

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of folic acid supplementation in patients with major depressive disorder receiving Citalopram.

Protocol summary

Study aim

Comparison of the effect of simultaneous administration of folic acid supplements in patients with major depressive disorder treated with selective serotonin reuptake inhibitors in patients who are only being treated with selective serotonin reuptake inhibitors.

Design

Clinical trial with control and intervention group, randomized

Settings and conduct

This study is carried out at the Zanzan Haft-Tir Clinique.

Participants/Inclusion and exclusion criteria

The patient is depressed, the Beck test result is above 15, the absence of other psychiatric disorders and psychosis, bipolar disorder, drug abuse, depression due to physical illness, pregnancy

Intervention groups

Control group: Depressed patients with a Beck score of over 15 who were only treated with citalopram.
Intervention group: Depressed patients with a Beck score of over 15 who were treated with citalopram with folic acid.

Main outcome variables

The level of blood folate, the severity of depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180115038373N1**

Registration date: **2018-10-06, 1397/07/14**

Registration timing: **retrospective**

Last update: **2018-10-06, 1397/07/14**

Update count: **0**

Registration date

2018-10-06, 1397/07/14

Registrant information

Name

Mina Islambulchilar

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

2018-01-05, 1396/10/15

Expected recruitment end date

2018-09-06, 1397/06/15

Actual recruitment start date

2018-01-05, 1396/10/15

Actual recruitment end date

2018-09-06, 1397/06/15

Trial completion date

2018-09-06, 1397/06/15

Scientific title

Effects of folic acid supplementation in patients with major depressive disorder receiving Citalopram.

Public title

effect of folic acid in depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

depressed people, the number of beck scale should be more than 15

Exclusion criteria:

having other psychotic disorders, like psychos, bipolar disorder, drug abusers, pregnancy, and depression because of an illness

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider

Sample size

Target sample size: **30**

Actual sample size reached: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples were available from clients referring to the psychiatric clinic, then placed in a control or intervention group from a bag containing 30 arrays containing 15 orbets with a label A and 15 orbets labeled B (control group: A The intervention group: B) took an orb

Blinding (investigator's opinion)

Single blinded

Blinding description

Study cases have been evaluated by our psychologist colleagues, by Hamilton test (tested depression severity),

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zanjan university of medical sciences

Street address

Gavazang blvd,school of pharmacy, Zanjan university of medical sciences

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Province

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Postal code

45139-56184

Approval date

2018-01-02, 1396/10/12

Ethics committee reference number

IR.ZUMS.REC.1396.246

Health conditions studied

1

Description of health condition studied

Major depressive disorder

ICD-10 code

F32.2

ICD-10 code description

Major depressive disorder, single episode, severe without psychotic features

Primary outcomes

1

Description

Depression severity with the results of Beck scale

Timepoint

Measuring the severity of depression at the beginning of the study, day 45, day90

Method of measurement

Beck and Hamilton scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receiving acid folic 1mg/day (Rouz Darou) and citalopram 20 mg/day

Category

Treatment - Drugs

2

Description

Control group: citalopram 20 mg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Haft tir clinic of Zanjan

Full name of responsible person

Masume Morovati

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Islambulchilar Mina

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Toxicology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

Undecided - It is not yet known if there will be 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