

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Investigating the efficacy of Levetiracetam adjunct to Olanzapine for acute manic episode of bipolar disorder, a Double-blind placebo controlled randomized clinical trial

Protocol summary

Study aim

Investigating the efficacy of Levetiracetam adjunct to Olanzapine for acute manic episode of bipolar disorder

Design

Double blind, placebo controlled, randomized clinical trial with parallel group design of 60 patients

Settings and conduct

To conduct this study, a sample of 60 people is needed which are selected from the patients attending Professor Mohrari hospital and clinic in Shiraz. The patients are informed about the study either in person or by phone. The conditions and the procedure are explained to them and their consent is obtained. Patients who meet the conditions for entering the study are divided into two groups of 30 people and receive the drugs according to the descriptions. In weeks 0, 4, 8 and 16, patients complete the YMRS questionnaire to evaluate their treatment process. In weeks 4, 8 and 16, the side effects of the drug are evaluated by a questionnaire.

Participants/Inclusion and exclusion criteria

Diagnosis of BID based on DSM-V Criteria YMRS more than 20: Drug abuse Pregnancy medical problems

Intervention groups

Control group: In the control group, olanzapine starts with a dose of 5 mg per day and reaches a maximum of 20 mg. Lithium also starts with a dose of 300 mg and reaches a maximum of 900 mg. This group receives placebo along with lithium and olanzapine. Intervention group: In the intervention group, olanzapine starts with a dose of 5 mg per day and reaches a maximum of 20 mg. Lithium also starts with a dose of 300 mg and reaches a maximum of 900 mg. In addition to lithium and olanzapine, this group receives levetiracetam at a dose of 250 mg per day until the end of the 12th week.

Main outcome variables

Young mania rating scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211118053093N6**

Registration date: **2023-07-31, 1402/05/09**

Registration timing: **prospective**

Last update: **2023-07-31, 1402/05/09**

Update count: **0**

Registration date

2023-07-31, 1402/05/09

Registrant information

Name

Kimia Sahraian

Name of organization / entity

Eghlid Higher Education Center

Country

Iran (Islamic Republic of)

Phone

+98 71 3630 3886

Email address

leilarazeghian1366@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty
Scientific title
Investigating the efficacy of Levetiracetam adjunct to Olanzapine for acute manic episode of bipolar disorder, a Double-blind placebo controlled randomized clinical trial
Public title
Levetiracetam in acute manic episode of bipolar disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
BID diagnosis based on DSM-V criteria Y-BOCS score equal or more than 20
Exclusion criteria:
Drug abuse Pregnancy Medical problems
Age
From 18 years old to 50 years old
Gender
Both
Phase
2
Groups that have been masked
• Participant • Data analyser
Sample size
Target sample size: 60
Randomization (investigator's opinion)
Randomized
Randomization description
For this purpose,the table of random numbers and the block randomization method is used. In this method, 60 patients who have conditions will be divided into 30 blocks including 2 patients with Simple randomization. Then one of the 2 patients in the block randomly received or placebo, and 30 patients are assigned to each group.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants do not know which group they are in. The data analyser does not know which group it is analysing. The number of weeks of drug use is the same, so the patient is blinded to the type of treatment.Data analysis is given only data and does not know what treatment was done for witch group.
Placebo
Used
Assignment
Parallel
Other design features
Secondary Ids
empty
Ethics committees

<u>1</u>
Ethics committee
Name of ethics committee
Research Ethics Committees of School of Medicine - Shiraz University of Medical Sciences
Street address
Kilometer 13 of Shiraz-Isfahan highway, Ostad Mohrari Hospital
City
Shiraz
Province
Fars
Postal code
71441-13331
Approval date
2023-03-27, 1402/01/07
Ethics committee reference number
IR.SUMS.MED.REC.1402.012
Health conditions studied
<u>1</u>
Description of health condition studied
Bipolar disorder type one
ICD-10 code
F30
ICD-10 code description
Manic episode
Primary outcomes
<u>1</u>
Description
Young mania rating scale
Timepoint
Week 0, 4, 8 and 16
Method of measurement
Young mania rating scale questionnaire
Secondary outcomes
empty
Intervention groups
<u>1</u>
Description
Control group: In the control group, olanzapine starts with a dose of 5 mg per day and reaches a maximum of 20 mg. Lithium also starts with a dose of 300 mg and reaches a maximum of 900 mg. This group receives placebo along with lithium and olanzapine.
Category
Treatment - Drugs
<u>2</u>
Description

Intervention group: In the intervention group, olanzapine starts with a dose of 5 mg per day and reaches a maximum of 20 mg. Lithium also starts with a dose of 300 mg and reaches a maximum of 900 mg. In addition to lithium and olanzapine, this group receives levetiracetam at a dose of 250 mg per day until the end of the 12th week.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Professor Moharari Psychiatric Hospital

Full name of responsible person

Leila RazeghianJahromi

Street address

13 km Shiraz-Isfahan, Ostad Mohrari Hospital

City

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Email

leilarazeghian1366@gmail.com

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

Shiraz University of Medical Sciences

Full name of responsible person

Mohammadhashem Hashempour

Street address

13 km Shiraz-Isfahan, Ostad Mehrari Hospital

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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

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Leila Razeghian Jahromi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available