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Two vs. one high-frequency rTMS session per day for treatment-resistant depression

Submission date
01/08/2014

Recruitment status
No longer recruiting

Registration date
18/08/2014

Overall study status
Completed

Last Edited
09/10/2017

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
High frequency repetitive transcranial magnetic stimulation (HF-rTMS) is a form of brain stimulation therapy that is often used, for example, to treat depression when other treatments have not worked (that is, treatment resistant depression). It involves using magnetic pulses to stimulate a part of the brain that controls mood. This causes an electric current to be passed to specific nerve (brain) cells. The therapy is believed to work by resetting brain wave frequencies to normal and therefore relieving the symptoms of depression. In this study, we are investigating how successful two sessions of HF-rTMS is in treating patients with treatment resistant depression compared to only one HF-rTMS session or either one or two sham (dummy) sessions. The results should help us to develop faster and more successful treatment for patients with treatment resistant depression.

Who can participate?
Adults aged 18-59 years, who are right handed, have treatment resistant depression and have not had HF-rTMS therapy before.

What does the study involve?
Participants are randomly allocated into one or 4 groups. Those in group 1 receive three weeks of treatment of two HF-rTMS sessions per day, group 2 recieve one HF-rTMS session per day, group 3 receive two sham sessions a day and group 4 receive one sham session per day. Each participant has a follow up session 2 weeks after the treatment.

What are the possible benefits and risks of participating?
Participants that receive HF-rTMS sessions might find that their depression symptoms are alleviated, particularly those in the two session a day group. Patients who have HF-rTMS therapy usually experience some slight pain or discomfort at the site of stimulation. Seizures can occur if specific safety guidelines are not followed, but this is very rare.

Where is the study run from?
First Department of Psychiatry, Eginition Hospital, National and Kapodistrian University of Athens, Athens (Greece).

When is the study starting and how long is it expected to run for?
July 2006 to December 2011

Who is funding the study?
The First Department of Psychiatry, Eginition Hospital, National and Kapodistrian University of Athens, Athens (Greece).

Who is the main contact?
Christos Theleritis
chtheler@med.uoa.gr or ctheleritis@gmail.com

Study website
http://www.eginitio.gr/Erevna/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
0527821514 1st Psychiatric Dept, Eginition University Hospital, National and Kapodistrian University of Athens, Athens, Greece

Study information

Scientific Title
Two vs. one high-frequency rTMS session per day for treatment-resistant depression: a randomized sham-controlled trial.

Study objectives

High frequency repetitive transcranial magnetic stimulation (HF-rTMS) has proven antidepressant effects, but the optimal frequency of sessions remains unclear. It is hypothesised that twice per day HF-rTMS sessions will be more effective than once per day session in patients with treatment resistant depression (TRD). The null hypothesis is that there will be no difference between once and twice per day sessions of HF-rTMS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First Department of Psychiatry Ethics Committee, Eginition University Hospital,02/05/2006, ref. 0527821514.

Study design
5-year parallel-group, randomized, sham-controlled one-site trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
We conducted a 3-week, sham- controlled trial to assess the antidepressant efficacy of one session/day compared to two active rTMS sessions/ day (A2 group) and equivalent sham sessions once/day and twice/ day in 98 patients with treatment-resistant major depression (TRD), with a subsequent 2-week follow-up period.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Difference from baseline in Hamilton Depression Rating Scale (HDRS) score and Clinician Global Impressions-Severity of Illness (CGI-S) score at the end of treatment and follow-up.

Secondary outcome measures
None

Overall study start date
01/07/2006

Completion date
01/12/2011

Eligibility

Key inclusion criteria
1. Meet DSM-IV-TR criteria for current non-psychotic major depressive disorder
2. Have treatment resistant depression (with failure of at least two trials of two different antidepressants)
3. 18-59 years of age
4. Right handed
5. Be naïve to TMS

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
59 Years

Sex
Both

Target number of participants
98

Key exclusion criteria
1. History of seizures
2. History of head injury with loss of consciousness
3. History of brain surgery
4. History of presence of metallic implants
5. History of dementia or other Axis I diagnosis
6. History of substance dependence or abuse within the previous 6 months
7. Pregnancy

Date of first enrolment
01/07/2006

Date of final enrolment
01/12/2011

Locations

Countries of recruitment
Greece

Study participating centre
72-74 Vas. Sofias Avenue
Athens
Greece
11528

Sponsor information

Organisation
First Psychiatry Dept., Eginition Hospital, National and Kapodistrian University of Athens (Greece)

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Sponsor type
Hospital/treatment centre

Website
http://www.eginitio.gr/

ROR
https://ror.org/04gnjpq42

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

First Department of Psychiatry, Eginition Hospital, National and Kapodistrian University of Athens (Greece)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	results	01/09/2017		Yes	No