

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)

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+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

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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

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

Mashhad University of Medical Sciences

Full name of responsible person

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Position

MD

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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

