

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparing efficacy of ECT with and without concurrent sodium valproate therapy in manic patients

Protocol summary

Summary

The objective of this study is to compare efficacy of ECT with and without concurrent sodium valproate therapy in manic patients. Patients hospitalized in Farshchian hospital during manic episode, and are upon sodium valproate therapy, and are going to receive ECT for any reason, will be selected. After obtaining informed consent, these patients will be randomly allocated to either "valproate continuation during ECT" or "valproate cessation during ECT" group. Two groups will be compared regarding symptom severity and illness improvement using YMRS and CGI measures, before ECT and after 2nd, 4th, 6th, and the last session of ECT.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901161743N3**

Registration date: **2010-04-20, 1389/01/31**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2010-04-20, 1389/01/31

Registrant information

Name

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Name of organization / entity

Research Center for Behavioral Disorders and Substance Abuse, Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research center for behavioral disorders and substance abuse, Hamadan University of Medical Sciences

Expected recruitment start date

2010-05-22, 1389/03/01

Expected recruitment end date

2011-01-21, 1389/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing efficacy of ECT with and without concurrent sodium valproate therapy in manic patients

Public title

Comparing efficacy of ECT with and without concurrent sodium valproate therapy in manic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: obtaining informed consent, Diagnosis of bipolar I disorder, manic episode, must be confirmed according to DSM IV-TR criteria, Manic episode refractory to pharmacotherapy, receiving therapeutic doses of valproate before ECT for at least 5 days, Serum levels of valproate ≥ 50 $\mu\text{g/ml}$, Administration of ECT by attending psychiatrist, age 18-60 years Exclusion criteria: Uncontrolled physical condition, Pregnant and nursing women, LFT: 3 fold greater than upper normal limits, receiving other anticonvulsant medications, History of epilepsy

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

N/A

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

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Hamadan University of Medical Sciences

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Shahid Fahmideh Street

City

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Postal code

65178/518

Approval date

2010-03-08, 1388/12/17

Ethics committee reference number

12-10-8-6-5-3-1

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

Manic episode of bipolar disorder

ICD-10 code

F31.1 and

ICD-10 code description

Bipolar affective disorder, current episode manic without psychotic symptoms, Bipolar affective disorder, current episode manic with psychotic symptoms

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

improvement rate of mania

Timepoint

after second, fourth, sixth and at the end of sessions of ECT

Method of measurement

CGI and YMRS

Secondary outcomes

empty

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

discontinuation of sodium valproate

Category

Treatment - Drugs

2**Description**

continuation of sodium valproate

Category

Treatment - Drugs

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

Farshchian hospital

Full name of responsible person

Gholamreza Bigdelo

Street address

Farshchian hospital

City

Hamadan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research center for behavioral disorders and substance abuse, Hamadan University of Medical Science

Full name of responsible person

Dr. Mohamad Ahmadpanah

Street address

Farshchian Hospital

City

Hamadan

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

Yes

Title of funding source

Research center for behavioral disorders and substance abuse, Hamadan University of Medical Science
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
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Person responsible for updating data

Contact

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