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Repetitive transcranial magnetic stimulation in the treatment of depression

Submission date	Recruitment status
20/12/2005	No longer recruiting
Registration date	**Overall study status**
20/12/2005	Completed
Last Edited	**Condition category**
31/12/2021	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

ClinicalTrials.gov (NCT)
NCT00220610

Protocol serial number
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

Study type(s)
Treatment

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(s)
Depression

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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 if 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)

ROR
https://ror.org/016jc2h42

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

Results and Publications

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