rTMS/CBT compared to antidepressant treatment

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rTMS in combination with CBT is a more (cost)effective treatment option for patients with non-psychotic depression with a moderate level of treatment resistance compared to treatment as usual (switching to a tricyclic antidepressant (TCA) or…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Depressed mood disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON24799

Source
NTR

Brief title
DETECT

Condition

- Depressed mood disorders and disturbances

Health condition

Major depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: ZonMw
Source(s) of monetary or material Support: ZonMw

Intervention

- Medical device

Explanation

Outcome measures

Primary outcome

Score on the Hamilton Depression Rating Scale (HDRS-17)

Secondary outcome

Remission (cost-effectiveness) Quality adjusted life years

Study description

Background summary

Rationale: Repetitive transcranial magnetic stimulation (rTMS) is widely used both in fundamental cognitive neuroscientific studies as well as clinical applied studies investigating its potential mood stabilizing role. Objectives: To examine the effect of high frequency rTMS over the left DLPFC in combination with CBT as a cost-effective treatment alternative for the current pharmacological switch in combination with CBT for depressed patients with a moderate level of treatment-resistance. Study design: A randomized, multicenter, prospective clinical superiority trial with regular assessments during a 12 month follow up from baseline onwards. 90 patients with moderate to severe, non-psychotic, unipolar depression, who did not respond to 2 adequate antidepressant trials, will be included. The intervention consists of max. 25 sessions of repetitive transcranial magnetic stimulation (rTMS) over the course of 8 weeks (schema of 4, 4, 4, 3, 3, 3, 2, 2 sessions per week) and cognitive behavior therapy (CBT) on top of continued antidepressants (AD) [rTMS + AD cont + CBT]. The control condition consists of a switch in AD according to the Dutch stepped care guidelines and CBT. Main study parameters/endpoints: Clinical outcome is determined by the reduction in depressive symptoms measured by the Hamilton depression rating scale (HDRS-17) after 8 weeks of treatment and 4 and 6 months follow up. We will also calculate remission (HDRS-17 <7) and response (50% reduction HDRS-17) rates at these time points. Quality of life and societal costs and health consumption will be assessed for the economic evaluation during the six month follow-up period. An extended follow-up until twelve months will be available for a subgroup of patients.

Study objective

rTMS in combination with CBT is a more (cost)effective treatment option for patients with

non-psychotic depression with a moderate level of treatment resistance compared to treatment as usual (switching to a tricyclic antidepressant (TCA) or augmenting TCA with an atypical antipsychotic or lithium, in combination with CBT).

Study design

Baseline, 8 weeks of treatment, follow-up at 4 and 6 months, extended follow-up at 9 and 12 months

Intervention

Repetitive Transcranial Magnetic Stimulation (rTMS) + cognitive behavioral therapy (CBT)
Treatment as usual (switching to TCA or augmenting TCA with atypical antipsychotic or lithium) + cognitive behavioral therapy (CBT)

Contacts

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Eligibility criteria

Age

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

Inclusion criteria

>18 years of age. Failed response to 2 adequate dose-duration trials with antidepressants. Current episode of less than two years. Moderate or severe depression (HDRS-17 > 16) without psychotic features.

Exclusion criteria

Lifetime diagnosis of bipolar disorder, schizophrenia or schizoaffective disorder, current substance abuse disorder, or organic brain syndrome. Presence of a concurrent significant medical condition impeding the ability to participate. Previous treatment with rTMS. Epilepsy, convulsion or seizure. 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. Previous treatment with ECT.

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-08-2019
Enrollment:	90
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO

Date:	06-05-2019

Application type:	First submission
Review commission:	METC Oost-Nederland
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Study registrations

Followed up by the following (possibly more current) registration

ID: 54536
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7628
CCMO	NL68540.091.19
OMON	NL-OMON54536

Study results