Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

A comparative effect of adding folic acid to the therapeutic diet of patients with mania

Protocol summary

Summary

Main outcome: Appointment of the effect of adding folic acid to the sodium valproate in response to treatment of patients with mania. Design: This study is a clinical trial. The study population includes 60 patients out of all patients with mania whom referred to Farabi Hospital. They will be divided in two equal groups. Patients in the study group will receive sodium valproate, one atypical anti psychotic drug, and folic acid (at a dose of 5 mg once daily). Yet the patients in the control group will be treated with an atypical antipsychotic, sodium valproate, and a placebo instead of folic acid. The sampling will be done by available method. Setting and conduct: Maximum replication between the study and control groups to apply. Therapeutic regimen program will be determined by a psychiatrist. Education Directory of Faculty of Pharmacy of Kermanshah University of Medical Sciences is responsible for supplying placebo. Evaluation and improvement of symptoms is determined by a bachelor in Clinical Psychology, who is not aware of the treatment program. The patients should be visited in the beginning of the study, and at intervals of two weeks in the first month and then monthly for two months later, to be evaluated by the Young Mania Rating Scale (YMRS). This scale includes 11 items, and is used to determine the presence and severity of the symptoms of manic disorder. Profile of drug treatment, including medication times per day, changes and reasons for changing the dosage or discontinuation of therapy and time of discontinuation will be recorded on a special form at each step and at the end of the study. Evaluation of symptoms, side effects of drugs, and the response to treatment will be recorded. This is an accidentally double blind study by using placebo controls which is conducted in Farabi Hospital. Inclusion criteria are: being older than 18 years; having diagnosis of BD type 1, 2 (DSM-IV-TR). Exclusion criteria include: IQ lower than 70; and contraindications of folate consumption. Sampling period would last two years, and the expected result is to increase response to adding folate to sodium valproate in patients with mania.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013031612825N1**
Registration date: **2014-07-09, 1393/04/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-07-09, 1393/04/18

Registrant information

Name
Faezeh Tatari
Name of organization / entity
Kermanshah University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 83 1432 2356
Email address
maryamflower98@yahoo.com

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2015-04-21, 1394/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative effect of adding folic acid to the therapeutic diet of patients with mania

Public title

The effect of adding folic acid to the therapeutic diet of patients with mania

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having diagnosis of BD type 1,2 (DSM-IV-TR); age> 18 years. Exclusion criteria: mental retardation (IQ<70); pervasive developmental disorders; patients need ECT or physical controlling; contraindication to use of folic acid and folate dependent tumors; pregnancy; substance abuse or dependency since 3 months ago; risk of suicide which needs preventive interventions; weight lower than 30 kg; schizophrenia; medical or neurological disorders (epilepsy and other seizure disorders); chronic gastrointestinal disorders; allergy to folic acid; renal disorders; use of supplements such as calcium, and D and B vitamins; chronic infection; anemia.

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

2-3

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

Ethics Committee Kermanshah Univercity of Medical Science

Street address

Shahid Beheshti Street, Kermanshah, Kermanshah, Iran

City

kermanshah

Postal code

6714673159

Approval date

2013-02-12, 1391/11/24

Ethics committee reference number

53534

Health conditions studied

1

Description of health condition studied

mania

ICD-10 code

F30-F39

ICD-10 code description

Other degenerative diseases of the nervous system

Primary outcomes

1

Description

To measure and compare the response to treatment in study and control groups based on YMRS scale.

Timepoint

After two weeks, one month, two months, three months.

Method of measurement

by using Young Mania Rating Scale.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Adding folic acid to therapeutic regime, in the form of 5 mg pill, once daily, for 4 months.

Category

Placebo

2

Description

Control group: Adding placebo to the therapeutic regime (sodium valproate), in the form of a pill, once daily, for 4 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Farabi Hospital
Full name of responsible person
Afsar Mehran Nia
Street address
Farabi Hospital, Dolat Abad Street.
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Farid Najafi
Street address
Research Unit, Kermanshah University of Medical Sciences, Shahid Beheshti Street.
City
Kermanshah
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah University of Medical Sciences
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
Member of Student Research Committee, Kermanshah University of Medical Sciences
Full name of responsible person
Maryam Pashabadi
Position
B.D. in Nursing
Other areas of specialty/work
Street address
Taleghani Hospital, Shahid Beheshti Street.
City
Kermanshah
Postal code
6717783141
Phone
+98 83 1432 2356
Fax
+98 83 1836 9850
Email
maryamflower@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Assistant Professor, Department of Psychiatry, School of Medicine.
Full name of responsible person
Faezeh Tatari
Position
Psychiatrist
Other areas of specialty/work
Street address
Kermanshah University of Medical Sciences, Shahid Beheshti Street.
City
Kermanshah
Postal code
iran
Phone
+98 83 1432 2356
Fax
Email
ftatari@kums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Kermanshah University of Medical Science
Full name of responsible person
Maryam Pasha Abadi
Position
B.D. in nursing
Other areas of specialty/work
Street address
Taleghani Hospital, Shahid Beheshti Street
City
Kermanshah
Postal code
6717783141
Phone
008314322356
Fax
+98 83 69850
Email
maryamflower98@yahoomail
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