

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Nanocurcumin adjunct to methylphenidate for attention-deficit/hyperactivity disorder: A randomized, double-blind, placebo-controlled trial

Protocol summary

Study aim

Studying the effect of nanocurcumin as an adjunctive treatment to methylphenidate for attention deficit/hyperactivity disorder

Design

Randomized double blind and placebo-controlled clinical trial

Settings and conduct

This study will be performed on patients attending Roozbeh Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: ADHD diagnosis based on DSM5 - Individuals between 6-17 years old. Exclusion criteria: Presence of severe medical illness, neurological problems and problems requiring surgery - Presence of any concomitant psychiatric disorder that requires treatment with psychiatric drugs except ODD - Consumption neuroleptic medication in the last 6 months - Weight less than 13.5 kg - Mental retardation - Uncontrolled seizure disorder - Systolic blood pressure above 125 mm Hg or Resting pulse rate less than 60 beats per minute or above 115 beats per minute - Using any medicine or supplement for the treatment of ADHD

Intervention groups

Control group: Participants receive methylphenidate at a dose adjusted according to body weight and clinical response (0.3–1.5 mg/kg/day). During the first week, they take one tablet daily (half in the morning and half at noon); in the second week, one tablet in the morning and one at noon; and from the third week, if their weight exceeds 30 kg, three tablets daily—morning, noon, and afternoon (4 p.m.). They also receive a placebo twice daily. Intervention group: Participants receive the same methylphenidate regimen but additionally takes 20 mg of nanocurcumin twice daily. All medications are administered orally.

Main outcome variables

Severity of ADHD symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090117001556N168**

Registration date: **2026-02-11, 1404/11/22**

Registration timing: **prospective**

Last update: **2026-02-11, 1404/11/22**

Update count: **0**

Registration date

2026-02-11, 1404/11/22

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

Email address

s.akhond@sina.tums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-02-20, 1404/12/01

Expected recruitment end date

2028-02-20, 1406/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Nanocurcumin adjunct to methylphenidate for attention-deficit/hyperactivity disorder: A randomized, double-blind, placebo-controlled trial

Public title

Nanocurcumin for the treatment of attention-deficit/hyperactivity disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

ADHD diagnosis based on DSM5 Individuals between 6-17 years old

Exclusion criteria:

Presence of severe medical illness, neurological problems and problems requiring surgery Presence of any concomitant psychiatric disorder that requires treatment with psychiatric drugs except ODD Consumption neuroleptic medication in the last 6 months Weight less than 13.5 kg Mental retardation Uncontrolled seizure disorder Systolic blood pressure above 125 mm Hg or Resting pulse rate less than 60 beats per minute or above 115 beats per minute Using any medicine or supplement for the treatment of ADHD

Age

From **6 years** old to **17 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization: using A and B blocks with n=4; AABB, ABAB, ABBA, BABA, BAAB, BBAA. We randomly use the blocks to achieve total sample size. ("A" and "B" are the study groups).

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, care providers and outcome assessors will be blind regarding grouping. All the participants believe that they are taking the main medication (the participants who are taking placebo are not aware of it). Care providers and outcome assessors do not know which participants have received the main medication and which participants have received placebo. Thus, there is no orientation in their work process.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of School of Medicine, Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Qhods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2025-08-23, 1404/06/01

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1404.706

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

ADHD

ICD-10 code

F90.2

ICD-10 code description

Attention-deficit hyperactivity disorder, combined type

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

Severity of ADHD symptoms

Timepoint

Week 0 - 5 - 10

Method of measurement

By ADHD Rating Scale (by parents and teacher)

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: Individuals receive methylphenidate (The dose will be adjusted based on standard clinical principles and tailored to the patient's weight and clinical response, within the range of 0.3 to 1.5 mg per kilogram of body weight per day). For the first week, one tablet daily (1.2 tablets at the morning, 1.2 tablets at the noon), and for the second week, one tablet at the morning and one tablet at the noon. If the patient's weight is over 30 kg, three pills are prescribed daily, 1 at the morning, 1 at the noon, and 1 at the afternoon (4 p.m.), from the third week. They also receive a placebo twice a day.

Category

Placebo

2

Description

Intervention group: Individuals receive methylphenidate (The dose will be adjusted based on standard clinical principles and tailored to the patient's weight and clinical response, within the range of 0.3 to 1.5 mg per kilogram of body weight per day). For the first week, one tablet daily (1.2 tablets at the morning, 1.2 tablets at the noon), and for the second week, one tablet at the morning and one tablet at the noon. If the patient's weight is over 30 kg, three pills are prescribed daily, 1 at the morning, 1 at the noon, and 1 at the afternoon (4 p.m.), from the third week. They also receive nanocurcumin at the dose of 20mg, twice per day. All medications are taken orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Dr. Mohammad Reza Mohammadi

Street address

Roozbeh Hospital, South Kargar Street, Tehran

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Tehran

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mohammadimr@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Ramin Kordi

Street address

TUMS, Qhods St., Keshavarz Blvd.

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Grant name

Grant code / Reference number

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

No

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Shahin Akhondzadeh

Position

Professor of clinical psychopharmacology

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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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

No - There is not a plan to make this available

Title and more details about the data/document

The data will be distributed through final report

When the data will become available and for how long

5 years from 2026 to 2031

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Users should cite the resource of data

From where data/document is obtainable

Prof. Shahin Akhondzadeh

What processes are involved for a request to access data/document

By E-mail

Comments