

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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

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Iran (Islamic Republic of)

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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

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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 Medicine

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

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Position

Assistant Professor / Child and Adolescent Psychiatrist

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Person responsible for updating data

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Position

Assistant Professor, Child and Adolescent Psychiatrist,

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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