

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Therapeutic Efficacy of Oxcarbazepine and Sodium Valproate in Acute Mania

#### Protocol summary

##### Summary

Objective: The objective of the present study was to compare the efficacy of oxcarbazepine and sodium valproate in the treatment of acute phase of mania. This research is a prospective double blind and randomized clinical trial. The sample included admitted patients in Ebne-sina hospital with Diagnosis of bipolar disorder in acute phase of mania who met the inclusion criteria. Patients were randomly allocated in two groups taking oxcarbazepine (maximum 900 to 2400 mg per day) and sodium valproate (maximum 20-30 mg/kg/day). The study consisted 3-14 days of base line phase and 4 weeks of double blind clinical trial. Assessment was done by using Minimal Status Examination (MMSE), Young Mania Rating Scale (YMRS), and Clinical Global Impression-scale (CGI-S) at baseline, After 3 and 6 weeks. Adverse effects of drugs were evaluated at weeks 3 and 6. For eligibility in the study patients had to be 18 to 60 years of age and with DSM- IV- TR axis I diagnosis of BMD-I in acute manic episode. Exclusion criteria included a primary diagnosis of Schizophrenia, delirium, anorexia nervosa, bulimia, autism, substance abuse, mental retardation and ADHD in recent 3 months.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201012055280N2**

Registration date: **2011-02-18, 1389/11/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-02-18, 1389/11/29

##### Registrant information

##### Name

Raheleh Nejati

##### Name of organization / entity

Mashhad University of Medical Sciences, Ibn-e- Sina Psychiatric Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancecellor for Research, Mashhad University of Medical Sciences

##### Expected recruitment start date

2009-07-04, 1388/04/13

##### Expected recruitment end date

2010-05-03, 1389/02/13

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Therapeutic Efficacy of Oxcarbazepine and Sodium Valproate in Acute Mania

##### Public title

Therapeutic Efficacy of Oxcarbazepine and Sodium Valproate in Acute Mania

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

For eligibility in the study patients had to be 18 to 60 years of age and with DSM- IV- TR axis I diagnosis of BMD-I in acute manic episode. Exclusion criteria included

a primary diagnosis of Schizophrenia, delirium, anorexia nervosa, bulimia, autism, substance abuse, mental retardation and ADHD in recent 3 months. Other exclusion criteria were a history of epilepsy, a history of psychogenic polydipsia, a history of symptomatic hyponatremia and patients who were taking other antimanic medications during the study prior or within one week before it. Patients were required to be free of psychotropic drugs with exceptions of diphenhydramin or lorazepam for control of agitation and aggression. Risperidone 2-4 mg/day was prescribed for all of patients.

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **48**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

**Street address**

Daneshgah street, Ghoreishi building

**City**

Mashhad

**Postal code****Approval date**

2009-06-30, 1388/04/09

**Ethics committee reference number**

T2259

**Health conditions studied****1****Description of health condition studied**

acute mania

**ICD-10 code**

F30.1

**ICD-10 code description**

Mania without psychotic symptoms

**Primary outcomes****1****Description**

Change of mood

**Timepoint**

base line, weeks 3,6

**Method of measurement**

Young Mania rating scale

**Secondary outcomes****1****Description**

Clinical Global Impression Scale

**Timepoint**

base line ,weeks 3 and 6

**Method of measurement**

change of scores

**Intervention groups****1****Description**

In the first group, during the 2 weeks titration phase, the Oxcarbazepine was started by 300 mg and increased every 2 days to a maximum dose of 900 to 2400 mg per days or the highest tolerated dose.

**Category**

Treatment - Drugs

**2****Description**

In the second group, Na Valporate was initiated by 600 mg/day and increased to a 20-36 mg/day or the highest tolerated dose for patients.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Ibn-e-Sina psychiatric Hospital

**Full name of responsible person**

Dr. Ali Talaei

**Street address**

Ibn-e-Sina psychiatric Hospital, Horre ameli avenue,boo Ali square

**City**  
Mashhad

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mashhad University of Medical Sciences

**Street address**

Daneshgah Street, Ghoreishi Building

**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**

Psychiatry and Behavioral Sciences Research Center,  
Ibn-e-Sina Hospital, Mashhad University of Medic

**Full name of responsible person**

Dr. Ali Talaei

**Position**

Assistant Professor of Psychiatry

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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Assistant Professor / Child and Adolescent Psychiatrist

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## Person responsible for updating data

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## 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*

**Data Dictionary**  
*empty*