

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of vitamin B1 and B6 as an adjunct therapy to improve the symptoms of mania phase of bipolar disorder type I; in a double-blind and placebo-controlled clinical trial

Protocol summary

Study aim

The aim of this study is the evaluation of the effect of vitamin B1 and B6 as supportive treatment in healing up the manic symptoms of bipolar patients, including mood symptoms, cognitive disorder, and sleep disorders.

Design

80 patients will be randomized through the table of random numbers and then they will be separated into three parallel groups in a double-blind study and get vitamin B1, vitamin B6, and placebo beside lithium bicarbonate in each group.

Settings and conduct

This is a double-blinded clinical trial. It will be accomplished in three groups of patients in the manic phase who are admitted to Imam Hossein hospital and medical education center.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of bipolar disorder in the manic phase Having at least 14 scores in Young-Mania questionnaire Aged between 18 to 50 Getting a consent letter from the patient's guardian Exclusion criteria: Having any serious comorbidity Existence of any other psychiatric diagnosis in axis I disorders IQ less than 70 Drug abuse (except nicotine and caffeine) concurrent Alcohol abuse Women in reproductive ages without using a safe contraception Patient with CHF (congestive heart failure) or liver disease Absence of consent for starting or continuing to participate

Intervention groups

There will be three groups of patients in an 8-week schedule as below: The first group will be treated with 1.5 mg/kg vitamin B1 plus 900 mg lithium bicarbonate each day, The second group will be treated with 0.6 mg/kg vitamin B6 plus 900 mg lithium bicarbonate each day, The third group will be treated with a placebo plus 900 mg lithium bicarbonate each day.

Main outcome variables

The main outcome of this study is the approval of vitamin B1 and B6 as supportive agents alongside the main treatment (mood stabilizers) in the manic phase extensively.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200307046712N1**

Registration date: **2020-04-06, 1399/01/18**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-06, 1399/01/18**

Update count: **0**

Registration date

2020-04-06, 1399/01/18

Registrant information

Name

Shaghayegh Mousavi

Name of organization / entity

Alborz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 26 3340 1629

Email address

mvishaghayegh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-14, 1398/12/24

Expected recruitment end date

2020-05-13, 1399/02/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of vitamin B1 and B6 as an adjunct therapy to improve the symptoms of mania phase of bipolar disorder type I; in a double-blind and placebo-controlled clinical trial

Public title

Evaluation of the effect of vitamin B1 and B6 in manic patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Having diagnostic criteria of DSM-V for mania phase of patients with bipolar disorder Having at least 14 scores in Young-Mania questionnaire Aged between 18 to 50 Getting conscious letter of satisfaction from patient tutor

Exclusion criteria:

Having any neurological, organic, cardiovascular and hepatic disorder according to patients's evidences or history Existence of any other diagnosis in axis I disorders according to DSM-V IQ less than 70 according to examiner clinical judge Drug abuse (except nicotine and caffeine) Alcohol abuse coincidentally Women in reproductive ages without using a safe contraception Patient with CHF (congestive heart failure) or liver disease Absence of satisfaction for starting or continuing participating

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **67**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization: simple Unit of randomization: individual Tools used in randomization: table of random numbers Randomization will be done in the absence of patients' sight.

Blinding (investigator's opinion)

Double blinded

Blinding description

According to double-blinding, all the groups of patients will take their drugs without any knowledge about types of them. Also, the patients' nurse will give these drugs to the them according to the randomization the physician has made, without consciousness about types of them.

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

Alborz University of Medical Science, Official settlement, North Taleghani boulevard, Taleghani Square, Karaj, Alborz Province

City

KARAJ

Province

Alborz

Postal code

3147734568

Approval date

2020-02-15, 1398/11/26

Ethics committee reference number

IR.ABZUMS.REC.1398.243

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

In this study, mood symptoms will be assessed in the beginning of and at the end of the 8th week of the clinical trial.

Method of measurement

Mood symptoms will be assessed according to the score of the Young-Mania questionnaire .

Secondary outcomes

1

Description

cognition state

Timepoint

In this study, the cognition state of the patients will be assessed in the beginning and at the end of the 8th week of the clinical trial.

Method of measurement

The cognition state of the patients will be assessed according to the score of the Minimal Mental State Exam (MMSE).

2

Description

the sleep state.

Timepoint

In this study, the sleep state of the patients will be assessed in the beginning and at the end of the 8th week of the clinical trial.

Method of measurement

The sleep state of the patients will be assessed according to the score of Pittsburgh Sleep Quality Questionnaire Index(PSQI).

Intervention groups

1

Description

First intervention group: This group will take 1.5 mg/kg vitamin B1 plus 900 mg lithium bicarbonate.

Category

Treatment - Drugs

2

Description

Second intervention group: This group will take 0.6 mg/kg vitamin B6 plus 900 mg lithium bicarbonate.

Category

Treatment - Drugs

3

Description

Control group: This group will take one placebo plus 900 mg lithium bicarbonate each day. The placebo will be made in the laboratory of the Alborz University of Medical Science.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Atefe Zandifar

Street address

Imam Hossein Hospital, Mansoorbakht Street,
Mohammad Shahr, Alborz province

City

Mohammadshahr

Province

Alborz

Postal code

3147734568

Phone

+98 26 3419 3000

Fax

+98 26 3419 3203

Email

zandifaratefe@gmail.com

Web page address

<http://emamhossein.abzums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Alborz University of Medical Science

Full name of responsible person

The assistant of research and technology of Alborz
University of Medical Science; Dr Noorisepehr

Street address

Alborz University of Medical Science, Official
settlement, North Taleghani boulevard, Taleghani
Square, Karaj, Alborz Province

City

Karaj

Province

Alborz

Postal code

3147734568

Phone

+98 26 3255 8920

Fax

Email

zandifaratefe@gmail.com

Web page address

<https://abzums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Alborz University of Medical Science

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

Alborz university of medical sciences

Full name of responsible person

Shaghayegh Mousavi

Position

Intern of medicine

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

528,120 AVE,ERAM BOULEVARD

City

KARAJ

Province

Alborz

Postal code

3185746957

Phone

+98 26 3340 1629

Fax

Email

mvishaghayegh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Alborz university of medical sciences

Full name of responsible person

Atefe Zandifar

Position

Psychiatrist

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Alborz University of Medical Science, Official settlement, North Taleghani boulevard, Taleghani Square, Karaj, Alborz Province

City

KARAJ

Province

Alborz

Postal code

3147734568

Phone

+98 26 3255 8920

Fax

Email

zandifaratefe@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Alborz university of medical sciences

Full name of responsible person

Shaghayegh Mousavi

Position

Intern of medicine

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

528,120 AVE,ERAM BOULEVARD

City

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Province

Alborz

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3185746957

Phone

+98 26 3340 1629

Fax

Email

mvishaghayegh@gmail.com

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

The data won't be released until the publication of the study.

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