Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Comparison of effectiveness of Bilateral repetitive transcranial magnetic stimulation Versus Unilateral repetitive transcranial magnetic stimulation in Patients with Bipolar Depression: a study randomized and Single blind

Protocol summary

Summary
The aim of this study is to investigate the effect of repetitive TMS in reduction of depressive symptoms in patients with bipolar depression. In a randomized, single blind clinical trials, 30 patients with Bipolar disorder in Atieh neuroscience center will be assigned to receive bilateral TMS and unilateral TMS, daily; for 20 sessions.The inclusion criteria are included BDI-II score >14 and diagnosis of Bipolar disorder according to DSM-IV-TR.The exclusion criteria areincluded risk of Seizure with any reasons and cardiac Pacemaker. The Depressive symptoms, anxiety symptoms, quality of life and qEEG will be assessed before the treatment (pre test) during the treatment (10th session), and after the treatment (post test).

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT201308204191N2**
Registration date: **2013-09-08, 1392/06/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date
2013-09-08, 1392/06/17

Registrant information
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Reza Kazemi
Name of organization / entity
University of Tehran
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Recruitment status
Recruitment complete

Funding source
Atieh Neuroscience Center

Expected recruitment start date
2013-08-23, 1392/06/01

Expected recruitment end date
2013-11-06, 1392/08/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Comparison of effectiveness of Bilateral repetitive transcranial magnetic stimulation Versus Unilateral repetitive transcranial magnetic stimulation in Patients with Bipolar Depression: a study randomized and Single blind

Public title
The Study of effectiveness of repetitive transcranial magnetic stimulation in Patients with Bipolar Depression

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: Outpatients male and female with the range of 18-65 years of age; The diagnosis of Bipolar disorder according to DSM-IV-TR; Completion of Consent Form; Being under Supervision of a psychiatrist; BDI-II

score >14; Being able to adhere to treatment Schedule; Having stable symptoms as defined by not requiring a change in medication for at least 4 weeks Exclusion Criteria: The history of rTMS treatment for any reason; Intracranial Implant and other ferromagnetic materials close to the head; Cardiac Pacemaker, drug Pumps, acute heart attack; having personality disorders in Axis II; The risk of Seizure with any reasons, high Intracranial pressure, The history of epilepsy or Seizure in the first relatives, any metal in Head, brain trauma, history of loss of consciousness for more than 5 minutes; Pregnancy, breastfeeding; High risk of Suicide.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
www.clinicaltrials.gov

Secondary trial Id
NCT01932749

Registration date
2013-08-22, 1392/05/31

Ethics committees

1

Ethics committee

Name of ethics committee
University Of Tehran

Street address
Faculty of Psychology & Education University of Tehran Jalal Al-e-Ahmad Ave.

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Tehran

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Approval date
2013-05-25, 1392/03/04

Ethics committee reference number
92/33736

Health conditions studied

1

Description of health condition studied
Bipolar Depression

ICD-10 code
F31.4

ICD-10 code description
Bipolar affective disorder, current episode severe depression without psychotic symptoms

Primary outcomes

1

Description
Bipolar Depression

Timepoint
Befor intervention, ten Session, after intervention

Method of measurement
Beck Depression Inventory

Secondary outcomes

1

Description
Anxiety

Timepoint
Befor intervention, Session ten,After Intervention

Method of measurement
Beck anxiety Inventory

2

Description
Qulaity of Life

Timepoint
Befor intervention, Session ten,After Intervention

Method of measurement
WHOQol-Brief Form

3

Description
brain waves

Timepoint
Befor intervention, Session ten,After Intervention

Method of measurement
Quantitiative EEG (QEEG)

Intervention groups

1

Description
1Hz unilateral repetitive transcranial magnetic stimulation is applied during 40 minutes in 20 sessions.

Category
Treatment - Devices

2

Description
10 Hz and 1Hz bilateral repetitive transcranial magnetic stimulation are applied during 40 minutes in 20 sessions
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Atieh Neuroscience Center
Full name of responsible person
Reza Kazemi
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No 23, Above of vanak Sq, Vali-nezhad St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Atieh NEuroscience Center
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Atieh NEuroscience Center
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty