Stability of non-invasive human neurophysiological parameters using transcranial magnetic stimulation

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cognitive and attention disorders and disturbances
Study type	Observational invasive

Summary

ID

NL-OMON40291

Source
ToetsingOnline

Brief title
Non-invasive human neurophysiology

Condition

- Cognitive and attention disorders and disturbances

Synonym
LTP / learning

Research involving
Human

Sponsors and support

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

Intervention

Keyword: humans, neurophysiology, non-invasive, TMS

Outcome measures

Primary outcome

The difference in the amplitude of the MEP of the APB muscle between baseline

TMS and after PAS, Theta-burst rTMS (TBS) or ppTMS as obtained during session 1

and session 2.

Secondary outcome

The neuropsychological tests scores.

Study description

Background summary

Long-term potentiation (LTP)-like plasticity and cortical inhibition can safely be measured by means of motor evoked potentials (MEPs) from the Abductor Pollicis Brevis (APB) thumb muscle as induced by Transcranial Magnetic Stimulation (TMS) of the motor cortex.

Study objective

- The primary objective of this proposal is to assess the intraindividual reliability of PAS TMS, Theta-burst rTMS and ppTMS indices as measures of neural plasticity and cortical inhibition, by performing test-retest measurements separated by a period of 2 weeks in healthy volunteers.
- The secondary objective is to explore relationships between indices of PAS TMS, Theta-burst rTMS and ppTMS, and neuropsychological test scores in healthy volunteers.

Study design

Observational test-retest design.

Study burden and risks

There are only minor risks associated with this study. TMS as used in this protocol is considered safe and without elevated risk of seizures. However, we will make use of a screening checklist for risk factors in order to avoid potential TMS-related side effects. The participants will visit the Erasmus MC twice, with at least 2 weeks in between the visits. During both sessions, identical measurements will be made regarding electromyography (EMG), PAS TMS, ppTMS and TBS. EMG measurements will be made from the right APB thumb muscle to record MEPs by means of surface EMG, using disposable electrodes in belly-tendon recording technique. For the PAS TMS measurements, 200 paired stimuli will be administered at a frequency of 0.25 Hz with an interstimulus interval (ISI) of 25 ms. For the ppTMS protocol, ISIs of 2, 3 and 15 ms will be investigated at 3 levels of subthreshold stimulation, with 15 stimuli delivered at random for each condition. The TBS protocol consists of bursts of three pulses given at 50 Hz repeated every 200 ms. The stimulation intensity used in this protocol is the 80% of the active motor threshold (AMT). Prior to the first TMS session, there will be an intake in which two questionnaires will be filled out and 6 neuropsychological tests will be performed. The total time investment for testing of the participants will be approximately 6 hours (1x 2 hours and 2 x 2 hours). The participants will be reimbursed for travel costs and they will receive ¤50,-.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

dr. Molewaterplein 50
Rotterdam 3015GE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

dr. Molewaterplein 50
Rotterdam 3015GE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Subjects can be included if:
• They are in good health, based on medical history information, including current physical and mental condition
• They are medication free (females: except for hormonal contraceptives) and abstinent from the use of illicit drugs
• They are right-handed
• They are capable and willing to give written informed consent
• They are within the age range of 18-40 years

Exclusion criteria

Subjects will be excluded if:
• They are women who are pregnant or lactating
• They have a history of psychiatric illness and/or psychotherapeutic treatments
• They have a history of neurological illnesses
• They fulfil any of the exclusion criteria concerning the safety of TMS as assessed by means of the Transcranial magnetic stimulation Adult Safety Screen (TASS)
• They cannot understand the Dutch language sufficiently to understand the purposes and implications of the experiment

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-05-2014
Enrollment:	96
Type:	Actual

Ethics review

Approved WMO Date:	20-12-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-06-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL45245.078.13