Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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

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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, Ḏaneshgah 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 Ave
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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
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

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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