Exploring the influence of vigilance state on MEP amplitude induced by TMS

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON42077

Source
ToetsingOnline

Brief title
Vigilance state and MEP

Condition

- Other condition

Synonym
impaired motor nerve conductivity, stroke

Health condition

cerebrovasculair accident (CVA) en myelopathie

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: MEP amplitude, Transcranial Magnetic Stimulation, Vigilance state

Outcome measures

Primary outcome

Variance in intraindividual MEP amplitude.

Secondary outcome

N.A.

Study description

Background summary

Stroke is a frequent cause of upper limb motor impairment. Currently, Transcranial Magnetic stimulation (TMS) is used to determine the presence or absence of motor evoked potentials (MEPs) and its relation to outcome in stroke. So far, few studies have employed the amplitude of MEPs for prognosis due to inherent intraindividual variability in MEP amplitude. Earlier research suggested that vigilance variations may be a source of MEP amplitude variability. We therefore hypothesize that by stabilizing vigilance, intraindividual MEP amplitude variability may be reduced and therefore reproducibility will be increased.
Furthermore, in patients with myelopathy, decisions to perform an operative intervention are not easily made solely based on MRI data. Often, multiple lesions are visible on MRI, but the specific lesion causing clinical symptoms cannot be identified. On the other hand, abnormalities that seem harmless may be causing the patient discomfort, as well. MEP measurements are then used in addition to radiological evidence (or non-evidence) to find the source of the patient*s functional problems. In this application, only MEP presence/absence is assessed and MEP amplitude is so far not taken into account, either. This group of patients therefore forms another elected group of subjects to incorporate in this study.

Study objective

The primary objective is to investigate the influence of vigilance state on MEP amplitude in healthy adults.
Secondary objectives are to develop a paradigm to stabilize vigilance state resulting in lower MEP amplitude variability in healthy adults and to test the feasibility and results of this paradigm in stroke patients in the first week after stroke and in myelopathy patients.

Study design

Healthy participants will be subjected to MEP and EEG measurements. Stroke patients and myelopathy patients will only be subjected to MEP measurements.

Healthy participants will undergo six MEP measurements performed in a single session. In each measurement, 20 measurable MEPs will be evoked. At the start of this session EMG surface electrodes will be attached to the first dorsal interosseous muscle (FDI), both left and right, for the measurement of electrical muscle activity and an EEG cap will be placed on the head of the participant for measuring electrical brain activity as a measure of vigilance. The first three measurement will be conducted according to the regular MEP paradigm. The first of these three measurements will be done using the circular coil placed on the vertex, during the other two (one for each hemisphere) measurements the figure-8 coil will be used. The second three measurements will be done according to the newly designed vigilance stabilizing paradigm. The first of these three measurements will be performed using the circular coil. In the remaining two measurements (one for each hemisphere) the figure-8 coil will be used. This new paradigm will be developed in a pilot group of healthy participants. Only when the new paradigm will result in lower MEP variability in healthy participants, the measurements in stroke patients and myelopathy patients will be pursued.

Stroke patients and myelopathy patients will undergo two MEP measurements (one for each hemisphere) using the new paradigm for minimizing influence of vigilance state. Each measurement will consist of 20 consecutive MEP measurements. At the start of the measurement session, EMG surface electrodes will be placed on the FDI muscle, both left and right.

Study burden and risks

TMS stimulation does not involve risks when common exclusion criteria are applied. Healthy participants will undergo a measurement session of approximately two hours (MEP with EEG). Patients will undergo a measurement session of approximately one hour (MEP only). No personal benefit to the participants is derived from this study, however participation in this study may improve diagnostic and prognostic methods for various neurological disorders in the future.

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

All participants must be over 18 years old and give informed consent
Healthy participants: (perceived) healthy
Stroke patients: first ever stroke, stroke must have occurred more than 72 hours but less than one week prior to measurement
Myelopathy patients: radiological evidence of spinal cord compression on MRI above the level of C8

Exclusion criteria

All participants: Medication influencing cortical excitability (except stroke patients), presence of metals in the head, presence of electronic implants, (suspected) history of epilepsy, history

of severe cerebral trauma, (possible) pregnancy
Stroke patients: aphasia, presence of cardiac lines

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2015
Enrollment:	55
Type:	Actual

Medical products/devices used

Generic name:	Transcranial magnetic stimulation
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	09-03-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL51816.042.14