Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jul 2026

Investigating the effectiveness of fluoxetine in the treatment of major depression compared to placebo in children 4-6 years old

Protocol summary

Study aim
Investigating the effectiveness of fluoxetine in the treatment of major depression compared to placebo in children 4-6 years old

Design
A randomized double-blind randomized controlled clinical trial is performed on 40 participants. Random blocking will be used for randomization.

Settings and conduct
In this study, patients referred to a psychiatric clinic are selected in double random blocks. A clinical interview is conducted by a psychiatric specialist before the start of treatment, 4 weeks later and 3 months later. The RCADS-P questionnaire is examined before starting the treatment, 4 weeks later and 3 months later. Then the patients in two groups are examined together and at different times.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 4-6 years old; diagnosis of depression based on the DSM-V criteria related to the diagnosis of depression in preschool children must be confirmed for the patient by a psychiatrist; absence of other psychiatric disorders; parents' consent to children's participation in this study; no history of previous use of fluoxetine or other psychiatric drugs; not taking drugs that interfere with fluoxetine; not having separate families. Exclusion criteria: lack of parental consent to continue studying at any time of the study; causing drug side effects due to fluoxetine use.

Intervention groups
In the first group (F), the prescribed dose of fluoxetine will be such that the prescribed dose for each child is 0.7 mg per kilogram of body weight, and in the therapeutic range 5-15 mg per day in the form of syrup. will be. In the second group (P), patients are treated with a placebo in a similar way to the first method, which is exactly the same as Fluoxetine in terms of shape, size and color, and is manufactured by the Department of Pharmaceutics of Isfahan University of Medical Sciences.

Main outcome variables
Major Depression

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220706055386N1**
Registration date: **2022-08-13, 1401/05/22**
Registration timing: **prospective**

Last update: **2022-08-13, 1401/05/22**
Update count: **0**

Registration date
2022-08-13, 1401/05/22

Registrant information
Name
Mahdieh Soltanian
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-09-06, 1401/06/15
Expected recruitment end date
2022-12-21, 1401/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effectiveness of fluoxetine in the treatment of major depression compared to placebo in children 4-6 years old

Public title
The effectiveness of fluoxetine in the treatment of depression

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 4-6 years old The diagnosis of depression based on the DSM-V criteria related to the diagnosis of depression in preschool children for the patient must be confirmed by a psychiatrist (severity of depression will be obtained based on a high score by the subject on the revised parent anxiety-depression scale = a score higher than 25). No other psychiatric disorders Parents' consent to children's participation in this study No history of previous use of fluoxetine or other psychiatric drugs Not taking drugs that interfere with fluoxetine Not having separate families (single-parent children, children of divorce, having a stepmother or stepfather, or the death of parents)

Exclusion criteria:
Lack of parental consent to continue studying at any time of the study Drug side effects caused by fluoxetine use

Age
From **4 years** old to **6 years** old

Gender
Both

Phase
N/A

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
As a block randomization, the patients will be divided into two groups, the first group will be treated with fluoxetine and the second group will be treated with placebo. In the randomized block method, we divide the studied subjects into blocks of 4 people, so that for the use of fluoxetine (F) or placebo (P) in each block of 4 people, there will be 6 possible situations (1. FPPF, 2. PFFP, 3. -PFPF, 4-FPFP, 5-FFPP, 6-PPFF). We create random numbers with a computer, and in case of a number between zero and one sixth, group one; If there is a number between one-sixth and two-sixths, we define two groups and in the same way the groups in 10 blocks.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to avoid bias and maintain blinding, the drugs of the intervention and placebo groups are coded, and the prescribing physician of the patients, the evaluator, and the statistical consultant do not know the type of drug. The psychiatrist who visits the patient and gives the packaged and coded medication to the patient, the researcher who fills out the questionnaire, the researcher who enters the data into the software, and the epidemiologist who analyzes, blinded people in are study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committees of Isfahan University of Medical Sciences

Street address
Ethics Committee, Isfahan University of Medical Sciences and Health Services, Hazar Jarib St.

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Isfahan

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81746-73461

Approval date
2022-06-28, 1401/04/07

Ethics committee reference number
IR.MUI.MED.REC.1401.137

Health conditions studied

1

Description of health condition studied
Major Depression

ICD-10 code
F06.32

ICD-10 code description
Mood disorder due to known physiological condition with major depressive-like episode

Primary outcomes

1

Description

Major Depression

Timepoint

Measurement of major depression at the beginning of the study (before the start of the intervention) and the fourth week and three months after starting the fluoxetine drug

Method of measurement

The Revised Child Anxiety and Depression Scales–Parent Version (RCADS-P)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, the prescribed dose of fluoxetine will be such that the prescribed dose for each of the children is 0.7 mg per kilogram of body weight, and in the therapeutic range 5-15 mg per day as It will be syrup.

Category

Treatment - Drugs

2

Description

Control group: In this group, patients are treated with placebo in the same way as the first method, which is exactly the same as Fluoxetine drug in terms of shape, size and color, and is manufactured by the Department of Pharmaceutics, Faculty of Pharmacy, Isfahan University of Medical Sciences.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Psychiatric clinics affiliated to Isfahan University of Medical Sciences

Full name of responsible person

Fatemeh Rajabi

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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

Mahdieh Soltanian

Position

Psychiatric resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Only part of the data, such as information about the main outcome or the like, can be shared.
When the data will become available and for how long
Start of access period 6 months after printing results
To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions
Under which criteria data/document could be used
Any type of analysis on the data delivered is permitted
From where data/document is obtainable
Mahdieh Soltanian
What processes are involved for a request to access data/document
Requests can be made by sending an email to the following address: m.soltanian1353@gmail.com
Comments