Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Investigating the effects of methylphenidate and atomoxetine on emotional intelligence, excutive function and self-efficacy of 12-18-year-old adolescents withThe effect of methylphenidate and automoxetine 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, excutive 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, Automecstin, 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

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Name of organization / entity

Hamadan University of Medical Sciences

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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, excutive function and self-efficacy of 12-18-year-old adolescents withThe effect of methylphenidate and automoxetine 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
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Farshchian Hospital, Mirzadeh Eshghi Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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

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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

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