

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The assessment of folic Acid and vitamin B6 effects add-in sodium valproate in bipolar mood Disorder in Acute phase of mania

#### Protocol summary

##### Summary

1)Purposes of trial: Investigation of adjunct treatment of folic acid and vitamin B6 to sodium valproate in acute mania disorder and their comparisons with eachother. 2) Study design :randomized ,double blind ,control with placebo , unicentral ,first step of trial 3) Trial method: Admitted patients in Mashhad Ebne Sina's hospital with diagnosis of bipolar mood disorder type I with recent mania episode with included criteria and without exclusion criteria of study, divide randomly in 3 groups a,b and c ,then will treat and compare in two basic and maintenance steps that will describe in detail at follow. 4)Participants :Inclusion criteria: 1)patients age between 18 to 45 years old according to birth certificate.2) Diagnosis of bipolar mood disorder I with recent episode of mania.3) Filling out informed consent. Exclusion criteria:1)Suicidal or homicidal idea.2)Have the positive pregnancy test. 5)Interventions: Case group 1: folic acid ,oral tab 5mg,once a day ,for six weeks /Case group 2: vitamin B6,oral tab 40mg,towice a day, for six weeks /Control group :placebo ,oral tab ,for six weeks 6)Main outcome varieties: severity of mania ,cognitive scale.both of tests will evaluate at baseline and end of the third and sixth weeks.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201112188106N1**  
Registration date: **2012-01-14, 1390/10/24**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-01-14, 1390/10/24

#### Registrant information

##### Name

Alireza Ebrahimi

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 1883 1993

##### Email address

ebrahimia871@mums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Mashhad University of Medical Sciences

#### Expected recruitment start date

2011-04-04, 1390/01/15

#### Expected recruitment end date

2011-06-22, 1390/04/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The assessment of folic Acid and vitamin B6 effects add-in sodium valproate in bipolar mood Disorder in Acute phase of mania

#### Public title

The assessment of folic Acid and vitamin B6 effects in bipolar patients

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria:1)Patients age between 18 to 45 years old according to birth certificate.2)Diagnosis of bipolar mood disorder I with recent episode of mania according

to DSM IV TR diagnosis criteria.3)Rolling out diagnosis of schizophrenia,delirium,anorexia nervosa,bulimia,autism,substance abuse(at least during 3 months ago ),mental retardation,adhd.4)Absence of psychiatric hospitalization history during 3 months ago.5)Absence of seizure history6)Absence of severe allergy history.7)Filling out informed consent.8)Absence of allergic history to sodium valproate. Exclusion criteria:1)Patients who evaluate at risk of suicide or homicide according to psychiatric diagnosis.2)Female patients are doubted for pregnancy, should test serum pregnancy test and will exclude from study if it is positive.3)Patients who take other drugs such as antimanic drugs that could not be able to stop them in two weeks before study or during it.

#### Age

From **18 years** old to **45 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **43**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Mashhad University of Medical Sciences

###### Street address

University Research Affairs-Research Vice-Mashhad  
University of Medical Science.Mashhad

###### City

Mashhad

###### Postal code

##### Approval date

2011-03-12, 1389/12/21

##### Ethics committee reference number

89827

### Health conditions studied

#### 1

##### Description of health condition studied

Bipolar disorder

##### ICD-10 code

F31.9

##### ICD-10 code description

Bipolar affective disorder, unspecified

### Primary outcomes

#### 1

##### Description

Severity of mania

##### Timepoint

Baseline,End of the third week,End of the six week

##### Method of measurement

Jung Mania Rating Scale(YMRS)

#### 2

##### Description

Cognitive scale

##### Timepoint

Baseline,End of the third week,End of the six week

##### Method of measurement

Mini Mental State Examination (MMSE)

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Case group 1: folic acid,oral tab 5mg,once a day,for six weeks

##### Category

Treatment - Drugs

#### 2

##### Description

Case group 2:vitamin B6,oral tab 40mg,towice a day, for six weeks

##### Category

Treatment - Drugs

#### 3

##### Description

Control group:placebo,oral tab,once a day,for six weeks

##### Category

Placebo

### Recruitment centers

#### 1

##### Recruitment center

**Name of recruitment center**

Ebne Sina's Hospital

**Full name of responsible person**

alireza ebrahimi

**Street address**

Ebne Sina Psychiatric Hospital,before Bou Ali square,Horre Ameli Bolvard,Mashhad

**City**

Mashhad

**Email**

ebrahimia871@mums.ac.ir/alireza.ebrahimi37@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Ali Talaei

**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

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**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr.Jalil Tavakol Afshari

**Street address**

The Vice Chancellor for Research.Mashhad University of Medical Sciences.Mashhad

**City**

Mashhad

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Alireza Ebrahimi

**Position**

Assistant Community of Psychiatry

**Other areas of specialty/work****Street address**

Ebne Sina Psychiatric Hospital,before Bou Ali square,Horre Ameli Bolvard,Mashhad

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**Postal code****Phone**

+98 51 1883 1993

**Fax****Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Alireza Ebrahimi

**Position**

MD

**Other areas of specialty/work****Street address****City**

Mashhad

**Postal code****Phone****Fax****Email****Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty*

