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

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
01/08/2014		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
18/08/2014	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
09/10/2017	Mental and Behavioural Disorders			

#### 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 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? Christos Theleritis chtheler@med.uoa.gr or ctheleritis@gmail.com

#### Study website

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

# Contact information

# Type(s)

Scientific

#### Contact name

**Prof Pavlos Sakkas** 

#### Contact details

72-74 Vas. Sofias Avenue Athens Greece 11528 +30 (0) 2107289324 psakkas@med.uoa.gr

# 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)

#### Sponsor details

72-74 Vas. Sofias Avenue Athens Greece 11528 +30 (0) 2107289324 egslelabath@hol.gr

#### 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