Feasibility of dual channel low field TMS for improvement of brain functioning.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21943

Source
NTR

Brief title
Dual low field TMS

Health condition

Impaired connectvity

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: University Medical Center Groningen

Intervention

Outcome measures

Primary outcome

1. The change in effective brain connectivity estimated by DCM for EEG;

2. The differences in concentrations of oxygenated (HBo) and de-oxygenated blood before, during and after the treatment (as estimated from NIRS measurements).

Secondary outcome

1. The estimated coherence of EEG recordings between electrodes;

2. The ERP from EEg recordings;

3. The accuracy from the cognitive test;

4. The accuracy from the Digit symbol substitution test;

5. The differences in concentrations of oxygenated (HBo) and de-oxygenated blood before, during and after the treatment (as estimated from NIRS measurements).

Study description

Background summary

Brain connectivity, which refers to the anatomical and functional connections between different brain regions, is often pathologically altered in patients with psychiatric or neurological disorders such as epilepsy. Transcranial magnetic stimulation (TMS) is a tool to non-invasively modulate brain function. It is known that TMS can influence brain connectivity, but epilepsy is one of the prime contra-indications for TMS research. We intend to overcome this limitation by using a very weak form of TMS, largely developed and implemented in-house: microTMS. This is a proof of principle study is required before this technique can be tested on patients.

Study objective

Using low field stimulation on two brain regions simultaneously, we aim to specifically alter the connectivity between one or more pairs of brain areas.

Study design

1. Participants recruitment immediately after METC approved;

2. Measurements finalized as soon as enough participants are found;

3. Primary and secondary outcomes up to 6 months after the data were collected for the last subject.

Intervention

Two electromagnets are fitted over the EEG/NIRS cap. Magnetic field flux densities <5mT are

applied to the head. The microTMS stimulus will consist of pulsed magnetic stimulation. Pulses will consist of random white noise (frequencies ranging from 0.3-100Hz) with a Gaussian envelope and will have a duration of 50 ms followed by 30 ms of rest.
Before and after the stimulation the subjects will perform a cognitive task, during and before which EEG/NIRS will be recorded (active and resting conditions). These measurement are needed to determine the functional brain connectivity between two targeted brain areas.

Contacts

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Eligibility criteria

Inclusion criteria

1. Adult healthy volunteers;

2. Native Dutch speaker;

3. Age 18-80.

Exclusion criteria

1. Psychiatric or neurological disease, present or past;

2. Visual or hearing limitations that can not be corrected for;

3. Alcohol or drug addiction;

4. Excessive intake of coffee (>10 units per day) or alcohol (>10 units per day);

5. Recent use of alcohol (within 1 day);

6. Recent use (within four weeks) of cannabis or any other non-prescription psychopharmaca;

7. Presence in the body of MRI-incompatible implants, electronic implants (e.g. cardiac pacemakers), or connectors of electronic equipment (e.g. electrodes);

8. Pregnancy, lactation.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-03-2012
Enrollment:	70
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL3174
NTR-old	NTR3318
Other	ABR number : 39489
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A