

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jul 2026

### Comparison of cognitive impairment and seizure characteristics in manic patients receiving electroconvulsive therapy with or without concurrent treatment with sodium valproate.

#### Protocol summary

##### Summary

After informed consent, we recruit hospitalized patients who are to receive ECT despite sodium valproate treatment. Diagnosis of manic episode by a psychiatrist and according to DSM-IV-TR and Receiving ECT because of drug resistance are inclusion criteria, while presence of seizure and other medical condition, and receiving of other anticonvulsants are exclusion criteria. We are studying the impact of concurrent sodium valproate and ECT on seizure characteristics and cognitive side effects. By continues sampling, we recruit 40 patients and divide them to two groups: continue valproate during ECT (case group), and stop valproate during ECT(control group). MMSE is measured before the first session, after the third and sixth sessions, and before discharge. ECT device shows seizure threshold and EEG is done for duration of seizure.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201101011743N4**

Registration date: **2011-08-27, 1390/06/05**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-08-27, 1390/06/05

##### 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

Hamadan university of medical sciences

##### Expected recruitment start date

2010-09-24, 1389/07/02

##### Expected recruitment end date

2011-11-23, 1390/09/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of cognitive impairment and seizure characteristics in manic patients receiving electroconvulsive therapy with or without concurrent treatment with sodium valproate.

##### Public title

Comparison of cognitive impairment and seizure characteristics in manic patients receiving electroconvulsive therapy with or without concurrent treatment with sodium valproate.

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1. Manic episode based on DSM IV-TR  
2. Age between 18 and 60 years 3. Elementary school

education (at least) 4. ECT administer by attending physician Exclusion criteria: 1. Concurrent anticonvulsant therapy (except sodium valproate) 2. Severe cognitive impairment (MMSE  $\leq$  19) before the first session of ECT 3. Uncontrolled physical condition 4. Pregnant and nursing women 5. History of epilepsy 6. LFT > 3 fold the normal range

#### 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: **40**

#### 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

Hamadan university of medical sciences

##### Street address

Honarestan street

##### City

Hamadan

##### Postal code

65168-4-8741

#### Approval date

2010-05-19, 1389/02/29

#### Ethics committee reference number

16/70/7/28614/پ

## Health conditions studied

### 1

#### Description of health condition studied

Bipolar disorder, Manic episode

#### ICD-10 code

F30

#### ICD-10 code description

Manic episode

## Primary outcomes

### 1

#### Description

Seizure threshold

#### Timepoint

all session of ECT

#### Method of measurement

observation

### 2

#### Description

Duration of seizure

#### Timepoint

all session of ECT

#### Method of measurement

EEG

### 3

#### Description

Cognitive side effect

#### Timepoint

Before the 1st ECT session and after 3rd and 6th session

#### Method of measurement

MMSE

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

During treatment with ECT that often lasts between 6 to 10 sessions, sodium valproate is continued in the control group.

#### Category

Treatment - Drugs

### 2

#### Description

During treatment with ECT that often lasts between 6 to 10 sessions, sodium valproate is discontinued in the case group.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Farshchian Hospital

##### Full name of responsible person

Dr. Hassan Hafezian

**Street address**  
Mirzade Eshghi Street, Shariati squar  
**City**  
Hamedan

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Hamedan univercity of medical science  
**Full name of responsible person**  
Dr Mohammad Haghighi  
**Street address**  
Shariati avenue, Shariati cross street  
**City**  
Hamadan  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Hamedan univercity 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

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**Full name of responsible person**  
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## Person responsible for scientific inquiries

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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*