Investigating the role of rTMS in the treatment of chronic depression

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(1) To investigate the effect of rTMS in a treatment set-up of 4 weeks including sham-rTMSas a control in 2 x 50 patients who have had at least two prior antidepressant therapies and psychotherapy according to the Dutch guideline of depression.(2)...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON43899

Source
ToetsingOnline

Brief title
rTMS in depression

Condition

- Mood disorders and disturbances NEC

Synonym
depression, major depressive disorder

Research involving
Human

Sponsors and support

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

Intervention

Keyword: depression, rTMS, therapy

Outcome measures

Primary outcome

Primary endpoint is the change in depressive symptoms between both groups after

rTMS treatment.

Secondary outcome

Secondary endpoint is the change in depressive symptoms after 5 weeks and

routine -outcome monitoring (ROM) parameters.

Study description

Background summary

Major depressive disorder (MDD) is one of the most prevalent psychiatric disorders and is the leading cause of disability worldwide. Despite tremendous development in the treatment of MDD, the chronic course in 1/3 of the patients remains a fundamental clinical problem. Repetitive transcranial magnetic stimulation (rTMS) of the dorsolateral prefrontal cortex (DLPFC) has been introduced for more than a decade as an antidepressive treatment option. However, study samples are often small and inclusion varies between treatment resistant depression on the one hand and moderate depression on the other hand. The current US Food and Drug Administration (FDA) Approval in the United States is for adults who have only failed a single antidepressant trial in the current depressive episode. Results can hardly be applied to the stepped care treatment of MDD in the Netherlands. Moreover, patients who do not respond to combination therapies of pharmacotherapy and psychotherapy clearly lack further options but informative studies are missing that provide information about cost effectiveness and follow-up outcome. Yet, additional treatment options are necessary

Study objective

(1) To investigate the effect of rTMS in a treatment set-up of 4 weeks including sham-rTMSas a control in 2 x 50 patients who have had at least two prior antidepressant therapies and psychotherapy according to the Dutch

guideline of depression.
(2) To analyze the change in symptoms over a follow-up course of 2 months in the rTMS treatment and control group.
(3) To investigate the neurobiological changes related to rTMS treatment using a combined EEG/FMRI longitudinal set-up.

Study design

A 2-year longitudinal study with 100 patients, between 18-65 years old, with chronic depression who will either receive rTMS or sham rTMS on top of their care as usual for 4 weeks (20 sessions) and then will be clinically investigated again 1 week after stop of treatment.

Intervention

RTMS and sham treatment will be done using Magstim Rapid 2. All rTMS parameters used in the proposed study are within the range considered safe according to the latest published safety guidelines (Rossi et al., 2009, 2011; Obermann et al., 2011). Firstly, the resting motor threshold (rMT) will be defined in each subject as the minimal stimulation intensity evoking an MEP of >= 0.05 mV in 50% of the trials in the muscle of the right thumb (M. abductor pollicis brevis).
Note that rMT will be determined before every treatment/sham session. TMS will be conducted in the form of *conventional rTMS*, whereby 30 trains of 10 Hz pulses with a duration of 5 seconds and an inter-train interval of 25 seconds are applied to the left dorsolateral prefrontal cortex (50 pulses per train, 6000 pulses per session).
We aim to control for placebo effects merely evoked by the regular treatment and therefore include a so-called sham condition using a sham-coil, which applies a similar electrical sensation to the skull.

Study burden and risks

All psychiatric measurements are administered routinely at our out- and inpatient depression unit. The actual rTMS treatment will take about 30 minutes 5 times a week whereby the side effects are mild. Additional EEG and MRI measurements do not have any side effects.

Contacts

Public
Selecteer

Reinier Postlaan 10
Nijmegen 6500 HB

NL
Scientific
Selecteer

Reinier Postlaan 10
Nijmegen 6500 HB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Males and females above 18 years of age
• First or recurrent unipolar major depressive disorder without psychotic symptoms (DSM-IV), with a chronic course during the last two years
• Treatment resistance for at least two antidepressants treatment and a form of psychotherapy.

Exclusion criteria

Presence of a current or past relevant somatic or neurological disorder
A comorbid diagnosis of bipolar disorder, schizophrenia or substance dependence disorders.;With regard to transcranial brain stimulation
• Epilepsy, convulsion or seizure (TMS)
• Serious head trauma or brain surgery
• Large or ferromagnetic metal parts in the head (except for a dental wire)
• Implanted cardiac pacemaker or neurostimulator
• Pregnancy
With regard to other experimental techniques
MRI-related exclusion criteria like claustrophobia, metal in body, pacemaker, pregnancy, etc.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-12-2013
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	14-03-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-02-2016
Application type:	Amendment
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	NL42420.091.12