The effect of a hand motor task on the cortical excitability measured by TMS

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38757

Source
ToetsingOnline

Brief title
The effect of a hand task on cortical excitability

Condition

- Other condition

Synonym
n.v.t.

Health condition

exciteerbaarheid van motor cortex

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: BrainGain;Smart Mix

Intervention

Keyword: cortical excitability, hand task, TMS

Outcome measures

Primary outcome

The primary outcome measure in this study is the mean MEP amplitude of the

single and paired TMS pulses.

Secondary outcome

not applicable

Study description

Background summary

In the last three decades Transcranial Magnetic Stimulation (TMS) has become an important scientific technique in clinical studies and in the field of neuroscience. By sending a large and rapid current through a copper coil a magnetic field is produced, that in its turn induces an electric field in the underlying tissue. When the coil is placed on top of the scalp it can depolarize neurons and evoke action potentials (EP), when the field reaches a certain threshold. For the motor cortex these evoked potentials can be objectified by measuring the motor evoked potential (MEP) in the corresponding contra-lateral muscle with the use of electromyography (EMG). The stimulation intensity needed to evoke an MEP with a specified amplitude is a measure for the individual cortical excitability at a specific point in time.

The cortical excitability, however, is not completely fixed and can be (temporarily) changed. This can be done, for example, with a simple motor task. This study is set up to see if a specific hand motor task, that is used to measure freezing in the upper part of the body of patients with Parkinson*s Disease (PD), induces changes in the cortical excitability. It is important to know if a certain task induces a change in the cortical excitability, before it is combined with TMS in a protocol. The knowledge gained here can be used to

design future protocols and help to explain unexpected results in complicated protocols that combine TMS and motor tasks.

Study objective

This study is set up to see if a specific hand motor task, that is used to measure freezing in the upper part of the body of patients with Parkinson*s Disease (PD), induces changes in the cortical excitability. It is important to know if this task induces a change in the cortical excitability to design future protocols and help to explain (possible) unexpected results in complicated protocols that combine TMS and this motor task.

We therefore state the following objectives:

The primary objective of this study is, to find out if a simple rhythmic flexion-extension of the index finger changes the cortical excitability of the primary motor cortex measurable with TMS.

In addition to this primary objective, we want to find out whether there is an effect of task difficulty on the changes in the cortical excitability of the primary motor cortex.

Study design

The study is designed as a within-subject experiment with healthy adult volunteers. It will span one intake session and two experimental sessions. During each of the two experimental sessions TMS will be combined with a hand motor task. The only difference between the sessions is the movement amplitude in the hand motor task. The first experimental session takes place in direct succession to the intake session on the first day. The second experimental session will take place on a different day.

1. During the intake session, the participants will be familiarized with the TMS procedure and the motor task.
2. Each session consists of six major parts, namely (1) the determination of the cortical hotspot and resting motor threshold (RMT), (2) TMS pre measurements, (3) a bimanual hand motor task, (4) TMS post 1 measurements, (5) rest and (6) TMS post 2 measurements. The total duration of one session is approximately 2 hours, including possible breaks. The TMS in (2), (4) and (6) will be applied over the cortical location that evokes the most constant response in the contra-lateral first dorsal interosseous (FDI) muscle. This muscle is also used in the motor hand task. In this task the subject has to flex and extend their index fingers with a specified frequency. The flexion and extension is performed in anti-phase. Each TMS block (2), (4) and (6) contains 100 single pulses and 20 trials of paired-pulse TMS.

The study takes place at the Department of Neurology, Radboud University Medical Centre Nijmegen.

Intervention

Per experimental session, each subject will receive 300 trials of single-pulse TMS, 60 trials of paired-pulse TMS and approximately 100 single pulses for determination of the hotspot and rest motor threshold (RMT).

Study burden and risks

The burden for the subjects is minimal. They have to be present during two experimental sessions of two hours. In advantage they have to withdraw from alcohol and drugs as stated in E4.

Concerning the benefits and risks:

Participants will not directly benefit from their participation in the study (except for the financial compensation in D11). Transcranial magnetic stimulation (TMS) is a widely used non-invasive brain stimulation technique, based on the principle of electromagnetic induction. During stimulation, the participant will likely hear the clicks of the TMS pulses and experience stimulation of nerves and muscles of the head. The most common side effect is a light transient headache (2-4% occurrence). A severe headache is uncommon (0.3-0.5% occurrence). In TMS studies of patient populations (e.g. epilepsy) or those exceeding the standard protocols (e.g. in intensity or frequency) epileptic seizures have been reported in rare cases. In the current study healthy participants will be stimulated with a protocol that falls within the safety guidelines. All subjects are screened for their relevant medical history and other TMS safety aspects (e.g. metal parts in the head). In summary, because the risk and burden associated with participation can be considered negligible-to-minimal, we do not expect serious adverse events during the project.

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

Only healthy and competent, 18 years or older, men and woman will be recruited. They can be right- and left handed.

Exclusion criteria

With regard to transcranial magnetic stimulation
• Epilepsy, convulsion or seizure
• Serious head trauma or brain surgery
• Large or ferromagnetic metal parts in the head (except for a dental wire)
• Implanted cardiac pacemaker or neurostimulator
• Pregnancy;With regard to other experimental techniques
• Skin diseases at intended electrode sites (EMG);With regard to general experimental requirements
• History or current presence of any neurologic or psychiatric disease
• Any prescribed medication that can alter cortical excitability (e.g. antiepileptics, tricyclic anti-depressives or benzodiazepines) or can have an influence on the participant*s vigilance or cognitive performance within two weeks prior to participation

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	04-03-2013
Enrollment:	12
Type:	Anticipated

Ethics review

Approved WMO

Date:	02-05-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL43561.091.13