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rTMS in chronic depression

Submission date	Recruitment status	[ ] Prospectively registered
10/04/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/06/2017	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/10/2022	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Depression is very common disease which affects one in five people in their lifetime and is associated with a large burden for patients and their caregivers. It can cause symptoms of unhappiness, hopelessness, anxiety, tiredness, and low mood. One in three patients will not benefit from first line treatments such as medication and psychotherapy (talking to a therapist), and may suffer from a chronic depression. Repetitive magnetic stimulation (rTMS) is a relative new treatment for depression that uses magnetic pulses to activate superficial areas (near the surface) in the brain that are underactive in depression. The aim of this study is to evaluate the use of rTMS as a treatment for chronic, treatment-resistant depression.

Who can participate?
Adults aged 18 and older who have major depressive disorder.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive 20 rTMS sessions over a period of four weeks. Those in the second group receive 20 sham sessions. Participants are measured at the beginning of the study and after every week of stimulation to evaluate their resting motor threshold. Depressive symptoms are measured before and after treatment to see how effective the treatment is at treating depression.

What are the possible benefits and risks of participating?
Participants may benefit from a better mood and relief of depression after the treatment. An incidental epileptic seizure is a rare complication, but has no further consequences.

Where is the study run from?
Radboud University Nijmegen Medical Centre (Netherlands)

When is the study starting and how long is it expected to run for?
November 2012 to November 2019

Who is funding the study?
Radboud University Nijmegen Medical Centre (Netherlands)

Who is the main contact?
Dr Philip van Eijndhoven

Contact information

Type(s)
Scientific

Contact name
Dr Philip van Eijndhoven

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL42420.091.12

Study information

Scientific Title
lnvestigating the role of rTMS in the treatment of chronic depression

Acronym
DREAMS

Study objectives
High frequent repetitive transcranial magnetic stimulation (10 Hz rTMS) over the left prefrontal cortex is superior than placebo in the treatment of chronic, treatment-resistant depression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee CMO regio Arnhem-Nijmegen, 14/03/2013, ref: 2012/498

Study design

Longitudinal randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Depression

Interventions
Patients were randomly assigned to one of two groups using block randomisation. Both investigators and patients are blinded (double blind study); the physicians and nurses who treat the patients are not blinded.

Intervention group: Participants receive 20 rTMS sessions (10Hz stimulation of left DLPFC) over a period of 4 weeks. This involves 5 sessions of approximately 30 minutes, per week. Magstim Rapid 2 TMS is used with a focal, 8-figure shaped 70mm coil. At the beginning of the study and after every week of stimulation, the resting motor threshold (resting MT) is measured of the right abductor pollicis brevis muscle. Treatment intensity was standardized at 110% of the resting MT.

Control group: Participants receive 20 sham sessions of equal duration in which the coil is tilted 45 degrees away from the scalp, making the stimulation site outside the skull. At the beginning of the study and after every week of stimulation, the resting motor threshold (resting MT) is measured of the right abductor pollicis brevis muscle.

After each session there there is a debriefing and each week there is an evaluation of treatments effect. A week after the last session participants hear if they had the real or placebo treatment. In case of placebo treatment, participants can then chose to undergo the real rTMS treatment. Participants are assessed one week after treatment for their depressive symptoms.

Intervention Type
Device

Primary outcome measure
Depressive symptoms are measured using the Hamilton Depression Rating Scale at baseline and one week after treatment end.

Secondary outcome measures

1. Response as defined as a ≥50% decrease of the HDRS score between baseline and one week after treatment end
2. Remission, as defined as a HDRS score ≤7, is assessed one week after the last rTMS treatment
3. Side-effects are assessed using a side-effect questionnaire at baseline and one week after treatment end
4. Neurobiological changes related to rTMS treatment are measured using a combined EEG/FMRI longitudinal set-up at baseline and one week after treatment end

Overall study start date
01/11/2012

Completion date
01/11/2019

Eligibility

Key inclusion criteria
1. Males and females above 18 years of age
2. Unipolar major depressive disorder without psychotic symptoms (DSM-lV), with a chronic course during the last two years
3. Treatment resistance for at least two antidepressants treatment and a form of psychotherapy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Total final enrolment
31

Key exclusion criteria
1. Presence of a current or past relevant somatic or neurological disorder
2. A comorbid diagnosis of bipolar disorder, schizophrenia or substance dependence disorders
3. Epilepsy, convulsion or seizure (TMS)
4. Serious head trauma or brain surgery
5. Large or ferromagnetic metal parts in the head (except for a dental wire)
6. lmplanted cardiac pacemaker or neurostimulator
7. Pregnancy

Date of first enrolment

01/07/2013

Date of final enrolment
01/07/2018

Locations

Countries of recruitment
Netherlands

Study participating centre
Radboud University Nijmegen Medical Centre
Geert Grooteplein Zuid 10
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6525 GA

Sponsor information

Organisation
Radboud University Nijmegen Medical Centre

Sponsor details
Department of Psychiatry
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Sponsor type
Hospital/treatment centre

Website
https://www.radboudumc.nl/afdelingen/psychiatrie

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Radboud University Nijmegen Medical Centre

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/07/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Philip.vaneijndhoven@radboudumc.nl

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2021	11/05/2020	Yes	No
Results article		01/09/2020	05/10/2022	Yes	No