

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of spironolactone as adjunctive therapy on the improvement of cognitive symptoms and mania(sleep , appetite) of type 1 bipolar disorder in randomized, double-blind, placebo-controlled clinical trial

#### Protocol summary

##### Study aim

The effect of spironolactone as adjunctive therapy on the improvement of cognitive symptoms and mania(sleep , appetite) of type 1 bipolar disorder in randomized, double-blind, placebo-controlled clinical trial

##### Design

A randomized clinical trial, with parallel groups and sample size of 60 (30 in each group)

##### Settings and conduct

The study will be conducted at Imam Ali Hospital, Karaj on patients with bipolar disorder. Patients who signed informed consent will be randomly divided into two groups. The intervention group receives a valproate sodium tablet (200 mg ) three times daily with spironolactone tablet (50 mg) for 8 weeks and the control group receives a valproate sodium tablet (200 mg ) three times daily with placebo in tablet form for 8 weeks. The final outcome of the study will be assessed by a third party who is unaware of the study process.

Also, the statistician will be unaware of the study process

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Having DSM-V diagnostic criteria for patients with bipolar disorder with mania phase; Age 18 to 50 years; Their minimum score is 14 based on young mania rating scale Exclusion criteria: Neurological disease; Cardiovascular and hepatic disease; IQ less than 70; Drug abuse (except nicotine and caffeine); pregnancy; Taking drugs that interfere with spironolactone

##### Intervention groups

Intervention group: valproate sodium tablet (200 mg ) three times daily with spironolactone tablet (50 mg) for 8 weeks Control group: valproate sodium tablet (200 mg ) three times daily with placebo in table form for 8 weeks

##### Main outcome variables

Mood symptoms Sleep quality improvement

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190316043072N2**

Registration date: **2021-04-29, 1400/02/09**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-04-29, 1400/02/09**

Update count: **0**

##### Registration date

2021-04-29, 1400/02/09

##### Registrant information

##### Name

Atefeh Zandifar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3255 4132

##### Email address

zandifaratefe@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-21, 1400/02/01

##### Expected recruitment end date

2021-08-21, 1400/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

The effect of spironolactone as adjunctive therapy on the improvement of cognitive symptoms and mania (sleep, appetite) of type 1 bipolar disorder in randomized, double-blind, placebo-controlled clinical trial

**Public title**

The effect of spironolactone as adjunctive therapy on the improvement of cognitive symptoms and mania

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having DSM-V diagnostic criteria for patients with bipolar disorder with mania phase Age 18 to 50 years Their minimum score is 14 based on Young Mania Rating Scale (YMRS)

**Exclusion criteria:**

Neurological disease Cardiovascular and hepatic disease IQ less than 70 Drug abuse (except nicotine and caffeine) pregnancy Taking drugs that interfere with spironolactone .

**Age**

From **18 years** old to **55 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization method used in this study will be the block randomization method developed by the statistics expert by using the STATA software in a randomization list format. Then, according to the randomization list, the type of intervention for each individual will be written on paper, and the paper will be put in a sealed envelope. Envelopes will be numbered according to the randomization list. The physician will examine the patient's eligibility, and if the patient is eligible, she will tell the hospital research assistant. The research assistant will then provide the sealed envelope to the physician, and the physician will begin the intervention according to the contents of the envelope

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

Completion of the final information is up to the person who is unaware of the type of treatment and also the specialist will be blind. Due to the type of intervention, participants are aware of the type of treatment

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Alborz University of Medical Sciences

**Street address**

Ethics committee unit, Vice Chancellor for Research, No.20, Saffarian alley, 45 Metri Golshahr street

**City**

karaj

**Province**

Alborz

**Postal code**

3149779453

**Approval date**

2021-03-06, 1399/12/16

**Ethics committee reference number**

IR.ABZUMS.REC.1399.319

**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**

Mood symptoms

**Timepoint**

Before and after the intervention

**Method of measurement**

Young Mania Rating Scale (YMRS), Mini-Mental State Examination (MMSE)

**2****Description**

Sleep quality improvement

**Timepoint**

Before and after the intervention

**Method of measurement**

Pittsburgh Sleep Quality Index (PSQI)

## Secondary outcomes

1

### Description

Appetite quality improvement

### Timepoint

Before and after the intervention

### Method of measurement

Simple appetite questionnaire

## Intervention groups

1

### Description

Intervention group: Taking valproate Sodium tablet (200 mg), 3 times daily with spironolactone tablet (50 mg) , Daily for 8 weeks

### Category

Treatment - Drugs

2

### Description

Control group: Taking valproate Sodium tablet (200 mg), 3 times daily with placebo in tablet form, Daily for 8 weeks

### Category

Placebo

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Imam Ali Hospital

#### Full name of responsible person

Dr. Atefe Zandifar

#### Street address

Resalat street, Karaj, Alborze

#### City

karaj

#### Province

Alborz

#### Postal code

3145686695

#### Phone

+98 26 3252 7576

#### Email

imamali@abzums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Karaj University of Medical Sciences

#### Full name of responsible person

Dr. Mohammad Norisephr

### Street address

Vice Chancellor for Research, No.20, Saffarian alley,  
45 Metri Golshahr street

### City

Karaj

### Province

Alborz

### Postal code

3198764653

### Phone

+98 26 3464 4255

### Email

Research@abzums.ac.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Karaj 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

Karaj University of Medical Sciences

#### Full name of responsible person

Dr. Atefe Zandifar

#### Position

Associate professor

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Psychiatrics

#### Street address

Alborz University of Medical Sciences, North  
Taleghani Blvd., Taleghani Square, Karaj

#### City

Karaj

#### Province

Alborz

#### Postal code

3149779453

#### Phone

+98 32563328026

#### Email

zandifatefe@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Karaj University of Medical Sciences

**Full name of responsible person**

Dr. Atefe Zandifar

**Position**

Associate professor

**Latest degree**

Medical doctor

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## Person responsible for updating data

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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**

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