714
Enschede 7500 AE
The Netherlands
+31 (0)53 4895310

Eligibility criteria

Inclusion criteria

1. Age between 18 and 60;

2. Righthanded.

Exclusion criteria

1. Personal history of epilepsy;

2. Lesion in the brain;

3. Hearing problems;

4. (Possible) pregnancy;

5. Metal objects in brain/skull;

6. Cochleair implant, implanted brain electrode or pacemaker;

7. Severe medical condition;

8. Take medications that lower the threshold for seizures
spinal surgery, drains in spinal cord or ventricles;

9. Use illegal drugs.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	20-07-2010
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-06-2010
Application type:	First submission

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
NTR-new	NL2246
NTR-old	NTR2373
Other	METC Medisch Spectrum Twente : P10-24
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A