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)

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Recruitment status

Recruitment complete

Funding source

Hamadan univercity 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 ≤ 19) befor 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 univercity 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
Cognetive side effect

Timepoint
Befor the 1st ECTsession 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
Name of organization / entity
Hamedan univercity of medical sciences
Full name of responsible person
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Position
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Other areas of specialty/work
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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