Transcranial Magnetic Stimulation in depression treatment

Published: 08-06-2010
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Finding out if adjustment of intensity and duration of rTMS stimulation will produce a more robust antidepressant effect.

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

Summary

ID

NL-OMON35230

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: Sint Lucas Andreas Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: depression, parietal, rTMS, stimulation

Outcome measures

Primary outcome

1. Percentage of change from baseline on the Hamilton Depression Rating Scale

(HAMD, 17 items)

2. Percentage of patients with clinical response (= 50 % reduction in HAMD

score)

3. Percentage of patients with partial clinical response (= 30 % reduction in

HAMD score)

Secondary outcome

Emotion Recognition Task

Study description

Background summary

Schutter et al. (2008) found a partial clinical effect on major depression by stimulating the right parietal cortex with rTMS. It is supposed that adjustment of intensity and duration of stimulation will produce a more robust antidepressant effect.

Study objective

Finding out if adjustment of intensity and duration of rTMS stimulation will produce a more robust antidepressant effect.

Study design

Randomized double-blind placebo controlled. Patients in the placebo condition may, on request, receive real rTMS treatment after the follow up period.

Intervention

rTMS on the right parietal cortex
2 Hz with an inter-impuls interval of 0,5 sec.

at 110 % of motor threshold
15 sessions of 20 minutes during a period of three weeks

Study burden and risks

Stimulation over the scalp with a magnetic coil is painless. There are no known side effects of rTMS stimulation other than a slight headache. Application of the proposed stimulation parameters has proven to be safe, and not to provoke epileptic seizures (lit. ...).

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

age from 18 yrs onward
unipolar depressive disorder
only the following medication is allowed: SSRI's, venlafaxine, mirtazapine, antihistamanics for sedation
medication to be kept constant during the trial

Exclusion criteria

bipolar disorder, dysthymic disorder
suicidality
Use of beta-blockers, other antidepressants or psychotropic medication, thyroid hormone, benzodiazepines, anti-epileptics
history of epilepsy or epileptic abnormalities on EEG
intracranial metal, pacemaker
schizophrenia, addiction, mental handicap, not speaking Dutch
lefthandedness

Study design

Design

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):	01-05-2011
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	08-06-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL26903.029.09