The influence of high frequency 10Hz repetitive transcranial magnetic stimulation (rTMS) on experimental pain measured through quantitative sensory testing in healthy subjects.

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to investigate the analgesic effect of high frequency 10 Hz rTMS on experimental pain measured through quantitative sensory testing (QST) in healthy subjects.

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

Summary

ID

NL-OMON43483

Source
ToetsingOnline

Brief title
rTMS on experimental pain in healthy subjects.

Condition

- Other condition

Synonym
Pain

Health condition

Pijn, Centraal Zenuwstelsel: Verwerking van pijn.

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Brain stimulation, Quantitative Sensory Testing (QST), repetitive transcranial magnetic stimulation (rTMS)., Sham controlled

Outcome measures

Primary outcome

Analgesic effect is measured through QST. QST measurements will be performed using different modalities, e.g. mechanical pressure, electrical stimulation and conditioned pain modulation (CPM). The primary outcome is pressure pain threshold (PPT).

Secondary outcome

Secondary outcomes are: Electric Sensation Threshold in mA, Electric Pain Threshold in mA, Electric Pain Tolerance Threshold in mA, Conditioned Pain Modulation Paradigm in kPa for PPT and mA for EPPT and VAS-score (0-10). Mask validity tests in % (for both rTMS and sham).

And Adverse events.

Study description

Background summary

Management of chronic pain showed to be generally unsatisfactory In the search for alternative pain treatments, there is accumulating evidence that repetitive transcranial magnetic stimulation (rTMS) is able to produce an analgesic effect

in patients. Single dose high-frequency rTMS of the motor cortex shows a small short-term effect on chronic pain. However, the heterogeneity in rTMS studies is highly significant and the evidence of these studies is of low-quality because of bias risk. Additionally, rTMS showed earlier to be a predictor for the effective different neurosurgical brain stimulating technique, motor cortex stimulation (MCS). The lack of effective chronic pain treatment, the possible predicting quality of rTMS for and promising results of MCS, the promising results of high frequency repetitive transcranial stimulation of the motor cortex, and the lack of studies with a high quality study design form the basis of the present research proposal.

Study objective

to investigate the analgesic effect of high frequency 10 Hz rTMS on experimental pain measured through quantitative sensory testing (QST) in healthy subjects.

Study design

A pilot study using a randomized, double-blind, sham-controlled, cross-over design.

Intervention

All subjects participate in two conditions in random sequence. These conditions contain either sham rTMS or active 10Hz rTMS. The rTMS is 10 Hz high frequency rTMS, stimulating the motor cortex with 80% of the resting motor threshold in a single session with a total of 3000 pulses.

Study burden and risks

Participation results in a total of 3 contacts of which 2 are visits and 1 is a telephone interview. After visit 1, including screening, the time from visit 1 to the final telephone interview will be 2 weeks. All visits will take place in the outpatient clinic of the Radboud University Medical Centre in Nijmegen, the *RadboudUMC*.
The participating subjects will obtain no direct personal benefit.

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

1. Subject is or is older than 18 years.
2. Subjects should be naïve to rTMS treatment

Exclusion criteria

1. Subject has an condition with risk of magnetic interference while using rTMS.
2. Subject has an condition with increased or uncertain risk of inducing epileptic seizures while using rTMS(active or history of epilepsy, lesions of the brain, interfering drugs/medication)
3. Subject has an conditions with increased risk of other events while using rTMS (pregnancy, severe hearth disease)
3. Subject has an history of, clinical signs/symptoms of, or concomitant acute or chronic pain.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2016
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	09-03-2016
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	NL56046.091.16