

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparision of the efficacy oral levetiracetam and injection levetiracetam in the acute mania in bipolar disorders

Protocol summary

Study aim

Evaluation of the efficacy of oral and injectable levetiracetam bipolar patients

Design

The clinical trial without a control group, with randomized parallel intervention groups, simple randomization using closed envelopes and is a single-phase phase 3 in which 40 eligible patients will be assigned.

Settings and conduct

Patients with bipolar disorder in the mania phase who refer to Ibn Sina Hospital in Mashhad during the study will be included in the study if they are eligible and will be studied randomly in two intervention groups. This study will be without a control group. The study will be performed single blind so only the analyzer is unaware of the patient's group.

Participants/Inclusion and exclusion criteria

Patients with bipolar disorder in the mania phase The patient has no other psychiatric disorder or problem. Exclusion criteria: The patient has not received shock therapy during the past year. pregnancy and breastfeeding.

Intervention groups

In this study, we will have two intervention groups. Without the control group, in the first group, levetiracetam is diluted in 500 mg per 100 ml of normal saline, dextrose or ringer. It is injected every 12 hours for 15 minutes and given for 7 days, then for Oral levetiracetam treatment will be continued for another 7 days, and in the second intervention group, 500 mg oral levetiracetam is given to bipolar patients every 12 hours for 14 days.

Main outcome variables

A) The score of cognitive function using the Stroop questionnaire before and after the intervention; (B) the Intensity of mania using the YMRS (Young Mania Rating Scale) questionnaire before and after intervention. Secondary consequence: None

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101130005280N39**

Registration date: **2021-07-31, 1400/05/09**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-31, 1400/05/09**

Update count: **0**

Registration date

2021-07-31, 1400/05/09

Registrant information

Name

Raheleh Nejati

Name of organization / entity

Mashhad University of Medical Scinces, Ibn-e- Sina Psychiatric Hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2540

Email address

nejatir2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy oral levetiracetam and injection levetiracetam in the acute mania in bipolar disorders

Public title

Evaluation the effect of levothiracetam in bipolar disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patient has no other psychiatric disorder or problem. Patients with bipolar disorder in the mania phase between 18 to 40 years old

Exclusion criteria:

shock therapy during the past year. Pregnancy and breastfeeding

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with table of random numbers available at "www.randomization.com" website will be used. Numbers will be placed in sealed envelopes and each envelope is assigned to one participant placing them in one of the two intervention groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study only analyzer, the one who analyzes the outcome, is not aware of the group of patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Daneshgah street, Ghoreishi building

City

Mashhad

Province

Razavi Khorasan

Postal code

91778-99191

Approval date

2021-02-09, 1399/11/21

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.190

Health conditions studied

1

Description of health condition studied

Bipolar disorder

ICD-10 code

F31

ICD-10 code description

Bipolar disorder

Primary outcomes

1

Description

Intensity of mania

Timepoint

At the beginning of the study (before the intervention) and after the treatment period

Method of measurement

YMRS (Young Mania Rating Scale) questionnaire

2

Description

Cognitive function

Timepoint

At the beginning of the study (before the intervention) and after the treatment period

Method of measurement

Stroop Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, levotiracetam is diluted at a dose of 500 mg per 100 ml of normal saline, dextrose or ringer. It is injected every 12 hours for 15 minutes and given for 7 days, then oral levotiracetam treatment will be continued for another 7 days.

Category

Treatment - Drugs

2

Description

Intervention group: In the second intervention group, oral levothiracetam 500 mg every 12 hours for 14 days is given to bipolar patients

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn Sina Hospital

Full name of responsible person

Ali Akhoond poor Mantegh

Street address

Ibn Sinal Hospital, Horre Ameli boulevard, Bu Ali Square

City

Mashhad

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Razavi Khorasan

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Email

Manteghia@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr.Mohsen Tafaghodi

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Ali Akhoond poor Manteghi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

Street address

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Person responsible for scientific 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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available