Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

randomized controlled trial folic acid combination with fluoxetine in treatment of patients with major depressive disorder under age 18

Protocol summary

Study aim
the effects of folic acid combination with fluoxetine in treatment of patients with major depressive disorder under age 18

Design
Double blinded randomized clinical trial, parallel group, randomized, phase3 on 44 MDD patients between age 6-18 years, randomization was done with computer randomization.

Settings and conduct
This trial will be conducted during 3 phases(0,1,3 month) in new MDD patients between age 6-18 that be visited in outpatient units or admission wards of department of child psychiatry of Isfahan University of Medical Sciences. all of participants, health care providers(that are involved in offering drug or placebo to participants) and data collectors and assessors will be blinded with similarity in form and shape of drug and placebo and numerical codes for each participants instead of name in all time of study.

Participants/Inclusion and exclusion criteria
inclusion criteria: clinical diagnosis of Major Depressive Disorder according to DSM-5,consent to participate in the study by completing the informed consent form by patient and family, negative history of receiving any antidepressant drug or mood stabilizers or drugs that could change appetite or weight during recent 3 month before study, lack of history of allergic reaction to drug. exclusion criteria: need for ECT during study and any new medical or mental conditions that change drug needs

Intervention groups
Intervention group will receive drug combination of fluoxetine and folic acid (drug A)and control group will receive fluoxetine and placebo(drug B)

Main outcome variables
In the beginning of study and in end of month 1 and 3, severity of MDD will be assessed as blood indices(RBC, hemoglobin, MCV)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230619058530N1**
Registration date: **2023-07-20, 1402/04/29**
Registration timing: **prospective**

Last update: **2023-07-20, 1402/04/29**
Update count: **0**

Registration date
2023-07-20, 1402/04/29

Registrant information

Name
Mostafa Haghshenas

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3792 8000

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-23, 1402/05/01

Expected recruitment end date
2025-01-20, 1403/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

randomized controlled trial folic acid combination with fluoxetine in treatment of patients with major depressive disorder under age 18

Public title
effects of folic acid combination with fluoxetine in treatment of patients with major depressive disorder under age 18
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
clinical diagnosis of Major Depressive Disorder according to DSM-5 criteria consent to participate in the study by completing the informed consent form by patient and patient Lack of any history of receiving any anti depressant drug or mood stabilizers during recent 3 month before study lack of history of allergic reaction to drug age between 6-18 years
Exclusion criteria:
need to ECT treatment during study any unexpected new physical or mental condition that could change medical care of patient
Age
From **6 years** old to **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
in ordering of entrance time, each sample will give specific code between 1-40 and then, using online computer randomization(random.org) will be randomized in intervention or placebo group with a simple randomization manner by a 1:1 ratio.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants in both intervention and control group will be blinded about drug or placebo with similarity in shape of drug and placebo. principle investigator will be blinded with random placing the participants in both control and intervention group so give each participant a numerical code. health care providers offer the drug and placebo base on A and B codes to participants and data collectors and outcome assessors will be blinded because they will collect data and assess them without any information about drug or placebo type.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Research Ethics Committee of the "Alzahra Research Centers"
Street address
Hezar-Jerib street
City
esfahan
Province
Isfehan
Postal code
8174673461
Approval date
2023-07-17, 1402/04/26
Ethics committee reference number
IR.ARI.MUI.REC.1402.093

Health conditions studied

1

Description of health condition studied
major depressive disorder
ICD-10 code
F32
ICD-10 code description
Major depressive disorder, single episode

Primary outcomes

1

Description
major depressive disorder
Timepoint
Before intervention and 1,3 months after intervention
Method of measurement
Children Depression Inventory (CDI)

2

Description
blood indices(red blood cells, hemoglobin and men corpuscular volume(
Timepoint
Before intervention and 1,3 months after intervention
Method of measurement
Lab kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: folic acid tablet (Folic acid-IRAN DAROO 1MG TAB) with dose 1-5mg daily, once daily orally for 3 month
Category
Treatment - Drugs

2

Description
Control group: placebo tablet(School of Pharmacy and Pharmaceutical SciencesSchool of Isfahan University of Medical Sciences) contains starch and calcium diphosphate with dose 1-5 tablet per day orally and once daily
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Amin hospital
Full name of responsible person
Majid Hosseinzadeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Mostafa Haghshenas
Position
assistant professor
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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