

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Comparing the effect of electroconvulsive therapy (ECT) with or without sodium valproate on cognitive impairments and treatment response in patients with bipolar disorder with manic episode: a double blind randomized clinical trial

Protocol summary

Summary

Objectives: To compare effect of electroconvulsive therapy (ECT) with or without sodium valproate on cognitive impairments and treatment response in patients with bipolar disorder with manic episode.

Design: a double blind randomized clinical trial. Setting and conduct: The eligible patients with bipolar disorder with manic episode who will refer to Baharan Hospital in Zahedan during the study period will be enrolled into the trial. Inclusion criteria: bipolar disorder with manic episode; Indication of electroconvulsive therapy.

Exclusion criteria: having other psychiatric disorders; contraindication for ECT; drug abuse; using anti-convulsion medications beside sodium valproate.

Intervention group: electroconvulsive therapy three times a week for two weeks plus tablet sodium valproate 200 mg three times a day for one month. **Control group:** electroconvulsive therapy three times a week for two weeks plus tablet placebo three times a day for one month. **Primary outcome:** (a) assessing cognitive impairments before and one month after treatment using Minimal Mental State Exam (MMSE); (b) assessing severity of mania before and one month after treatment using Young Mania Rating Scale (YMRS). **Secondary outcome:** Nothing. **Randomization:** The patients will be randomly assigned to intervention and control groups using block randomization of 4 group. **Blinding:** Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608049014N108**

Registration date: **2016-08-14, 1395/05/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-08-14, 1395/05/24

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Zahedan University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of electroconvulsive therapy (ECT) with or without sodium valproate on cognitive impairments and treatment response in patients with bipolar disorder with manic episode: a double blind randomized clinical trial

Public title

Comparing the effect of electroconvulsive therapy (ECT) with or without sodium valproate on cognitive impairments and treatment response in patients with bipolar disorder with manic episode

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: bipolar disorder with manic episode; Indication of electroconvulsive therapy. Exclusion criteria: having other psychiatric disorders; contraindication for ECT; drug abuse; using anti-convulsion medications beside sodium valproate.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zahedan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology, Zahedan University of Medical Sciences, Daneshgah Ave.

City

Zahedan

Postal code

سیستان و بلوچستان

Approval date

2016-06-05, 1395/03/16

Ethics committee reference number

IR.ZAUMS.REC.1395.42

Health conditions studied

1

Description of health condition studied

Bipolar disorder

ICD-10 code

F31

ICD-10 code description

Bipolar affective disorder

Primary outcomes

1

Description

cognitive impairment

Timepoint

before and one month after treatment

Method of measurement

using Minimal Mental State Exam (MMSE)

2

Description

severity of mania

Timepoint

before and one month after treatment

Method of measurement

using Young Mania Rating Scale (YMRS)

Secondary outcomes

empty

Intervention groups

1

Description

electroconvulsive therapy three times a week for two weeks plus tablet sodium valproate 200 mg three times a day for one month

Category

Treatment - Drugs

2

Description

electroconvulsive therapy three times a week for two weeks plus tablet placebo three times a day for one month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baharan Hospital

Full name of responsible person

Hasan Golabchifard

Street address

Baharan Hospital, Imam Komeini Ave.

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Zahedan University of Medical Sciences

Full name of responsible person

Dr Refighdoost

Street address

Zahedan University of Medical Sciences, Daneshgah
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Zahedan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice-chancellor for Research the Technology, Zahedan
University of Medical Sciences

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

Baharan Hospital

Full name of responsible person

Hasan Golabchifard

Position

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Web page address

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