Paired pulse TMS-EEG in epilepsy: improving the evaluation of therapeutic efficacy

Published: 19-08-2014
Last updated: 15-05-2024

The primary objective of this study 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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Seizures (incl subtypes)
Study type	Interventional

Summary

ID

NL-OMON47189

Source
ToetsingOnline

Brief title
Paired pulse TMS-EEG in epilepsy - therapeutic efficacy

Condition

- Seizures (incl subtypes)

Synonym
convulsion, epilepsy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cortical excitability, epilepsy, therapeutic efficacy, transcranial magenetic stimulation

Outcome measures

Primary outcome

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).

Secondary outcome

Secondary study parameters include 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.

Other study parameters which are documented include: age, gender, handedness, seizure history, type of epilepsy; generalized or focal, type and dose of AEDs, EEG abnormalities (if applicable) and MRI abnormalities (if applicable).

Study description

Background summary

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 by applying magnetic pulses, while simultaneously measuring the response of the brain to the applied pulse. In this way TMS provides the opportunity to assess 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.

Study objective

The primary objective of this study 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.

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.

Study burden and risks

For each TMS session: Applying the EEG cap and EMG electrodes takes ~15 minutes, locating the motor hot spot and determining the rMT ~10 minutes for each side, and the TMS session ~45 minutes. A total of 600 paired pulses and ~100 single pulses are applied. During the TMS session subjects will be seated in a comfortable chair.

The EEG and EMG measurements, and listening to the noise sounds, will only

produce minor discomfort and do not have associated risks. Paired pulse TMS is generally well tolerated and considered to be non-invasive, safe, and painless.

Possible side-effects and risks include: hearing problems, syncope, headache, local pain, discomfort or seizures.
Overall, the risk of this study is low.

The subjects will have no benefit from participating in this study.

Contacts

Public
Universiteit Twente

Drienerlolaan 5
Enschede 7522 NB
NL
Scientific
Universiteit Twente

Drienerlolaan 5
Enschede 7522 NB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Drug naïve epilepsy patients starting with AEDs
* 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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-09-2016
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	19-08-2014
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	30-04-2018

Application type:	Amendment
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28473
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL49901.044.14
OMON	NL-OMON28473