

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

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

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

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3827 4184

Email

azizsharifi91@gmail.com

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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

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****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr Aziz Sharifi

Position

Resident of Psychiatry

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3827 4184

Email

azizsharifi91@gmail.com

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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ahmadpanah

Position

Clinical Psychologist

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3827 4184

Email

m1ahmad2000@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.ac.ir

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