Low field TMS as depression treatment.

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Low field TMS can reduce depression scores in treatment resistant patients.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27196

Bron
Nationaal Trial Register

Verkorte titel
microTMS-DEPR

Aandoening

Major depressive disorder

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: Ohra NUTS

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Hamilton Depression Rating Scale 17 point version.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Major depressive disorder (MDD) is a common and severe psychiatric condition for which currently available treatments (psychotropic medication and psychotherapy) are not always effective. There is a strong need for additional treatment options in MDD. A novel intervention that was recently approved by the FDA for the treatment of MDD is transcranial magnetic stimulation (TMS), a noninvasive neurostimulation in which strong magnetic pulses are applied to a specific frontal scalp region. Interestingly, weak TMS with pulsed electromagnetic fields, here called PEMF, was recently reported to have rapid antidepressant effects. This method is much more feasible (cheaper and less cumbersome because it is more versatile).

Objective:

This proposal aims at replication, in a pilot study, of the antidepressant effects of PEMF in patients with a refractory depression. We also aim to study the effects on brain activation and brain derived neuronal growth factor (BDNF) levels in blood as well as the remaining antidepressant effects at five and fifteen weeks after the treatment period.

Study design:

Randomized, stratified and minimised, double-blind placebo controlled intervention study. Treatment lasts for five weeks. Measurements are made in the week preceding initiation of treatment, during the treatment period, at the end of the treatment period and five and fifteen weeks after the end of treatment.

Study population:

In-patients and out-patients with at least moderately severe MDD, 18 - 80 yr old, not having responded to two different antidepressants.

Intervention:

One group receives 30 minutes of PEMF treatment per day for five days per week, for five weeks in a row (PEMF group). The other group receives placebo (SHAM group). In both groups normal treatment with an antidepressant will be continued.

Main study parameters/endpoints:

Hamilton Depression Rating Scale (HAMD17), change in score between baseline (week 0) and endpoint (week 5).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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, spread out over 5 weeks. Each session lasts for no longer than 60 minutes. During the scans patients lie in the MR-scanner, 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 vena-punctions (2x 10 mL per sample).

No other behaviours are enforced or prohibited.
Patients have to continue the antidepressant to which they did not respond prior to the study but may be switched later to other medication and/or psychotherapy.

Doel van het onderzoek

Low field TMS can reduce depression scores in treatment resistant patients.

Onderzoeksopzet

End of week -1, 1, 2, 3, 4, 5, 10, 20.

Onderzoeksproduct en/of interventie

30 minutes of PEMF to the head, 5 days per week, 5 weeks in a row.

The control group will receive sham treatment meaning the stimulator will be applied but no actual stimulation will be given.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Diagnosis of MDD, first or recurrent major depressive episode (MDE), as established by MINI-Interview;

2. Age range: 18-80 years;

3. At least moderately severe depression (>17 on HAMD17);

4. Not having responded (i.e. maintained in a MDE) to at least two antidepressants during the current episode, both given for at least four weeks and in an adequate dose (i.e. the defined daily dose (DDD) (Ruhe et al 2012);

5. Good understanding of spoken and written Dutch;

6. In-patient or out-patient.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Presence of a relevant neurological disorder such as dementia or epilepsy;

2. Other relevant major psychiatric disorders such as a primary psychotic disorder or an antisocial or borderline personality disorder;

3. Major depressive episode with psychotic features;

4. Visual or hearing problems that cannot be corrected;

5. Suicidal thoughts (>2 on HAMD17 for suicidal ideation) or a previous serious suicide attempt;

6. Recent (past three months) alcohol or drug abuse or dependence;

7. Pregnancy, lactation;

8. Inability to comply with treatments and/or assessments;

9. Recent change (last four weeks) in antidepressant medication or requirement to change antidepressant medication during the course of the study;

10. Use of mood stabiliser (lithium or anticonvulsant) or antipsychotic within the last four weeks or during the course of the study;

11. 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;

12. Use of somatic medication that may affect mood within the last four weeks;

13. Excessive use of: coffee (>10 units per day), alcohol (>5 units per day);

14. 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;

15. MR incompatible implants in the body (such as ear prothesis, insulin pump, or other metal implants);

16. Any risk of having metal particles in the eye, due to manual work without proper eye protections;

17. Tattoos containing red pigments;

18. (Suspected) pregnancy; if the patient is in doubt a pregnancy test is performed;

19. Claustrophobia;

20. The refusal to be informed of structural brain abnormalities that could be detected during the experiment.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-11-2013
Aantal proefpersonen:	52
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	13-11-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3552
NTR-old	NTR3702
Ander register	UMCG : microTMS002
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A