Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the Efficacy of Piracetam as an Adjunct to Methylphenidate in the Treatment of Symptoms of Attention-Deficit/Hyperactivity Disorder in Children: A Randomized Double-Blind Clinical Trial

Protocol summary

Study aim

To evaluate the effect of piracetam as an adjunctive therapy to methylphenidate on attention-deficit/hyperactivity disorder (ADHD) symptoms and executive functioning in children attending the Child and Adolescent Psychiatry Outpatient Clinic of Golestan Hospital, Ahvaz.

Design

A phase II, randomized, double-blind, placebo-controlled, parallel-group clinical trial conducted on 48 children with attention-deficit/hyperactivity disorder.Randomization was performed using block randomization using R software.

Settings and conduct

This randomized, double-blind, placebo-controlled clinical trial will be conducted at the Child and Adolescent Psychiatry Subspecialty Clinic of Golestan Hospital, Ahvaz. Children with ADHD will be randomly assigned to receive methylphenidate plus piracetam or methylphenidate plus placebo. Participants, parents, clinicians, outcome assessors, and data analysts will remain blinded to treatment allocation.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Children referred to the Child and Adolescent Psychiatry Subspecialty Clinic of Golestan Hospital, Ahvaz, with a diagnosis of ADHD, who do not have any serious medical illness and are not currently receiving medication for ADHD treatment. Exclusion Criteria: Presence of any major psychiatric disorder, such as psychotic disorders or mood disorders, as well as metabolic disorders or chronic underlying medical diseases.

Intervention groups

Intervention Group: Participants in this group will receive standard treatment with methylphenidate plus adjunctive piracetam. Control Group: Participants in this group will receive standard treatment with methylphenidate plus placebo instead of piracetam.

Main outcome variables

Change in attention-deficit/hyperactivity disorder (ADHD) symptoms; change in executive functioning; occurrence of treatment-related adverse effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111207008317N3**
Registration date: **2026-10-13, 1405/07/21**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-13, 1405/07/21**
Update count: **0**

Registration date

2026-10-13, 1405/07/21

Registrant information

Name

Ashraf Tashakori

Name of organization / entity

Jundi Shapur University of Medical Sciences

Country

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-23, 1405/07/01

Expected recruitment end date

2027-03-21, 1406/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Efficacy of Piracetam as an Adjunct to Methylphenidate in the Treatment of Symptoms of Attention-Deficit/Hyperactivity Disorder in Children: A Randomized Double-Blind Clinical Trial

Public title

Effect of adjunctive piracetam on adhdh children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children referred to the Child and Adolescent Psychiatry Subspecialty Clinic of Golestan Hospital, Ahvaz. A diagnosis of ADHD according to the DSM-5, established based on the independent clinical judgment of two child and adolescent psychiatrists. No use of medication for the treatment of ADHD during the preceding two weeks. Written informed consent obtained from the parents or legal guardians Absence of any serious medical illness.

Exclusion criteria:

Presence of any major psychiatric disorder, such as psychotic disorders, mood disorders, or other major psychiatric conditions. Children with metabolic disorders or chronic underlying medical diseases. Children with any neurological disorder or severe developmental delay. Presence of an acute medical illness at the time of study enrollment. History of substance abuse. Use of any medication for the treatment of ADHD within the two weeks prior to the initiation of the intervention. Intolerance, hypersensitivity, or severe adverse effects related to methylphenidate or piracetam that could compromise participant safety. Presence of severe learning disorders that could interfere with the assessment of ADHD symptoms. Inability to comply with study procedures or withdrawal from the study for any reason during the study period. Refusal of the parents or legal guardians to provide consent for participation in the study.

Age

From **7 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible participants will be randomly assigned to the intervention and control groups in a 1:1 allocation ratio using block randomization with variable block sizes of 4 and 6 to maintain balance between the groups throughout the study while minimizing the predictability of treatment allocation. The individual participant is the unit of randomization. Each eligible child will be independently assigned to one of the two study groups. Stratified randomization will not be used in this study. The randomization sequence will be generated using R software and randomizer package which is develped to help randomization in clinical trials, and this will be generated by an independent researcher who is not involved in participant recruitment, treatment administration, or outcome assessment. The allocation sequence will be kept in sequentially numbered, opaque, sealed envelopes (SNOSE). The allocation sequence will be generated using a computer-generated random number algorithm based on permuted block randomization with variable block sizes of 4 and 6 and a 1:1 allocation ratio. The sequence will remain concealed until the time of participant assignment. Allocation concealment will be ensured using sequentially numbered, opaque, sealed envelopes (SNOSE) containing the treatment assignments. After confirming eligibility and obtaining written informed consent, the next envelope in sequence will be opened by a designated individual responsible for dispensing the study medication. Investigators, participants, parents or legal guardians, treating physicians, and outcome assessors will remain blinded to treatment allocation throughout the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

To maintain blinding, piracetam and placebo will be identical in appearance, color, size, packaging, and labeling, and will be identified only by study codes. Participants and their parents/legal guardians will be blinded to the treatment allocation. The treating child and adolescent psychiatrist and the principal investigator, who are responsible for clinical evaluation and patient follow-up, will remain blinded to group assignment throughout the study. Outcome assessors and data collectors will also be blinded to treatment allocation. The statistical analyst will analyze the data using coded treatment groups (e.g., Group A and Group B) and will remain blinded to the treatment assignments until completion of the primary statistical analysis. Only the independent researcher responsible for generating the randomization sequence and preparing/dispensing the coded study medications will have access to the allocation codes. This individual will have no role in participant recruitment, clinical assessment, outcome evaluation, or data analysis. The allocation codes will remain confidential until completion of data collection and the primary statistical analysis. Emergency unblinding will be permitted only when knowledge of the assigned treatment is essential for the clinical

management and safety of a participant.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Jondishapour University of Medical Sciences

Street address
University City, Ahvaz – Vice-Chancellor for Research and Technology Building, Ahvaz Jundishapur University of Medical Sciences and Health Services – Ground Floor

City
Ahvaz

Province
Khouzestan

Postal code
1579461357

Approval date
2026-08-02, 1405/05/11

Ethics committee reference number
IR.AJUMS.REC.1405.211

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
ADHD score on the Conner's Parent Rating Scale-48 (CPRS-48) questionnaire

Timepoint
Before the start of the trial and then weekly until the end of the sixth week

Method of measurement
Conner's Parent Rating Scale-48 (CPRS-48) questionnaire

2

Description
The child's overall performance score based on the Children's Global Assessment Scale (CGAS) questionnaire

Timepoint
Before the start of the trial and then weekly until the end of the sixth week

Method of measurement
Children's Global Assessment Scale (CGAS) questionnaire

3

Description
Executive function based on Behavior Rating Inventory of Executive Function (BRIEF-2) questionnaire

Timepoint
Before the start of the trial and then weekly until the end of the sixth week

Method of measurement
Behavior Rating Inventory of Executive Function (BRIEF-2) questionnaire

Secondary outcomes

1

Description
Heart rate

Timepoint
Before the start of the trial and then weekly until the end of the sixth week

Method of measurement
Pulse Oximeter

2

Description
Blood pressure

Timepoint
Before the start of the trial and then weekly until the end of the sixth week

Method of measurement
sphygmomanometer

Intervention groups

1

Description
Intervention group:Participants will receive 33% piracetam syrup at a dose of 60 mg/kg/day for six weeks as an adjunct to methylphenidate treatment. The piracetam syrup will be dispensed in containers identical to those used for the placebo and will be indistinguishable to both the investigator and participants.

Category
Treatment - Drugs

2

Description

Control group:Participants will receive placebo as an adjunct to methylphenidate treatment daily for six weeks. The placebo will be identical to the piracetam syrup in appearance, color, odor, viscosity, weight, container, and packaging, and will be prepared by the School of Pharmacy, Ahvaz Jundishapur University of Medical Sciences.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Golestan Hospital Child Psychiatry Clinic in Ahvaz

Full name of responsible person
Ashraf Tashakori

Street address
Golestan Street, Golestan Hospital, Child Psychiatry Clinic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Ashraf tashakori

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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
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Ashraf tashakori

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Psychiatrics

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
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Latest degree
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Person responsible for updating data

Contact
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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
All data can potentially be shared after de-identifying individuals.
When the data will become available and for how long
Access period begins 2 months after publication of results.
To whom data/document is available
Researchers employed at academic and scientific institutions
Under which criteria data/document could be used
Research purposes
From where data/document is obtainable
ali.vz.ali@gmail.com +989213659375 Ali Vaziri Esfarjani
What processes are involved for a request to access data/document
Coordination with the university and relevant faculty must be carried out first
Comments