Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Zanjan 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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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
Measureing 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

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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
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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