Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

A comparative study: the effect of valproate sodium oral and intravenous loading dose on treatment of patients with acute mania

Protocol summary

Summary

Aim: This double blind study will be done to assess the effect of valproate sodium oral and intravenous loading dose on treatment of patients with acute mania episode. Sample: 60 patients will be selected according to diagnostic and statistical Manual IV –TR criteria and divided into two experiment and control group randomly. Groups will be matched on age, sex, marriage status, educational level, mania type and its episode and severity. We will use psychological test as a pre and post test: Clinical Global Impression Scale and Young mania rating scale. Intervention: 20mg /kg intravenous valproate sodium (injection) plus placebo tablet in experimental Group; valproate sodium tablet orally plus placebo (injection) in control group. Valproate sodium Plasma level will be measured in 1, 3 and 7 days after injection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108087260N1**
Registration date: **2011-10-25, 1390/08/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-10-25, 1390/08/03

Registrant information

Name

Mehdi Sharifmehr

Name of organization / entity

Hamadan university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research center for behavioral disorders and substances abuse & Vice chancellor for research, Hamadan university of medical sciences

Expected recruitment start date

2011-09-14, 1390/06/23

Expected recruitment end date

2012-09-12, 1391/06/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study: the effect of valproate sodium oral and intravenous loading dose on treatment of patients with acute mania

Public title

The effect of valproate sodium on treatment of patients with mania

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients who are in acute mania episode. Exclusion criteria: patients with other psychiatric disorders.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double 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
Farshchian hospital, Shariati street, Pastor cross road
City
Hamadan
Postal code
518/65178
Approval date
2011-05-30, 1390/03/09
Ethics committee reference number
785/9/35/16/د/پ

Health conditions studied

1

Description of health condition studied
bipolarity- mania episode
ICD-10 code
F30
ICD-10 code description
Manic episode

Primary outcomes

1

Description
plasma level
Timepoint
one, three and seven days after injection
Method of measurement
measure of plasma level

Secondary outcomes

empty

Intervention groups

1

Description
Control group: 20mg/kg of valproate sodium tablet plus placebo for injection
Category
Treatment - Drugs

2

Description
Experiment group: 20mg/kg intravenous valproate sodium and placebo as a tablet
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Research institute for behavioral disorders and substances abuse, Farshchian Hospital
Full name of responsible person
Dr. Ali Ghaleiha
Street address
Farshchian hospital , Shariati squire, Mirzadeh Eshghi street
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor of research and technology & Research institute for behavioral disorder and substanc
Full name of responsible person
Dr. Ali Ghaleiha
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
Vice chancellor of research and technology & Research institute for behavioral disorder and substanc
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

Hamadan university of medical sciences

Full name of responsible person

Dr. Mehdi Sharifmehr

Position

resident of psychiatry

Other areas of specialty/work

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Web page address

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