Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Levetiracetam as adjuvant therapy in acute mania : a double blind controlled trial

Protocol summary

Study aim
The efficacy of levetiracetam as an adjuvant agent in the treatment of bipolar disorder (mania episode)

Design
Randomized double blind and placebo-controlled clinical trial

Settings and conduct
The study will be conducted among adults with moderate to severe mania (BID) attending Roozbeh Hospital.

Participants/Inclusion and exclusion criteria
Inclusion criteria: meeting the DSM-5 criteria for Bipolar Disorder(manic episode); age between 18 and 60 years old; a score of at least 20 points on the Young Mania Rating Scale. Exclusion criteria: hyper- or hypothyroidism; substance dependence (except for Nicotine or caffeine); IQ lower than 70; lactating or pregnant women; severe hepatic disease.

Intervention groups
The participants will be randomly allocated into two groups. Intervention group (20 persons) will receive levetiracetam (20 mg/kg which will be increased to 50 mg/kg within 4 weeks) and quetiapine (100 mg per day which will be increased to 300 mg/ day within 2 weeks) and control group (20 persons) will receive quetiapine (100 mg per day which will be increased to 300 mg/ day within 2 weeks) and placebo for 6 weeks.

Main outcome variables
Severity of mania

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090117001556N117**
Registration date: **2019-03-15, 1397/12/24**
Registration timing: **prospective**
Last update: **2019-03-15, 1397/12/24**
Update count: **0**

Registration date
2019-03-15, 1397/12/24

Registrant information

Name
Shahin Akhondzadeh

Name of organization / entity
Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 5541 2222

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-05, 1398/01/16

Expected recruitment end date
2021-04-04, 1400/01/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Levetiracetam as adjuvant therapy in acute mania : a double blind controlled trial

Public title
Levetiracetam as adjuvant therapy in acute mania

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Meeting the DSM-IV criteria for Bipolar Disorder-manic episode Age between 18 and 60 years old A score of at least 20 points on the Young Mania Rating Scale
Exclusion criteria:
Hyper- or hypothyroidism Substance dependence(except for Nicotine and caffeine) IQ lower than 70 Lactating or pregnant women Severe hepatic disease

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Random permuted block

Blinding (investigator's opinion)
Double blinded

Blinding description
The participants, clinicians and outcome raters will be blind regarding grouping

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences Ethics Committee

Street address
Tehran University of Medical Sciences, Ghods Avn., Keshavarz Blvd.

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2019-03-08, 1397/12/17

Ethics committee reference number
IR.TUMS.VCR.REC.1397.948

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
Severity of mania

Timepoint
Baseline and weerks: 2, 4, 6

Method of measurement
by Young Mania Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: tablet quetiapin (100 mg/day which will be increased to 300 mg per day within 2 weeks) plus capsule levetiracetam (20 mg per kg/day which will be increased to 50 mg/kg/day) as intervention group for 6 weeks

Category
Treatment - Drugs

2

Description
Control group: tablet quetiapin (100 mg/day which will be increased to 300 mg per day within 2 weeks) plus capsule placebo as control group for 6 week

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Roozbeh Hospital

Full name of responsible person
Prof. Shahin Akhondzadeh

Street address
Roozbeh Hospital, South Kargar Sreeet

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Prof.Shahin Akhondzadeh
Position
Professor of clinical psychopharmacology
Latest degree
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Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
The data will be distributed through final report
When the data will become available and for how long
5 years from 2021 to 2026
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
by citing the resourse
From where data/document is obtainable
Professor Shahin Akhondzadeh
What processes are involved for a request to access data/document
by E mail
Comments