

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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

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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	Parallel
Public title effects of folic acid combination with fluoxetine in treatment of patients with major depressive disorder under age 18	Other design features
Purpose Treatment	Secondary Ids empty
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	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 Isfahan Postal code 8174673461 Approval date 2023-07-17, 1402/04/26 Ethics committee reference number IR.ARI.MUI.REC.1402.093
Age From 6 years old to 18 years old	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
Gender Both	Primary outcomes 1 Description major depressive disorder Timepoint Before intervention and 1,3 months after intervention Method of measurement Children Depression Inventory (CDI)
Phase 3	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
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	

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

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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

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

Latest degree

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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