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

Gepubliceerd: 24-03-2011 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24037

Bron
NTR

Verkorte titel
TMS02

Aandoening

Epilepsia
TMS
transcranial magnetic stimulation

Ondersteuning

Primaire sponsor: Prof. dr. ir. M.J.A.M. Van Putten
Universiteit Twente
Overige ondersteuning: PIDON (Pieken in de Delta Oost Nederland)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age between 18 and 60;

2. Patients: Focal epilepsy.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2011
Aantal proefpersonen:	21
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-03-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2691
NTR-old	NTR2821
Ander register	METC : P11-14
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A