Anti-depressant Effecte of Pulsed ElectroMagnetic Fields (PEMF) in patients with treatment resistant depression

Published: 06-06-2012
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Can this effect be utilised clinically, especially in patients with major depressive disorder?

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

Summary

ID

NL-OMON39674

Source
ToetsingOnline

Brief title
Antidepressant microTMS

Condition

- Mood disorders and disturbances NEC

Synonym
depression, major depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,NutsOhra

Intervention

Keyword: depression, intervention, magnetism, non-invasive

Outcome measures

Primary outcome

17-point version of the 'Hamilton Depression Rating Scale' (HAMD17)

Secondary outcome

NEO-FFI

Questions relating to neuroticism are used.

Treatment expectancy

Verbal analogue scale (0 to 10) to indicate how effective the patient thinks

the treatment will be.

DM-TRD

Questionnaire to measure treatment resistance.

Exit interview

Patient is asked if they think they received PEMF or placebo.

MRI

Magnetic resonance spectroscopy

Resting state brain activity: fMRI.

Reward induced brain activity: fMRI.

HR and HRV

BDNF concentration in serum

Biomarkers in urine.

IDS-SR

Self-completed depression questionnaire.

BAI

Questionnaire for anxiety symptoms

EQ-5D

Questionnaire for health related quality of life.

Wais Digit Symbol Substitution

Questionnaire for health related quality of life.

TiC-P

Self-completed questionnaire to assess medical consumption.

Smoking

1. # smoked cigarettes per day.

2. Fagerstrom test for nicotine dependence

Gender, age, treatment resistance

Medication

Body weight

Study description

Background summary

According to the literature, exposure to weak pulsating magnetic fields has a potential antidepressive effect on experimental animals and human subjects.

Study objective

Can this effect be utilised clinically, especially in patients with major depressive disorder?

Study design

Intervention study, double blind,completely placebo controlled randomised

parallel design.

Intervention

A head cap with small electromagnets is placed on the head. Magnetic fields with flux densities of <5 mT are applied to the head.

Study burden and risks

Patients visit the treatment room for five weeks. Daily visits on working days lasting one hour each. Therefore in total it takes 25 hours in the treatment room.
The treatment itself might be experienced as boring by the patients, because they have to sit still for 30 minutes.
Reading is allowed to alleviate this.
No adverse events or risks due to the intervention are expected.

There are two MRI sessions: one at baseline and one after five weeks. Each session lasts for no longer than 60 minutes. During the scans patients lie in the MRscanner, which is a narrow space and are required to lie still. During certain periods they perform tasks.

The questionnaires constitute a negligible to mild burden.

Three venapunctions.
Three urine samples.

No switching of antidepressant medication is allowed during the study.

No other behaviours are enforced or prohibited. Patients may continue their normal medication and/or psychotherapy.

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

• Diagnosis of MDD, first or recurrent major depressive episode (MDE), as established by MINI-Interview
• Age range: 18-80 years
• At least moderately severe depression (>17 on HAMD17)
•
• Not having responded (i.e. maintained in a MDE) to one antidepressant during the current episode, given for at least four weeks and in an adequate dose (i.e. the defined daily dose (DDD) (Ruhe et al 2012).
• Good understanding of spoken and written Dutch
• In-patient or out-patient

Exclusion criteria

• Presence of a relevant neurological disorder such as dementia or epilepsy
• Other relevant major psychiatric disorders such as a primary psychotic disorder or an antisocial or borderline personality disorder
• Major depressive episode with psychotic features
• Visual or hearing problems that cannot be corrected
• Suicidal thoughts (>2 on HAMD17 for suicidal ideation) or a previous serious suicide attempt
• Recent (past three months) alcohol or drug abuse or dependence
• pregnancy, lactation
• inability to comply with treatments and/or assessments.
• Recent change (last four weeks) in antidepressant medication or requirement to change

antidepressant medication during the course of the study.
• Use of benzodiazepine(s) in excess of 2 mg lorazepam (or equivalent) per day within the last four weeks or during the course of the study
• Use of somatic medication that may affect mood within the last four weeks
• Excessive use of: coffee (>10 units per day), alcohol (>5 units per day)
• Recent use (within four weeks) of cannabis or any other non-prescription psychopharmaca, except St John*s Wort, or unwillingness to abstain from these substances during the study.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-05-2012
Enrollment:	52
Type:	Actual

Medical products/devices used

Generic name:	Transcranial magnetic stimulation
Registration:	No

Ethics review

Approved WMO

Date:	06-06-2012

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Not approved Date:	23-04-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-07-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-09-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	31-07-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL39450.042.12
Other	NTR12336