

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

Submission date 01/08/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 18/08/2014	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 09/10/2017	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 of 4 groups. Those in group 1 receive three weeks of treatment of two HF-rTMS sessions per day, group 2 receive 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?

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Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

None

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

59 years

Sex

All

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)

ROR

<https://ror.org/04gnjppq42>

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

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes