# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

30 Jun 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, cognitional 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)
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**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 patientsگ 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 pf 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 international 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
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Imam Hossein Hospital, Mansoorbakht Street, Mohammad Shahr, Alborz province
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## 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 Sciensce; Dr Noorisepehr
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**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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Position**
Intern of medicine

**Latest degree**
Medical doctor

**Other areas of specialty/work**
Psychiatrics

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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**
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