Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Effect of levetiracetam versus placebo on the clinical signs of in bipolar patients in the manic episode: a double-blind randomized clinical trial

Protocol summary

Study aim
To assess the effect of levetiracetam versus placebo on the clinical signs of in bipolar patients in the manic episode

Design
This is a double-blind randomized clinical trial, phase II, in which 72 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
The bipolar patients in manic episode who will refer to Sina Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician who will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 16 to 65 years, Bipolar disorder in the manic phase, Young score ≥20 Exclusion criteria: Bipolar disorder in the depressive phase

Intervention groups
Intervention group: Standard treatment plus tablet levetiracetam 250 mg three times daily for 28 days Control group: Standard treatment plus tablet placebo three times daily for 28 days

Main outcome variables
Primary outcome: Clinical signs) Sleep quality Cognitive function Secondary outcome: Gastric complications

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N293**
Registration date: **2019-09-13, 1398/06/22**
Registration timing: **prospective**
Last update: **2019-09-13, 1398/06/22**
Update count: **0**

Registration date
2019-09-13, 1398/06/22

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-02, 1398/07/10

Expected recruitment end date
2020-10-01, 1399/07/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of levetiracetam versus placebo on the clinical signs of in bipolar patients in the manic episode: a double-blind randomized clinical trial

Public title
Effect of levetiracetam versus placebo on the clinical signs of in bipolar patients in the manic episode

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 16 to 65 years, Bipolar disorder in the manic phase, Young score ≥20

Exclusion criteria:

Bipolar disorder in the depressive phase

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions Thus, the trial will be run as triple blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2019-07-20, 1398/04/29

Ethics committee reference number

IR.UMSHA.REC.1398.336

Health conditions studied

1

Description of health condition studied

Bipolar patients in the manic episode

ICD-10 code

F31.2

ICD-10 code description

Bipolar disorder, current episode manic severe with psychotic features

Primary outcomes

1

Description

Clinical signs

Timepoint

Before the intervention and 14 and 28 days after that

Method of measurement

Using the Young Mania Rating Scale (YMRS)

2

Description

Sleep quality

Timepoint

Before the intervention and 14 and 28 days after that

Method of measurement

Using the Pittsburgh Standard Questionnaire

3

Description

Cognitive function

Timepoint

Before the intervention and 14 and 28 days after that

Method of measurement

Using the Montreal Cognitive Assessment (MoCA)

Secondary outcomes

1

Description

Gastric complications

Timepoint
28 days after the intervention
Method of measurement
By history taking

Intervention groups

1

Description
Intervention group: Standard treatment plus tablet levetiracetam 250 mg three times daily for 28 days
Category
Treatment - Drugs

2

Description
Control group: Standard treatment plus tablet placebo three times daily for 28 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital in Hamadan City
Full name of responsible person
Dr Aziz Sharifi
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Sponsors / Funding sources

1

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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
Hamedan 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
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