Paired pulse TMS-EEG in epilepsy: improving the diagnostics process

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

Summary

ID

NL-OMON47679

Source
ToetsingOnline

Brief title
Paired pulse TMS-EEG in epilepsy - diagnostic process

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, diagnostics, epilepsy, 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 (if diagnosis epilepsy is confirmed afterwards), 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. However, between the epileptic seizures, the brain may function completely or almost normally. This results in the limited sensitivity of the routine electroencephalogram (EEG); approximately 45% of the routine EEGs recorded in epilepsy patients do not show any epileptiform abnormalities. This makes that 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 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 diagnose or rule out epilepsy 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 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
4) To collect TMS-EMG and TMS-EEG data of healthy subjects to be used as control data for other epilepsy studies

Study design

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

Intervention

The first seizure patients will undergo one paired pulse TMS session (selection of 30 patients will undergo two TMS sessions) and thirty healthy controls will undergo two paired pulse TMS sessions, with one week in between. Furthermore, ten healthy controls will undergo one single pulse TMS session.

Single and paired pulse TMS are non-invasive, safe and painless techniques.

Study burden and risks

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. During the single pulse TMS session in ten healthy controls a total of 600 single pulses are applied.

The EEG and EMG measurements, and listening to the noise sounds, will only produce minor discomfort and do not have associated risks. Single and 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

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

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 or if they have a lesion in the brain, be it vascular, traumatic, infectious or metabolic.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-11-2014
Enrollment:	175
Type:	Actual

Ethics review

Approved WMO Date:	19-08-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-11-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-04-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-12-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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: 20996
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL49854.044.14
OMON	NL-OMON20996