Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Compare Effectiveness of Adding Folic Acid to Sodium Valproate in Treating patients with Acute Mania

Protocol summary

Study aim
Determination of the Effect of Simultaneous Use of Folic Acid and Sodium Valproate in the Treatment of Acute Mania

Design
A placebo controlled, double blind randomized clinical trial with parallel groups with 60 patients.

Settings and conduct
Since the study is designed blind, therapists and prescribing nurses and also data analyzer do not know the type of medication prescribed for the patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria: diagnosis of type 1 bipolar disorder in the Mania episode based on DSM-V diagnostic criteria. Exclusion criteria: the presence of anemia, History of ADHD, history of admission to psychiatric hospital during the past three months, positive pregnancy test in women, receiving other medications such as anti-mania treatment during two weeks prior to the study or During the study, a history of sensitivity to sodium valproate.

Intervention groups
A sample of 60 patients was selected and randomly divided into two groups of case and control (each group was 30 patients).The case group will be treated with sodium valproate and folic acid and the control group will be treated with placebo and sodium valproate.

Main outcome variables
Acute mania improvement (using Young Mania Rating Scale score and short mental state test 1 score)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180103038196N2**
Registration date: **2018-06-07, 1397/03/17**
Registration timing: **retrospective**
Last update: **2018-06-07, 1397/03/17**
Update count: **0**

Registration date
2018-06-07, 1397/03/17

Registrant information

Name
Amir Hossein Salimi Kordasiabi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-02-20, 1396/12/01

Expected recruitment end date
2018-04-21, 1397/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Compare Effectiveness of Adding Folic Acid to Sodium Valproate in Treating patients with Acute Mania

Public title
Efficacy of Adding Folic Acid to Sodium Valproate on patients with Acute Mania

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Being at the age of 18 to 50 years Diagnosis of type 1 bipolar disorder, being in mania episode based on diagnostic criteria DSM-5 (By a semi-structured interview by a psychiatrist and diagnosis based on minimum score 20 from the Young Mania Rating Scale)

Exclusion criteria:

Intolerance to increase the dose of the drug over a specified period of time. Presence of anemia Abnormal folic acid levels Changing the diagnosis and rejection of the initial diagnosis during the course of treatment History of ADHD psychiatric diagnosis combined with medication and other diseases history of admission to the psychiatric hospital during the past three months, Positive pregnancy test in women receive other medications, such as anti-mania treatments, two weeks prior to study or during the study history of sodium valproate sensitivity

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

A sample of 60 patients was selected based on the inclusion criteria and randomly divided into two groups of intervention and control (each group was 30 patients). Patients will be matched for age and sex.

Blinding (investigator's opinion)

Double blinded

Blinding description

Therapists and prescribing nurses and also data analyzer did not know the type of medication prescribed for patients. Therefore the study was double blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of golestan University of Medical Sciences

Street address

Falsafi compelex, 5th kilometer, Gorgan- sari road.

City

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Province

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Postal code

4934174515

Approval date

2017-10-24, 1396/08/02

Ethics committee reference number

IR.GOUMS.REC.1396.82

Health conditions studied

1

Description of health condition studied

Acute Mania

ICD-10 code

F31.1

ICD-10 code description

Bipolar disorder, current episode manic without psychotic features

Primary outcomes

1

Description

Improvement of acute mania based on the results of the used tests

Timepoint

The beginning of the study (before the intervention) and 3 and 6 weeks after the intervention

Method of measurement

Young Mania Rating Scale and Mini-Mental State Examination 1

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients receiving folic acid + sodium valproate .Sodium valproate starts at 400 mg per day and will increase up to maximum of 20 mg per kg per day or the highest dose that the patient can withstand. In addition sodium valproate, the group will receive one tablet of folic acid 5 milligrams a day.

Category

Treatment - Drugs

2

Description

Control group: patients receiving placebo + sodium valproate . Sodium valproate starts at 400 mg per day

and will increase up to a maximum of 20 mg per kg per day or the highest dose that the patient can withstand.In addition to sodium valproate, the control group will receive one placebo tablet

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Panje Azar Hospital

Full name of responsible person

Dr Peyman Rad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Gorgan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Dr Peyman Rad

Position

assistant

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person
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Latest degree
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General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
All data is shareable

When the data will become available and for how long
from 2018

To whom data/document is available
Professors and people studying at medical universities

Under which criteria data/document could be used
All data is shareable

From where data/document is obtainable
salimia92@gmail.com

What processes are involved for a request to access data/document
not have

Comments