

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 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 are included 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

Name

Reza Kazemi

Name of organization / entity

University of Tehran

Country

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Email address

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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.

City

Tehran

Postal code

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

Before intervention, ten Session, after intervention

Method of measurement

Beck Depression Inventory

Secondary outcomes

1

Description

Anxiety

Timepoint

Before intervention, Session ten, After Intervention

Method of measurement

Beck anxiety Inventory

2

Description

Quality of Life

Timepoint

Before intervention, Session ten, After Intervention

Method of measurement

WHOQol-Brief Form

3

Description

brain waves

Timepoint

Before intervention, Session ten, After Intervention

Method of measurement

Quantitative 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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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Atieh NEuroscience Center

Full name of responsible person

Dr. Reza Rostami

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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**Contact****Name of organization / entity**

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PHD Student

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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