

Repetitive transcranial magnetic stimulation in the treatment of depression

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 31/12/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00220610

Secondary identifying numbers
NTR224; CCMO03.3741/SH/P03.1231L;

Study information

Scientific Title

Right parietal inhibition with repetitive transcranial magnetic stimulation (rTMS) in the treatment of depression

Acronym

TMS

Study objectives

Repetitive transcranial magnetic stimulation (rTMS) has a positive effect in the treatment of depression.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Randomised, double-blind, placebo controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Depression

Interventions

Repetitive transcranial magnetic stimulation daily on 10 consecutive weekdays (five sessions per week), during 20 minutes per session. During the rTMS session, the coil was centered flat over the right parietal cortex. Patients were followed-up for 12 weeks after the two weeks of rTMS (follow-up period) to measure depression with different rating scales.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Depression

Secondary outcome measures

1. Changes in anxiety
2. Autonomic changes
3. Changes in the emotional attention, in the emotional memory and in the emotional recognition
4. Biochemical changes
5. Changes in the electroencephalogram (EEG)

Overall study start date

01/05/2004

Completion date

01/12/2006

Eligibility

Key inclusion criteria

1. In- and out-patients, aged between 16 and 65 years
2. Meet Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) criteria for major depressive episode
3. Have a score of 25 or higher on the 10-item Montgomery Asberg Depression Rating Scale (MADRS)

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

40

Total final enrolment

55

Key exclusion criteria

1. A history of epilepsy or any other medical disorder that should preclude the administration of rTMS. Only selective serotonin reuptake inhibitors (SSRIs), mirtazapine and promethazine as psychotropic medication was accepted if the dosage of antidepressive medication had not been changed for 6 weeks, and if the dosage of promethazine had not been changed for 2 weeks prior to inclusion.
2. Antidepressive medication had to remain stable during the 14 weeks of the study
3. Schizophrenic disorder
4. A piece of metal in the brain

- 5. Pacemaker
- 6. Left-handed patients

Date of first enrolment

01/05/2004

Date of final enrolment

01/12/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

St. Lucas Andreas Ziekenhuis

Amsterdam

Netherlands

1016 AE

Sponsor information

Organisation

St. Lucas Andreas Hospital (Netherlands)

Sponsor details

Department of Psychiatry

Jan Tooropstraat 164

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Sponsor type

Hospital/treatment centre

Website

<http://www.slaz.nl/>

ROR

<https://ror.org/016jc2h42>

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/10/2004	31/12/2021	Yes	No