

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of vitamin B6 as adjunctive therapy in ameliorating symptoms of acute mania in patients with bipolar disorder Type 1 hospitalized in Roozbeh Hospital; a double-blind placebo-controlled clinical trial

Protocol summary

Study aim

the effect of vitamin B6 as adjunctive therapy in ameliorating the symptoms of mania in patients with bipolar I disorder hospitalized in Roozbeh Hospital

Design

A randomized, double-blind, placebo-controlled clinical trial

Settings and conduct

Fifty patients with bipolar disorder at Roozbeh Hospital will be treated with placebo and double-blind placebo-controlled intervention with vitamin B6 adjuvant therapy. The therapist and the patient are blind and do not know the type of medication.

Participants/Inclusion and exclusion criteria

Inclusion: 18-65 years old, diagnosis of type 1 bipolar disorder in early mania based on DSM-V diagnostic criteria (by semi-structured interview by psychiatrist and confirmation of diagnosis with score of at least 20 from Young's Maniac Scale), Possible consent Presence of the patient's legal guardian Exclusion: no psychosis in the patient, no history of drug sensitivity to lithium carbonate or vitamin B6, no diagnosis of schizophrenia, delirium, anorexia neurosis, bulimia neurosis, autism, substance abuse (at least 3 months ago), retardation, mental retardation Type 2 bipolar disorder.

Intervention groups

Fifty patients with type 1 bipolar disorder in the mania phase are randomly divided into two groups. One group is treated with standard lithium carbonate and vitamin B6 and the other group is treated with standard lithium carbonate and placebo for 6 weeks. Mania symptoms improve and cognitive symptoms and brain map.

Main outcome variables

Mania Symptoms (Young Mania Questionnaire)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200317046801N1**

Registration date: **2020-03-27, 1399/01/08**

Registration timing: **retrospective**

Last update: **2020-03-27, 1399/01/08**

Update count: **0**

Registration date

2020-03-27, 1399/01/08

Registrant information

Name

Rahim Badrfam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 9151

Email address

rbadrfam@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-01, 1398/08/10

Expected recruitment end date

2020-02-18, 1398/11/29

Actual recruitment start date

2019-11-01, 1398/08/10

Actual recruitment end date

2020-02-18, 1398/11/29

Trial completion date

2020-06-20, 1399/03/31

Scientific title

Evaluation of the effect of vitamin B6 as adjunctive therapy in ameliorating symptoms of acute mania in patients with bipolar disorder Type 1 hospitalized in Roozbeh Hospital; a double-blind placebo-controlled clinical trial

Public title

The effect of vitamin B6 in bipolar patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Subjects aged 18 to 65 years old Diagnosis of type 1 bipolar disorder in early-onset mania based on DSM-V diagnostic criteria (by semi-structured interview by a psychiatrist and confirmation of diagnosis with a score of at least 20 on the Young Mania Scale). Consent of the possibility of being present on the patient's legal guardian

Exclusion criteria:

Absence of psychosis in patients A history of drug sensitivity to lithium carbonate or vitamin B6 Absence of diagnoses of schizophrenia, delirium, anorexia nervosa, bulimia nervosa, autism, substance abuse (at least 3 months ago), retardation Bipolar type 2 seizures (Existence of suicide due to lack of suicide risk factor for use of evaluated drugs as well as weekly weekly medications and low weekly prescription drugs are not included in the plan).

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is simple and individual, is a random tool of random numbers and how to construct a random sequence. In order to prevent selection bias, the researchers employ a randomization method as well as hiding random allocation to report it correctly. These researchers can gain valid results by better understanding this method and its proper implementation....

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, lead investigator, healthcare personnel (physicians, nurses, physiotherapists, etc.) responsible

for patient care, data collection and outcome assessors, and the Data Safety and Monitoring Committee Those who draft the article are not aware of any type of prescription drug.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

North Kargar Ave.Lashgar Road.Rozbeh Hospital

City

Tehran

Province

Tehran

Postal code

1333715914

Approval date

2019-03-07, 1397/12/16

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.935

Health conditions studied

1

Description of health condition studied

BIPOLAR DISORDER

ICD-10 code

F31

ICD-10 code description

Bipolar mood disorder

Primary outcomes

1

Description

Mania Symptoms by Young Mania Questionnaire

Timepoint

Baseline and weeks 3, 4, and 8 after vitamin B6 start

Method of measurement

Yang Mania questionnaire

Secondary outcomes

1

Description

Sleep quality

Timepoint

Baseline and weeks 3, 4, and 8 after vitamin B6 start

Method of measurement

Petersburg questionnaire

2

Description

Nutrition and appetite status

Timepoint

Baseline and weeks 3, 4, and 8 after vitamin B6 start

Method of measurement

Appetite Rating Scale

3

Description

Mini mental status

Timepoint

Baseline and weeks 3, 4, and 8 after vitamin B6 start

Method of measurement

Mini mental status examination

4

Description

Brain Mapping

Timepoint

Baseline and week , 8 after vitamin B6 start

Method of measurement

QEEG | Quantitative Electroencephalogram Test

Intervention groups

1

Description

Fifty Patients with type 1 bipolar disorder in the mania phase are randomly divided into two groups. 25patients in the intervention group receive standard lithium carbonate and vitamin B 6medication treatment, and they will be evaluated for improvement of mania symptoms, cognitive symptoms, and brain map within 8 weeks.

Category

Treatment - Drugs

2

Description

25 patients in the control group receive standard lithium carbonate and placebo treatment and are treated for 8 weeks for improvement in manic and cognitive symptoms and brain map.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Hospital

Full name of responsible person

Rahim Badrfam

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Rozbeh Hospital, South Kargar Ave.

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2

Recruitment center

Name of recruitment center

Psychiatry and Psychology Research Center of Tehran
University of Medical Sciences

Full name of responsible person

Mohammadreza Mohammadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraeian

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Vice Chancellor for Research and Technology, Sixth
Floor, Qods Ave., Keshavarz Boulevard, Tehran, Iran

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Grant name

Vice chancellor for research, Tehran University of Medical Sciences

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

Rahim Badrfam

Position

Rezidnt

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data

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Position

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

After the article is published, all the results will be made available to those interested

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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