Transcranial magnetic stimulation during fMRI; investigating neuronal activation during TMS

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The objective of the current study is to validate computational models that predict neuronal activation during TMS.

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

Summary

ID

NL-OMON46090

Source
ToetsingOnline

Brief title
TMS in fMRI

Condition

- Other condition

Synonym
n.v.t.

Health condition

geen, onderzoek in gezonde proefpersonen

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: DeNeCor EU grant (FP7)

Intervention

Keyword: fMRI, Neuronal activation, TMS

Outcome measures

Primary outcome

The main study parameters are the TMS induced percent signal change in BOLD MR images over the whole brain, and the spatial correspondence between activated brain areas measured by BOLD and predicted by TMS field modelling.

Secondary outcome

A secondary endpoint is the ECG/EMG output from thumb movement during TMS application.

Study description

Background summary

Transcranial magnetic stimulation (TMS) is a method that can temporarily alter brain activity in a safe and non-invasive way. It is currently used in many different clinical and research settings. However, as of yet there is restricted knowledge about the TMS induced field patterns and accurate TMS dosage. Previous research has attempted to predict neuronal activation during TMS by making electromagnetic models and validating these by mapping TMS magnetic fields with an MR scanner. However, most studies attempting to map the magnetic field of TMS coils have used simplifications of current TMS techniques, making it difficult to generalize these results to a more realistic TMS setup. Recently, our group has developed a new TMS-MRI setup that makes it possible to accurately map TMS magnetic fields using a realistic TMS setup as often used both in clinical and research settings. Using this setup, we can validate electromagnetic models of TMS coils and correct guidance and dosimetry for concurrant TMS-MRI, so that more crude methods such as the motor threshold

to determine individual TMS dosage is no longer needed.

Study objective

The objective of the current study is to validate computational models that predict neuronal activation during TMS.

Study design

We aim to observe the effect of TMS on the healthy brain by having 10 healthy adults undergo one session of concurrent TMS stimulation and an MRI scan, and one session of MRI without concurrent TMS. During the session with concurrent TMS and MRI we will also use the scanner*s default ECG apparatus, normally used for heart rate measurement during MR scans, to measure TMS-induced thumb movement of the hand. This measurement will be repeated outside the scanner with a dedicated EMG device at a later visit.
In the MRI, we will stimulate two of the most important locations in the brain for TMS research; M1 in the motor cortex and the left dorsolateral prefrontal cortex (DLPFC), and the temporo-parietal junction (TPJ).
This is an observational study in which healthy participants will undergo concurrent TMS stimulation ,fMRI measurements, DTI measurements and MR phase mapping methods in order to evaluate the TMS field.
The total duration of study participation will be approximately five hours.

Study burden and risks

The risk associated with participating in an fMRI-TMS experiment is minimal. It is not considered greater than when fMRI or TMS is applied in isolation. The potential risks of bringing a TMS coil into the bore of an MRI scanner have been eliminated by the special setup that is designed by our research group. A comparable setup was used in a previous study by our group, which has been used in x participants without any adverse events. The setup currently developed even has an extra safety built in, controlling not only the opening but also the closing of the relay. For known potential hazards of fMRI and TMS, the usual precautions are taken such as careful screening of participants.

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

Healthy participants aged 18 years or older

Exclusion criteria

- Ferrous objects in or around the body that can not be removed
- Drug or alcohol abuse over a period of six months prior to the experiment
- History of closed- or open-head injury
- History of neurological illness or endocrinological dysfunction
- History of psychiatric disease
- History of epilepsy
- Occurrence of epilepsy in 1st degree family
- Major medical history
- Chronic use of medication
- For women: pregnancy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-10-2016
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	01-09-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-12-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	01-02-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL57722.041.16