Dubbel puls TMS-EEG bij epilepsie: verbeteren van de diagnostiek

No registrations found.

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

Summary

ID

NL-OMON20996

Source
Nationaal Trial Register

Brief title
TMS-03

Health condition

epilepsy
epilepsie
transcranial magenetic stimulation (TMS)
transcraniële magneetstimulatie (TMS)

Sponsors and support

Primary sponsor: University of Twente
Source(s) of monetary or material Support: projectgebonden financiering vanuit Stichting TWIN (Toegepast Wetenschappelijk Instituut voor Neuromodulatie)

Intervention

Outcome measures

Primary outcome

The main study parameters are the presence and characteristics of the TMS-EMG (MEP) and

TMS-EEG (TEP) response.

1) MEP response

• Resting motor threshold (rMT) - Tesla

• Long intracortical inhibition (LICI) - percentage ratio of the mean peak-to-peak amplitude of the response to the second test pulse (TR) and the first conditioning pulse (CR) at each ISI (TR/CR%)

2) TEP response

• Amplitude of peaks - microV

• Latencies of peaks - ms

Secondary outcome

Additional signal analysis methods applied on the MEP and TEP. For example, wavelet analysis of early and late TEPs and the spatio-temporal characteristics of the TEP.

Study description

Background summary

Rationale:

Epilepsy is one of the most common neurological disorders. Due to an increased cortical excitability of the brain of epilepsy patients, epileptic seizures can occur. However, between the epileptic seizures, the brain may function completely or almost normally. This results in the limited sensitivity of the routine electroencephalogram (EEG), making the diagnostic process in epilepsy is often time-consuming and labour-intensive. Transcranial magnetic stimulation (TMS) in combination with EEG makes it possible to stimulate the brain, while simultaneously assessing cortical excitability. The combination of paired pulse TMS-EEG makes it hopefully possible to diagnose or rule out epilepsy faster and more reliable.

Objective:

The primary objective is to evaluate differences in motor evoked potential (MEP) and TMS evoked potential (TEP) to paired pulse TMS between epilepsy patients and healthy controls.

Secondary objectives are:

1) To evaluate differences in MEP and TEP to paired pulse TMS between patients presenting with a first (epileptic) seizure who are diagnosed with epilepsy afterwards and those who are not

2) To evaluate reproducibility of the MEP and TEP to paired pulse TMS

3) To explore (additional) signal analysis techniques for characterising the MEP and TEP to paired pulse TMS

Study design:

Interventional study at the Clinical Neurophysiology and Neurology departments of the Medisch Spectrum Twente.

Study population:

Approximately 135 patients presenting with a first (epileptic) seizure and 30 healthy controls. In the end we need 20 first seizure patients who are not diagnosed with epilepsy, 20 first seizure patients who are diagnosed with generalized epilepsy, and 20 first seizure patients who are diagnosed with focal epilepsy. Subjects are excluded when they are younger than 18 years, have an (absolute) contra-indication for TMS or when follow-up is impossible for logistical reasons. Furthermore, the healthy controls are not included if they have a personal history of epilepsy or if they have a lesion in the brain.

Intervention:

The first seizure patients will undergo one paired pulse TMS session (selection of 30 patients will undergo two TMS sessions) and the healthy controls will undergo two paired pulse TMS sessions, with one week in between. Paired pulse TMS is a non-invasive, safe and painless technique..

Primary study parameters:

Primary study parameters are the characteristics of the MEP (resting motor threshold (rMT)

and long intracortical inhibition (LICI)) and TEP (amplitude and latency of peaks).

Study objective

Due to an increased cortical excitability of the brain of epilepsy patients, epileptic seizures can occur. Since, transcranial magnetic stimulation (TMS) provides the opportunity to assess cortical excitability, paired pulse TMS is a candidate technique to improve the diagnostic process in epilepsy. We expect to measure an increased cortical excitability in epilepsy patients compared to healthy controls as well as in first seizure patients who are afterwards diagnosed with epilepsy compared to those who are not. Hopefully, it is thus possible to diagnose or rule out epilepsy faster and more reliable.

Study design

The first TMS sessions is performed within two weeks after the first seizure and before anti-epileptic medication is started.

The second TMS session is performed approximately one week after the first session and is used to investigate the reproducibility of paired pulse TMS measurements.

Intervention

TMS (transcranial magnetic stimulation) is a non-invasive, safe, easy, and painless technique to stimulate the brain. In this study TMS is combined with both EMG and EEG.

Prior to the TMS measurements, the motor hot spot and resting motor threshold (rMT) of the abductor digiti polices brevis muscle are determined on both sides. Furthermore, a 64 channel EEG is applied.

Hereafter, 50 pairs of pulses (conditioning pulse followed by test pulse) are given randomly at six different interstimulus intervals (ISIs): 50, 100, 150, 200, 250 and 300 ms. Both pulses are given at an intensity of 120% the rMT.

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Eligibility criteria

Inclusion criteria

1) Patients presenting with a first (epileptic) seizure

• Presentation of a first (epileptic) seizure

• Ability to understand and comply with the instructions for the TMS session

2) Healthy controls

• Ability to understand and comply with the instructions for the TMS session

Exclusion criteria

• Younger than 18 years

• Contra-indications of TMS (although not absolute): (possibility of) pregnancy, metal objects in brain/skull, cochlear implant, deep brain stimulator, history of spinal cord surgery, drains in the spinal cord or ventricles, use of seizure threshold lowering or enhancing medication

• Follow-up impossible due to logistical reasons

In addition, healthy subjects are excluded if they have a

• Personal history of epilepsy

• Lesion in the brain, be it vascular, traumatic, infectious or metabolic

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:	Recruiting
Start date (anticipated):	01-09-2014
Enrollment:	165
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-09-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47679
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4650
NTR-old	NTR4793
CCMO	NL49854.044.14
OMON	NL-OMON47679

Study results

Summary results
N/A