Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparsion 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 levotiracetam 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, levotiracetam 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 levotiracetam treatment will be continued for another 7 days, and in the second intervention group, 500 mg oral levotiracetam 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)
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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
Comparsion 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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91959 83134
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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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9177899191
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+98 51 3841 2081
Email
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

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Full name of responsible person
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Position
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Person responsible for updating data

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