Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Comparative study of the effectiveness of atomoxetine with Ritalin and fluoxetine on anxiety, the severity of attention deficit hyperactivity disorder and the performance of children with ADHD - Attention Deficit Hyperactivity Disorder

Protocol summary

Study aim

Determining the effectiveness of atomoxetine in comparison with the combination of Ritalin and fluoxetine on anxiety, the severity of attention deficit hyperactivity disorder and the performance of children with ADHD - Attention Deficit Hyperactivity Disorder

Design

A randomized, double-blinding clinical trial, with the parallel groups, Phase 2 on 100 patients

Settings and conduct

In this randomized double-blind clinical trial, 100 eligible patients referred to the neurology clinics of Khorshid Psychiatric Clinic, and Amin in Isfahan will be included in the study and will be randomly divided into two groups. Patients in the first group will be prescribed Ritalin and fluoxetine and in the second group atomoxetine. The intervention will be performed in such a way that the patient and the researcher will have no knowledge of the type of intervention and the double-blind conditions will be established. The severity of hyperactivity and anxiety in children will then be compared between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria included students aged 6 to 12 years referred to Khorshid Psychiatric Clinic, and Amin, attention deficit hyperactivity disorder, and anxiety disorder based on DSM-5 primary school age (6 to 12 years). Exclusion criteria include having any chronic illness and having a family history of psychosis and mood disorders in the first-degree family.

Intervention groups

Intervention group 1: Patients in this group are given Ritalin at a dose of 5 mg twice a day orally and an increase of 10 mg weekly. Fluoxetine also starts at a dose of 2.5-5 mg and is increased weekly. Intervention group 2: Patients in this group start with atomoxetine at a dose of 0.5 mg per kg and increase it weekly to a dose of 1.4 mg per kg.

Main outcome variables

The severity of Anxiety; Severity of Attention, Performance score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211004052670N2**
Registration date: **2022-01-19, 1400/10/29**
Registration timing: **prospective**

Last update: **2022-01-19, 1400/10/29**
Update count: **0**

Registration date

2022-01-19, 1400/10/29

Registrant information

Name

afsaneh karbasi amel

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3641 1255

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-04, 1400/11/15

Expected recruitment end date
2022-06-22, 1401/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the effectiveness of atomoxetine with Ritalin and fluoxetine on anxiety, the severity of attention deficit hyperactivity disorder and the performance of children with ADHD - Attention Deficit Hyperactivity Disorder

Public title
The effectiveness of atomoxetine with Ritalin and fluoxetine on anxiety, the severity of attention deficit hyperactivity disorder, and the performance of children with ADHD - Attention Deficit Hyperactivity Disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Students 6 to 12 years old referred to Khorshid Psychiatric Clinic, and Amin Attention Deficit Hyperactivity Disorder and Anxiety Disorder based on DSM-5 Primary age (6 to 12 years)
Exclusion criteria:
Having any chronic illness Family history of psychosis and mood disorder in the family first degree
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 100 eligible patients are randomly selected. For this, the letter A is written on 50 sheets, the letter B is written on 50 sheets, and each of them is placed in an envelope. Each patient is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of two groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to observe blindness, the drugs are prepared in the same shape before the intervention and are coded and given to the physician. They prescribe them without knowing the type of each drug. Therefore, the patient, the patient, the person recording the clinical and baseline information of the patients as well as the statistical analyst will not be aware of the type of intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq
City
Isfahan
Province
Isfehan
Postal code
8179964167
Approval date
2021-05-16, 1400/02/26
Ethics committee reference number
IR.MUI.MED.REC.1400.111

Health conditions studied

1

Description of health condition studied
Attention Deficit Hyperactivity Disorder and Anxiety Disorders
ICD-10 code
F90+F40
ICD-10 code description
Attention-deficit hyperactivity disorders + Phobic anxiety disorders

Primary outcomes

1

Description
Severity of Anxiety Disorders
Timepoint
Before the intervention, 1 and 4 months after the start of the intervention
Method of measurement
The child and parent Screen for Child Anxiety Related Emotional Disorders (SCARED)

2

Description
Severity of Attention Deficit Hyperactivity Disorder
Timepoint
Before the intervention, 1 and 4 months after the start of the intervention
Method of measurement
Conners' Continuous Performance Test

3

Description
Performance score
Timepoint
Before the intervention, 1 and 4 months after the start of the intervention
Method of measurement
The Child Anxiety Impact Scale (CAIS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Patients in this group are given Ritalin at a dose of 5 mg twice a day (morning and evening) orally and an increase of 10 mg weekly (until clinical response and parental consent). Fluoxetine also starts at a dose of 2.5-5 mg and is increased weekly until it is eventually increased to a dose of 10 to 20 mg. It is given once a day, often in the morning.
Category
Treatment - Drugs

2

Description
Intervention group 2: Patients in this group start with atomoxetine at a dose of 0.5 mg per kg and increase it weekly to a dose of 1.4 mg per kg. The medicine is given in the morning.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khorshid hospital
Full name of responsible person
Afsaneh Karbasi Amel
Street address
Isfahan University of Medical Sciences and Health Services , Hezar Jerib St.
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Esfahan
Province
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Postal code
8174673461
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afsanehkarbasi@yahoo.com

2

Recruitment center
Name of recruitment center
Amin Hospital
Full name of responsible person
Afsaneh Karbasi Amel
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Ibn Sina Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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afsanehkarbasi@yahoo.com
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

Afsaneh Karbasi Amel

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shahrzad Aghili

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Shahrzad Aghili

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available