# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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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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

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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

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## Person responsible for scientific inquiries

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**Full name of responsible person**
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## Person responsible for updating data

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**Full name of responsible person**
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**Position**
Professor of clinical psychopharmacology
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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**