

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Folic acid supplementation on response to the standard treatment in patients with major depressive disorder.

Protocol summary

Summary

This randomized, double-blinded clinical trial is conducted on patients with major depressive disorder, aged 20-50 years. Patients with psychotic symptoms are excluded from the study. Patients in both groups receive the standard treatment for major depressive disorder consisting of 20 mg citalopram, daily. The cases receive 2.5 mg of folic acid per day and the controls are treated with placebo. The outcomes are evaluated using the Beck Depression Inventory and reduction of the depression score is interpreted as the response to treatment. Outcomes are measured at 4, 6 and 8 weeks after the treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014082518922N1**

Registration date: **2014-12-06, 1393/09/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-06, 1393/09/15

Registrant information

Name

Narges Gholampoor

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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gholampour@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2013-11-06, 1392/08/15

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Folic acid supplementation on response to the standard treatment in patients with major depressive disorder.

Public title

Effect of Folic acid supplementation on the therapeutic regimen for major depressive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: To have a definite diagnosis of major depressive disorder according to the DSM-IV-TR criteria; Being between 20 and 50 years old; To get the minimum score of 12 from the BDI 2 scoring system; Having stopped taking any other antidepressant medications since 4 weeks before starting folic acid; Patients who sign the written informed consent after being provided with the detailed information about the study; Not having anemia based on a Complete Blood Count (CBC) test; The absence of pregnancy; No alcohol or substance use in 6 months prior to the study; The absence of manic episodes; The absence of psychotic symptoms; The absence of mental retardation; Depression not due to a

general medical condition or substance; The absence of any severe or chronic physical illnesses. Exclusion criteria: Having any acute and severe medical conditions; The incidence of any severe psychiatric disorders (suicidal thoughts, psychotic symptoms, manic phase symptoms, etc.); Failure to follow-up for at least 4 weeks; The concomitant use of other psychotropic drugs; The incidence of severe complications during treatment.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

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

Kashan University of Medical Sciences

Street address

Vice chancellor for research, Kashan Medical Sciences complex, Ghotbe Ravandi Blvd.

City

Kashan

Postal code

Approval date

2013-10-26, 1392/08/04

Ethics committee reference number

29/5/1/458/پ

Health conditions studied

1

Description of health condition studied

Major depression

ICD-10 code

F32

ICD-10 code description

Depressive episode

Primary outcomes

1

Description

depression severity

Timepoint

4, 6 and 8 weeks after starting the treatment

Method of measurement

The Beck Depression Inventory 2nd Edition

Secondary outcomes

empty

Intervention groups

1

Description

Folic acid tablet, one half of 5 mg tablets, once per day for 8 weeks

Category

Treatment - Drugs

2

Description

Tablets without the active ingredient with the same size and shape of Folic acid tablet, a half tablet daily, for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Kargarnejad Hospital

Full name of responsible person

Dr. Narges Gholampur

Street address

Kargarnejad Hospital, Ghotbe Ravandi Blvd.

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, Kashan University of Medical Sciences

Full name of responsible person

Dr. Gholam Ali Hamidi

Street address

Vice Chancellor for research, Pezeshk Blvd., Ghotbe

Ravandi Blvd.
City
Kashan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research, Kashan 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
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Person responsible for updating data

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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