

# 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

Mohammad Haghighi

###### Name of organization / entity

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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1827 4184

##### Email address

haghighi@umsha.ac.ir

##### 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  $\geq 50$   $\mu\text{g/ml}$ , 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

##### Street address

Shahid Fahmideh Street

##### City

Hamadan

##### 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**  
Research center for behavioral disorders and substance abuse, Hamadan university of medical sciences  
**Full name of responsible person**  
Gholamreza Bigdelo  
**Position**  
Resident of psychiatry  
**Other areas of specialty/work**  
**Street address**  
Farshchian Hospital  
**City**  
Hamadan  
**Postal code**  
8741-465168  
**Phone**  
+98 81 1828 5015  
**Fax**  
**Email**  
rbigdelo@yahoo.com  
**Web page address**

## Person responsible for scientific inquiries

**Contact**  
**Name of organization / entity**  
Research center for behavioral disorders and substance abuse, Hamadan university of medical sciences  
**Full name of responsible person**  
Dr. Leyla Jahangard  
**Position**  
Assistant professor of psychiatry  
**Other areas of specialty/work**  
**Street address**  
Farshchian Hospital  
**City**  
Hamadan  
**Postal code**  
8741-4-65168  
**Phone**  
+98 81 1828 5015  
**Fax**  
**Email**  
jahangard\_li\_ps@yahoo.com  
**Web page address**

## 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*