Drie aspecten in transcraniele magnetische stimulatie: Geluidsmaskering, puls intensiteit en plaatsing van de spoel.

No registrations found.

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

Summary

ID

NL-OMON24037

Source
NTR

Brief title
TMS02

Health condition

Epilepsia
TMS
transcranial magnetic stimulation

Sponsors and support

Primary sponsor: Prof. dr. ir. M.J.A.M. Van Putten
Universiteit Twente
Source(s) of monetary or material Support: PIDON (Pieken in de Delta Oost Nederland)

Intervention

Outcome measures

Primary outcome

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

1. Auditory evoked potential:

A. Amplitude (microV);

B. Latency (msec).

2. MEP:

A. Amplitude (mV);

B. Latency (msec);

C. Motor Threshold (Tesla).

3. TMS-EEG response:

A. Amplitude of peaks (microV);

B. 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

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 and epilepsy patients.

Objective:

The main objective is to investigate 3 methodological issues
for TMS-EEG.

Study design:

Interventional study.

Study population:

1. 11 Healthy volunteers, age between 18 and 60 years,
who do not take pro-epileptogenic medication or drugs and without a personal history of epilepsy;

2. 10 Epilepsy patients who have focal
epilepsy.

Intervention:

Healthy subjects: three single-pulse TMS sessions during
one day. Epilepsy patients: one single-pulse TMS session on the first day and three single-pulse TMS sessions on a second day.

Main study parameters/endpoints:

Auditory evoked potential (amplitude), motor threshold (%), TMS-MEP response (amplitude, latency), TMS-EEG
response (amplitude, latency, frequency content).

Study objective

Before we start with our research on assessing the diagnostic value of TMS-EEG in epilepsy, we perform this pilot study to investigate a number of methodological aspects. To be able to develop a sound protocol these aspects need to be explored in healthy subjects and in patients who already are diagnosed with epilepsy.

Study design

Healthy subjects: 1 half day of TMS measurements;

Epilepsy patients: 1 half day of TMS measurements. If they show abnormal responses, there will be a second half day of TMS measurements.

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.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age between 18 and 60;

2. Patients: Focal epilepsy.

Exclusion criteria

1. Hearing problems;

2. (Possible) pregnancy;

3. Metal objects in brain/skull;

4. Cochleair implant, implanted brain electrode or pacemaker;

5. Severe medical condition;

6. Take medications that lower the threshold for seizure;

7. Spinal surgery, drains in spinal cord or ventricles;

8. Use illegal drugs.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2011
Enrollment:	21
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-03-2011
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	NL2691
NTR-old	NTR2821
Other	METC : P11-14
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A