

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

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Cognitive and attention disorders and disturbances
<b>Study type</b>	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

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## 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