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)

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Dr. Mohammad Norisephr
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Vice Chancellor for Research, No.20, Saffarian alley, 45 Metri Golshahr street
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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
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
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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