

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Investigating the effects of methylphenidate and atomoxetine on emotional intelligence, executive function and self-efficacy of 12-18-year-old adolescents with ADHD

The effect of methylphenidate and atomoxetine on emotional intelligence, executive function and self-efficacy of adolescents aged 12 to 18 years with Attention Deficit Hyperactivity Disorder (ADHD)

Protocol summary

Study aim

Investigating the effects of methylphenidate and atomoxetine on emotional intelligence, executive function and self-efficacy of 12-18-year-old adolescents with ADHD

Design

In a clinical trial, a parallel-group, double-blinded, randomized, and placebo-controlled study is conducted on 76 patients. These patients are randomly assigned to either the intervention group or the control group using a block randomization method.

Settings and conduct

This clinical trial is being carried out on patients diagnosed with Attention-Deficit/Hyperactivity Disorder (ADHD) at Farshchian Hospital in Hamedan. The outcome assessor will remain unaware of the patient's treatment type (drug therapy), ensuring that the study is single-blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Consent to participation in the study by parents; Ages 12 to 18 years; Suffering from Attention Deficit Hyperactivity Disorder (ADHD) Exclusion criteria :The existence of a range of psychotic disorders; Autism Spectrum disorders; Severe physical illnesses; intellectual disability

Intervention groups

In a group, Ritalin (manufactured by Karan Pharmaceutical Company, Iran) is initially prescribed at a dose of three-tenths of a milligram per kilogram of body weight per day. Subsequently, the medication dosage is increased up to 1 milligram per kilogram of body weight based on individual needs. The treatment duration is 12 weeks. In another group, Atomoxetine, manufactured by Tehran Darou Pharmaceutical Company in Iran, is initially

prescribed at a dose of 40 milligrams per day for up to three days, and then gradually increased to 80 milligrams.

Main outcome variables

Investigating emotional intelligence, executive function and self-efficacy before and after the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160523028008N31**

Registration date: **2024-02-21, 1402/12/02**

Registration timing: **prospective**

Last update: **2024-02-21, 1402/12/02**

Update count: **0**

Registration date

2024-02-21, 1402/12/02

Registrant information

Name

Mohammad Faryadras

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3428 9706

Email address

m.faryadras@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-28, 1402/12/09

Expected recruitment end date

2024-05-19, 1403/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effects of methylphenidate and atomoxetine on emotional intelligence, executive function and self-efficacy of 12-18-year-old adolescents with ADHD. The effect of methylphenidate and atomoxetine on emotional intelligence, executive function and self-efficacy of adolescents aged 12 to 18 years with Attention Deficit Hyperactivity Disorder (ADHD)

Public title

The effects of methylphenidate and atomoxetine on emotional intelligence, executive function and self-efficacy of 12-18-year-old adolescents with ADHD

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Consent to participation in the study by parents Ages 12 to 18 years Suffering from Attention Deficit Hyperactivity Disorder (ADHD)

Exclusion criteria:

The existence of a range of psychotic disorders Autism spectrum disorders Severe physical illnesses intellectual disability

Age

From **12 years** old to **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Single blinded

Blinding description

The person evaluating the outcomes is unaware of patient allocation to intervention or control groups; therefore, the study is conducted as a single-blind trial.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethic Committee of Hamadan University of Medical Science

Street address

Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2023-12-29, 1402/10/08

Ethics committee reference number

IR.UMSHA.REC.1402.619

Health conditions studied**1****Description of health condition studied**

Attention Deficit Hyperactivity Disorder (ADHD)

ICD-10 code

F90.0

ICD-10 code description

Attention-deficit hyperactivity disorder, predominantly inattentive type

Primary outcomes**1****Description**

Emotional Intelligence

Timepoint

Before the intervention and 12 weeks after the intervention

Method of measurement

Schutt Revised Emotional Intelligence Questionnaire (MSIS)

2

Description

Executive Function

Timepoint

Before the intervention and 12 weeks after the intervention

Method of measurement

Behavior Rating Inventory of Executive Function - Second Edition (BRIEF-2)

3

Description

Self-Efficacy

Timepoint

Before the intervention and 12 weeks after the intervention

Method of measurement

The Self-Efficacy Questionnaire for Children and Adolescents (SEQ-C)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The medication Ritalin, manufactured by Kareen (Iran), is initially prescribed at a dose of three-tenths of a milligram per kilogram of body weight per day. Subsequently, the dosage is increased based on individual needs, up to a maximum of 1 milligram per kilogram of body weight. The treatment duration typically spans 12 weeks

Category

Treatment - Drugs

2

Description

Intervention group: Atomoxetine, manufactured by Tehran Darou Pharmaceutical Company in Iran, is initially administered at a dose of 40 milligrams per day for up to three days, and then gradually increased to 80 milligrams per day. The treatment duration, typically spans 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Hospital

Full name of responsible person

Helen Behmanesh

Street address

Farshchian Hospital, Mirzadeh Eshghi Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 939 448 4107

Email

Behmanesh.Helen@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokohei

Street address

Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh street

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

vc_research@umsha.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Parisa Tavkoli

Position

Resident Psychiatric

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Farshchian Hospital, Mirzadeh Eshghi Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 1828 5015

Email

tavkoliparisa08@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Helen Behmanesh

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Hamadan

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 939 448 4107

Email

Behmanesh.Helen@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Parisa Tavkoli

Position

Resident Psychiatric

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Farshchian Hospital, Mirzadeh Eshghi Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 1828 5015

Email

tavkoliparisa08@gmail.com

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

No - There is not a plan to make this available

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