Dubbel puls TMS-EEG bij epilepsie: het evalueren van de therapeutische werkzaamheid

No registrations found.

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

Summary

ID

NL-OMON28473

Source
NTR

Brief title
TMS-04

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. Once the diagnosis of epilepsy is confirmed, in most patients anti-epileptic drugs (AEDs) are prescribed. These AEDs should reduce the number and/or severity of the epileptic seizures. Because, absence or re-occurrence of seizures after prescribing medication is the only indication to assess whether therapy is successful or not, evaluation of therapeutic efficacy is often time-consuming. 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 evaluate the therapeutic efficacy of prescribed AEDs 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 with a successful response to AEDs and those who do not (refractory patients).
Secondary objectives are:

1) To evaluate differences in MEP and TEP to paired pulse TMS in epilepsy patients with different types of epilepsy or using different types of AEDs

2) 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:

40 drug naïve patients with generalized epilepsy and 40 drug naïve patients with focal epilepsy, who are starting with AEDs. 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.

Intervention:

All patients will undergo 3 to 4 paired pulse TMS sessions, over a period of one year. The first TMS session will take place while the patient is still drug naïve, the second session 8 to 12 weeks after starting with AEDs, and the final session 1 year after starting with AEDs. Optionally, an additional fourth TMS session will take place, in case a second AED is prescribed (8-12 weeks after starting the second AED). 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 evaluate the therapeutic efficacy of anti-epileptic drugs (AEDs) in epilepsy. We expect to measure an increased cortical excitability in drug naïve epilepsy patients prior to AED use, which decreases to normal values in case the patient responds to AEDsm while it remains increased in case the patient does not respond to AEDs. Hopefully, it is thus possible to evaluate the therapeutic efficacy of prescribed AEDs faster and more reliable.

Study design

All patients will undergo 3 to 4 paired pulse TMS sessions, over a period of one year.

The first TMS session will take place while the patient is still drug naïve, the second session 8 to 12 weeks after starting with AEDs, and the final session 1 year after starting with AEDs. Optionally, an additional fourth TMS session will take place, in case a second AED is prescribed (8-12 weeks after starting the second AED).

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

• Diagnosis of epilepsy, either generalized or focal

• Drug naïve, no prior use of AEDs

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

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 medication

• Follow-up impossible due to logistical reasons

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2014
Enrollment:	80
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: 47189
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4652

Register	ID
NTR-old	NTR4795
CCMO	NL49901.044.14
OMON	NL-OMON47189

Study results

Summary results
N/A