

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 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)

###### Phone

+98 21 5541 2222

###### Email address

s.akhond@sina.tums.ac.ir

##### 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 weeks: 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 Sreet

**City**

Tehran

**Province**

Tehran  
**Postal code**  
1333715914  
**Phone**  
+98 21 5541 2222  
**Email**  
s.akhond@sina.tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Dr. Mohammad Ali Sahraian  
**Street address**  
Keshavarz Blvd  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1417653761  
**Phone**  
+98 21 8898 7381  
**Email**  
msahrai@tums.ac.ir

#### 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**  
Ph.D.  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**

Roozbeh Hospital, South Kargar Street  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1333715914  
**Phone**  
+98 21 5541 2222  
**Fax**  
+98 21 5541 9113  
**Email**  
s.akhond@sina.tums.ac.ir

## Person responsible for scientific 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**  
Ph.D.  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
Roozbeh Hospital, South Kargar Street, Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1333715914  
**Phone**  
+98 21 5541 2222  
**Fax**  
**Email**  
s.akhond@sina.tums.ac.ir

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Prof. Shahin Akhondzadeh  
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Professor of clinical psychopharmacology  
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**Phone**

+98 21 5541 2222

**Fax**

+98 21 5541 9113

**Email**

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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 resource

**From where data/document is obtainable**

Professor Shahin Akhondzadeh

**What processes are involved for a request to access data/document**

by E mail

**Comments**