

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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)

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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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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