# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Investigating the effect of adding memantine to a long-acting stimulant on executive function deficits in adolescents with attention deficit hyperactivity disorder

## Protocol summary

**Study aim**
Determining and comparing the total score of the self-report scale of attention deficit hyperactivity disorder (ASRS) in adolescents in the two study groups, before and after the intervention

**Design**
A controlled, parallel-group, triple-blind, randomized, phase 3 clinical trial on 44 patients. Endnote software was used for randomization.

**Settings and conduct**
The study is a triple-blind randomized clinical trial. Patients, therapists, and statistical consultants are unaware of the control and intervention groups. The target population of the study is adolescents aged 12 to 18 years, and patients in both the intervention and control groups are being treated with long-acting methylphenidate (stimulant) within the therapeutic dose range.

**Participants/Inclusion and exclusion criteria**
Diagnosis of ADHD by a psychiatrist using a questionnaire Existence of functional deficits in the adolescent Age 12 to 18 years Normal intelligence quotient using an IQ test Exclusion criteria: Presence of major medical disorders (heart disease, diabetes, asthma, renal failure, etc.) Presence of comorbid psychiatric disorders that require pharmacological interventions. Use of another medication in addition to a long-acting stimulant

**Intervention groups**
In the intervention group receive the drug memantine + long-acting stimulant. The control group receives placebo + long-acting stimulant.

**Main outcome variables**
The severity of executive dysfunction; the severity of attention deficit and hyperactivity

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20250917067279N1**
Registration date: **2026-01-20, 1404/10/30**
Registration timing: **registered_while_recruiting**

Last update: **2026-01-20, 1404/10/30**
Update count: **0**
**Registration date**
2026-01-20, 1404/10/30

**Registrant information**
**Name**
Farnaz Golmohammadi
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
**Phone**
+98 31 3668 0048
**Email address**
fgmohammadi@med.mui.ac.ir

**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2025-10-23, 1404/08/01
**Expected recruitment end date**
2026-10-23, 1405/08/01
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Investigating the effect of adding memantine to a long-acting stimulant on executive function deficits in adolescents with attention deficit hyperactivity disorder

**Public title**
Studying the effect of adding memantine to a long-acting stimulant on executive function deficits in adolescents with attention deficit hyperactivity disorder referred to a pediatric psychiatric clinic in 2015.

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Diagnosis of ADHD by a psychiatrist using a questionnaire Presence of functional deficits in the adolescent Age 12 to 18 years Normal intelligence quotient using an IQ test

**Exclusion criteria:**
Having any medical illness Using any medication except long-acting stimulant

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

**Gender**
Both

**Phase**
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Data analyser

**Sample size**
Target sample size: **44**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Patients who have a history of visiting the clinic and have been treated with a long-acting stimulant, if they are eligible, are included in the study as patients. This method is called sequential sampling. After identifying the study subjects, the first two people show us a block. Then, we randomly assign the subjects in each block to the usual treatment + memantine group (A) and the usual treatment + placebo group (B). The next two people are also randomly assigned to group A and the other to group B until we reach a sufficient sample size.

**Blinding (investigator's opinion)**
Triple blinded

**Blinding description**
The therapist only gives the patient the medicine they need for a month based on whether the patient belongs to group A or B, but he is not aware of the contents of the medicine packets A or B, and finally, the statistical consultant is not informed of the patient group when performing statistical calculations.

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Isfahan University of Medical Sciences

**Street address**
isfahan University of Medical Sciences, Hezar Jarib Ave. Azadi Sq.

**City**
Isfahan

**Province**
Isfehan

**Postal code**
8179964167

**Approval date**
2025-09-14, 1404/06/23

**Ethics committee reference number**
IR.MUI.MED.REC.1404.228

## Health conditions studied

### 1

**Description of health condition studied**
Attention deficit-hyperactivity disorder

**ICD-10 code**
F90

**ICD-10 code description**
Attention-deficit hyperactivity disorders

## Primary outcomes

### 1

**Description**
Executive functioning score in the Brief questionnaire

**Timepoint**
Upon arrival and 30 days later

**Method of measurement**
BRIEF questionair

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
First Intervention group: patients in this group are given memantine (Alzixa) orally, adding to long-acting stimulant, at a dose of 9 mg daily (divided in three doses daily)

**Category**

Treatment - Drugs

**2**

**Description**
Control group: patients in this group are given placebo at dose of 9 mg daily divided(adding to long-acting stimulants.)
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Amin hospital
**Full name of responsible person**
Farnaz Golmohammadi
**Street address**
Sonbolestan Street.,Ebnesina St.,Isfahan city
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174673461
**Phone**
+98 31 3445 5051
**Email**
amin@mui.ac.ir
**Web page address**
http://amin.mui.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Dr.Gholamreza Asgari,Vice President for Research and Technology
**Street address**
Hezarjarib Ave.,Isfahan,Isfahan University of Medical Sciences
**City**
Isfahan
**Province**
Isfehan
**Postal code**
81746-73461
**Phone**
+98 31 3668 0048
**Email**
research@mui.ac.ir
**Web page address**
https://mui.ac.ir/fa
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Esfahan 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**
Esfahan University of Medical Sciences
**Full name of responsible person**
Farnaz Golmohammadi
**Position**
Assistant professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Psychiatrics
**Street address**
Khorshid hospital, Ostandari Ave.
**City**
Isfahan
**Province**
Isfehan
**Postal code**
81458-33117
**Phone**
+98 31 3222 2127
**Email**
fgmohammadi@med.mui.ac.ir
**Web page address**
https://nour.mui.ac.ir/fa

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Farnaz Golmohammadi
**Position**
Assistant professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Psychiatrics
**Street address**
Khorshid hospital, Ostandari Ave.
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**Phone**
+98 31 3222 2127
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fgmohammadi@med.mui.ac.ir
**Web page address**
https://nour.mui.ac.ir/fa

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Farnaz Golmohammadi
**Position**
assistant professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Psychiatrics
**Street address**
Khorshid hospital, Ostandari Ave.
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174673461
**Phone**
0983136680048
**Email**
fgmohammadi@med.mui.ac.ir
**Web page address**
https://nour.mui.ac.ir/fa

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available
**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available
**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available