Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of vitamin B6 as an add-on treatment to lithium compared to placebo on the symptoms of acute mania and the recurrence of mood episodes and suicidal thoughts in patients with bipolar disorder type 1; A double-blind clinical trial

Protocol summary

Study aim

Investigating the effect of vitamin B6 as an adjunctive treatment to lithium in improving sleep disorders in a 24-week follow-up of patients with bipolar disorder type I

Design

A randomized clinical trial with block method using STATA software, with a control group, with parallel design, double-blind, phase 3 and a sample size of 80 people.

Settings and conduct

1- Place of conducting this study: It is in the psychiatry department of Imam Hossein Hospital in Karaj. 2- Study population: people with bipolar disorder type 1 3- Type of blinding: double-blind 4-How to blind: patients do not know the type of treatment. Prescribed medicines are in the form of pills with same shape, color, size, smell, and taste. Completing the final information is the responsibility of the person unaware of the type of treatment. Also, the statistician will be a blind treatment type

Participants/Inclusion and exclusion criteria

Inclusion criteria: having DSM-V diagnostic criteria for bipolar patients in mania phase; their minimum score should be 20 according to Young Mania; Age of 18 to 50 years. Exclusion criteria: suffering from neurological disease; chronic cardiovascular, liver and kidney diseases; IQ less than 70; drug abuse (except nicotine and caffeine); Pregnant and lactating women.

Intervention groups

Intervention group: lithium carbonate tablet 300 mg three times a day along with vitamin B6 tablet, 40 mg for 24 weeks. Control group: lithium carbonate tablet 300 mg three times a day along with placebo for 24 weeks.

Main outcome variables

Mood symptoms, sleep quality, cognition, suicidal thoughts

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190316043072N4**
Registration date: **2024-01-05, 1402/10/15**
Registration timing: **prospective**

Last update: **2024-01-05, 1402/10/15**
Update count: **0**

Registration date

2024-01-05, 1402/10/15

Registrant information

Name

Atefeh Zandifar

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-04-19, 1403/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of vitamin B6 as an add-on treatment to lithium compared to placebo on the symptoms of acute mania and the recurrence of mood episodes and suicidal thoughts in patients with bipolar disorder type 1; A double-blind clinical trial

Public title

Investigating of vitamin B6 in Bipolar Mood disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having DSM-V diagnostic criteria for bipolar patients (through a semi-structured interview by a psychiatrist and confirming the diagnosis with a score of at least 20 on the Young Mania scale). Being at the age of 18 to 65 years old

Exclusion criteria:

Suffering from neurological disease, cardiovascular and liver disease and chronic kidney disease IQ less than 70 Drug abuse (except nicotine and caffeine) History of drug sensitivity to lithium carbonate or vitamin B6 Pregnancy and breastfeeding chronic kidney disease (CKD)

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method used in this study will be the block method, which will be designed by a statistician and STATA software, mainly a randomization list. Then, according to the randomization list, the type of intervention desired for each person will be written on a paper and the paper will be placed in a sealed envelope. The envelopes will be numbered according to the order included in the list. The doctor checks the conditions of the patient to enter the study and if he is eligible, he informs the resident research expert at the hospital. Then the research expert will provide the sealed envelope to the doctor and the doctor will start the desired intervention according to the content inside the envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients do not know the type of treatment. Prescribed medicines are in the form of pills with the same shape ,color, size, smell and taste. Completing the final information is the responsibility of the person who is unaware of the type of treatment. Also, the statistician will be a blind treatment type.

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, Research and Technology Deputy, No. 20, Safarian Alley, Golshahr 45 Meter street

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2023-12-18, 1402/09/27

Ethics committee reference number

IR.ABZUMS.REC.1402.269

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 (at intervals of weeks 0-4-8-12-18-24-32)

Method of measurement

Young Mania standard questionnaire and brief clinical examination test

2

Description
Improve sleep quality
Timepoint
Before and after the intervention (at intervals of weeks 0-4-8-12-18-24-32)
Method of measurement
Petersburg Sleep Quality Questionnaire

3

Description
Cognitive symptoms
Timepoint
Before and after the intervention (at intervals of weeks 0-4-8-12-18-24-32)
Method of measurement
Mini-Mental State Examination (MMSE)

4

Description
suicidal thoughts
Timepoint
Before and after the intervention (at intervals of weeks 0-4-8-12-18-24-32)
Method of measurement
Beck suicide questionnaire

Secondary outcomes

1

Description
Symptoms of depression
Timepoint
Before and after the intervention (at intervals of weeks 0-4-8-12-18-24-32)
Method of measurement
Beck depression questionnaire

2

Description
Anxiety symptoms
Timepoint
Before and after the intervention (at intervals of weeks 0-4-8-12-18-24-32)
Method of measurement
Beck's anxiety questionnaire

Intervention groups

1

Description
Intervention group: lithium carbonate tablets (300 mg), three times a day along with vitamin B6 (40 mg) a day for 24 weeks.
Category
Treatment - Drugs

2

Description
Control group: lithium carbonate tablets (300 mg), three times a day with a placebo for 24 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Dr. Atefeh Zandifar
Street address
No104; Mansour; Bakht St; Imam Khomeini Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Razia Lotfi
Street address
Karaj; 45 meters from Golshahr; Safarian Street; Alborz University of Medical Sciences Research and Technology Vice-Chancellor
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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
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Dr. Atefeh Zandifar
Position
Assistant Professor
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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