Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Investigating the effect of adding pregabalin to fluoxetine in the Treatment of children aged 9 To 14 years with anxiety disorders referred To a child and adolescent psychiatric clinic

Protocol summary

Study aim
Determining the effect of adding pregabalin to fluoxetine in the treatment of children with anxiety disorders

Design
Two arm parallel group randomized trial with blinded on 60 Anxious 9 to 14-year-old child.

Settings and conduct
Patients will be randomly assigned to two intervention groups (fluoxetine and pregabalin treatment recipients) and control group (fluoxetine and placebo treatment recipients). The intervention group will receive daily pregabalin at a dose of 2.5 mg/kg for 8 weeks in addition to their main treatment (fluoxetine syrup in the first week with a dose of 2.5 cc daily and a dose of 5 cc daily from the second week) for 2 months. The control group will also receive a placebo medicine, which looks and tastes the same as pregabalin capsules, in addition to their main treatment (fluoxetine syrup with the same dose and duration). Patients in both groups will be evaluated by questionnaires at the beginning and at the end of the study (end of week 8).

Participants/Inclusion and exclusion criteria
Inclusion criteria age 9–14 years Children with anxiety disorders based on psychiatrist diagnosis and DSM-5 criteria All samples are new Exclusion criteria: having co-occurring mood disorder Psychotic disorder Pervasive developmental disorder Receive any type of psychotherapy Taking psychiatric medications other than SSRIs History of complications and drug sensitivity History of seizures Lack of consent of the patient or legal guardian during the plan Mental and physical retardation If you have any concomitant medical disorder (such as autism and epilepsy) Suffering from physical diseases such as liver diseases, heart diseases, kidney disease

Intervention groups
Intervention group (Fluoxetine and Pregabalin treatment recipients) and control group (Fluoxetine and placebo treatment recipients)

Main outcome variables
Anxiety intensity Anxiety disorder score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170108031818N5**
Registration date: **2023-06-13, 1402/03/23**
Registration timing: **prospective**

Last update: **2023-06-13, 1402/03/23**
Update count: **0**

Registration date
2023-06-13, 1402/03/23

Registrant information

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fatemeh mehravar

Name of organization / entity
Golestan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-21, 1402/06/30

Expected recruitment end date
2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of adding pregabalin to fluoxetine in the Treatment of children aged 9 To 14 years with anxiety disorders referred To a child and adolescent psychiatric clinic

Public title

The effect of adding pregabalin to fluoxetine in the treatment of children with anxiety disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 9-14 years Children with anxiety disorders based on psychiatrist diagnosis and DSM-5 criteria New case

Exclusion criteria:

Having accompanying mood disorder - psychotic disorder - pervasive developmental disorder Receive any type of psychotherapy Taking psychiatric medications other than SSRIs History of complications and drug sensitivity History of seizures Lack of consent of the patient or legal guardian during the plan Mental and physical retardation In case of any concomitant medical disorder such as IP, autism, epilepsy Having physical diseases such as liver disease, heart disease, kidney disease

Age

From **9 years** old to **14 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, after informed consent was obtained from the parents of eligible children, the participants were divided into two groups A (receivers of fluoxetine and pregabalin main treatment) and B (fluoxetine and placebo) by random block method. They will be. In this way, first, the size of the blocks is considered to be four. Therefore, according to the treatment groups, 6 different combinations are created. Therefore, in the form of randomly placed sampling, 15 blocks are selected based on the table of random numbers obtained by the computer program, and based on that, the samples included in the study will be entered into different groups. This will continue until we reach a sufficient number of samples in each group. For example, if block number 1 is selected in the first selection, it means that the first two samples will enter group A, and the third and fourth samples will enter group B, and the block will be selected again for the next 4 samples. B B A A ۱ B A B A ۲ A B B A ۳ A A B B ۴ A B A B ۵ B A A B ۶

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is double-blind, the patient and the examining psychiatric assistant will not know the type of treatment.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Golestan University of Medical Sciences

Street address

Shast kola St, Golestan University of Medical Sciences

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Postal code

4915789468

Approval date

2023-04-25, 1402/02/05

Ethics committee reference number

IR.GOUMS.REC.1402.039

Health conditions studied

1

Description of health condition studied

Anxiety disorder

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

Anxiety disorder score

Timepoint

Beginning of the study and 8 weeks after the start of the intervention

Method of measurement

Anxiety questionnaire for children and adolescents (YAM-5)

2

Description
Anxiety severity based on CGAS
Timepoint
Beginning of the study and 8 weeks after the start of the intervention
Method of measurement
Children Global Assessment Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:For 2 months, in addition to their main treatment (fluoxetine syrup in the first week with a dose of 2.5 cc daily and a dose of 5 cc daily from the second week), they will receive daily pregabalin with a dose of 2.5 mg/kg for 8 weeks.
Category
Treatment - Drugs

2

Description
Control group: In addition to their main treatment (fluoxetine syrup with the same dose and the same duration), they will receive a placebo drug that looks and tastes the same as pregabalin capsules.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Child and Adolescent Psychiatry Clinic of 5 Azar Medical Education Hospital
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Sponsors / Funding sources

1

Sponsor
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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
Gorgan 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

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Name of organization / entity
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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