Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The study of the effects of adding folic acid to the therapeutic diet (citalopram) in patients with depression.

Protocol summary

Summary

Summary: Objectives: Optimal level of folates is essential for normal functioning of the brain and body. Recently, studies have focused on the effect of folates on cognitive disorders. More recent studies have demonstrated that plasma levels of folates in people with mood disorders such as depression is less than desirable. This research is designed to determine the effects of folic acid on patients with depression. Main outcome: The effect of adding folic acid to the therapeutic diet (citalopram) in patients with depression. Design: This study is a clinical trial. The study population is all patients with depression referred to Kermanshah Farabi Hospital. The sample size consists of 60 patients who would be chosen by available method and divided in two equal groups. Citalopram in a dose of 60 mg/d will be prescribed in both groups. The study group will receive folic acid at a dose of 5 mg once daily. In controls placebo will be recommended once daily. Setting and conduct: Maximum replication between the study and control groups would be done. A psychiatrist determines the treatment program. Faculty of Pharmacy of Kermanshah University of Medical Sciences is responsible for supplying placebo. Beck Standard Inventory is used to measure the severity of symptoms. A bachelor in clinical psychology, who is not aware of treatment, will use the questionnaire. This questionnaire includes of 21 questions. The total score ranges are from 0 to 63 which specifies four degrees of depression as follows: 0 to 10 normal; 11 to 16, slightly depressed; 17 to 20 require a consultation with the doctor; 21 to 30 moderately depressed; 31 to 40 severe depression, and higher than 41 very sever depression. The valuation and improvements of the patients will be measured at the first visit; 2 weeks later; first month; and second and third months then after. Profiles of drug treatment, including medication times, changes and reasons for changes in dosage or discontinuation of therapy will be recorded on a special form. At each step and at the end of the survey, evaluation of symptoms, side effects of drug therapy, and the response to treatment will be discussed. Inclusion criteria: age>18years; having diagnosis of depression (DSM.IV.TR). Exclusion criteria: IQ<70; schizophrenia; major medical or neurological disorders; pregnancy; contraindication for using of folates; and gastric or renal disorders. The sampling period would last about two years. The expected outcome is an improvement in depression symptoms in response to folic acid therapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013033112825N2**
Registration date: **2014-08-12, 1393/05/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-08-12, 1393/05/21

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Kermashah University of Medical Sciences

Expected recruitment start date
2013-06-18, 1392/03/28
Expected recruitment end date
2015-06-18, 1394/03/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The study of the effects of adding folic acid to the therapeutic diet (citalopram) in patients with depression.

Public title
The effects of folic acid in treatment of patients with depression.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: patients' age>18years; having diagnosis of depression (DSM.IV.TR). Exclusion criteria: IQ less 70; schizophrenia; major medical or neurological disorders; pregnancy; any contraindications for using folates; wight lower than 30 kg; gastric or renal disorders; use of supplements such as B vitamins; chronic infections; 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
Kermanshah University of Medical Sciences
Street address
Shahid Beheshti blv.
City
Kermanshah
Postal code
6714673159
Approval date
2013-06-18, 1392/03/28
Ethics committee reference number
12372

Health conditions studied

1

Description of health condition studied
Depression
ICD-10 code
F32
ICD-10 code description
Depressive episode

Primary outcomes

1

Description
Response to trapy
Timepoint
At the beginning of study, 2 weeks later, 1 month then, After 2 months, after 3 months.
Method of measurement
Beck Standard Inventory

Secondary outcomes

1

Description
Response to trapy
Timepoint
At the beginning of study, 2 weeks later, 1 month then, After 2 months, after 3 months.
Method of measurement
Beck Standard Inventory

Intervention groups

1

Description
Adding folic acid (5mg/d) to the therapeutic diet (citalopram) in patients with depression, for 4 month in interventions.
Category
Treatment - Drugs

2

Description
Adding plasbo to the therapeutic diet (citalopram) in patients with depression, for 4 month in controls.

Category
Treatment - Drugs

Recruitment centers

1

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

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University Medical Sciences
Full name of responsible person
Dr. Farid Najafi
Street address
Research Unit, 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 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

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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