Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The efficacy of electroconvulsive therapy plus olanzapine on patients with bipolar mood disorder

Protocol summary

Summary

This is a double blind randomized control clinical trial about the safety and efficacy of concomitant Electroconvulsive therapy and atypical antipsychotics in 45 patients with bipolar mood disorder. The sample will be randomly allocated to one the two groups in ratio of 2:1. The first group will receive ECT plus olanzapine (5 to 10mg/day, PO, generally in 2 doses) and the second group will receive ECT plus placebo. Young Mania Rating Scale (YMRS) is used to assess clinical efficacy on mania symptoms. The cognitive functions of the patients before and after taking ECT are assessed using a modified version of Mini Mental Status Evaluation (MMSE).All the patients require to be applied electroconvulsive therapy be treating psychiatrist. Lack of written informed consent is an exclusive criterion.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107143930N8**
Registration date: **2011-08-17, 1390/05/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-08-17, 1390/05/26

Registrant information

Name

Ahmad Ghanizadeh

Name of organization / entity

Research Center for Psychiatry and Behavioral Sciences, Shiraz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1627 3070

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ghanizad@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2011-07-07, 1390/04/16

Expected recruitment end date

2011-11-07, 1390/08/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of electroconvulsive therapy plus olanzapine on patients with bipolar mood disorder

Public title

Electroconvulsive therapy plus olanzapine on patients with bipolar mood disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusive criteria: age range of 17 to 60 years; None of them has contraindications for ECT taking and/or olanzapine under study. Exclusion criteria: pregnant and lactating women; clinically estimated mental retardation, and refusal of the patient or her or his legal representative for participation in the study.

Age

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

Gender

Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
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 Shiraz University of Medical Sciences
Street address
Vice-chancellery of Research Affairs, Shiraz University of Medical sciences, Zand Street
City
Shiraz
Postal code
Approval date
2011-07-14, 1390/04/23
Ethics committee reference number
CT-90-2976

Health conditions studied

1

Description of health condition studied
Bipolar Mood disorder
ICD-10 code
F30-F39
ICD-10 code description
Bipolar affective disorder- Manic episode

Primary outcomes

1

Description
Young Mania Rating Scale
Timepoint
4 weeks
Method of measurement
Interview

Secondary outcomes

1

Description
Mini Mental Status Evaluation
Timepoint
before intervention, after every session of ECT
Method of measurement
Interview

Intervention groups

1

Description
ECT + olanzapine (5 to 10mg/day, PO, generally in 2 doses)
Category
Treatment - Drugs

2

Description
ECT + Placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Research Center for Psychiatry and Behavioral Sciences, Shiraz University of Medical Sciences
Full name of responsible person
Ahmad Ghanizadeh
Street address
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shiraz University of Medical Sciences
Full name of responsible person
Gholam Reza Hatam
Street address
Vice-chancellery of Research Affairs, Shiraz University of Medical sciences, Zand Street
City
Shiraz
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, Shiraz 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical sciences

Full name of responsible person

Ahmad Ghanizadeh

Position

MD

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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