

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Evaluation of therapeutic effects of adding memantine to stimulants in children with attention deficit hyperactivity disorder

#### Protocol summary

##### Study aim

Determining and comparing the therapeutic effects of adding memantine to stimulants in children with attention deficit hyperactivity disorder

##### Design

A randomized, triple-blinding clinical trial, with parallel groups, Phase 3 on 80 patients

##### Settings and conduct

In this triple-blind randomized clinical trial study, 80 eligible patients referred to Imam Hossein and Amin Hospitals of Isfahan will be included in the study and will be randomly divided into two groups. For patients in the first group, the usual treatment along with memantine will be prescribed, and in the second group only the usual treatment will be prescribed. Then, the dimensions of the Conners and Brief scales will be evaluated for them and compared between the two groups.

##### Participants/Inclusion and exclusion criteria

The inclusion criteria include children with attention deficit hyperactivity disorder (ADHD), aged 6 to 12 years, treated with methylphenidate, and parental consent to participate in the study. Exclusion criteria include having major medical disorders (diabetes, asthma, heart diseases, seizures), having co-occurring psychiatric disorders (mood and anxiety disorders, and behavioral and confrontational disorders - disobedience), taking other drugs in addition to long-acting stimulants, mental retardation, and drug sensitivity.

##### Intervention groups

Intervention group: Patients in this group receive their usual treatment. In addition, they will be treated with memantine. Control group: patients in this group receive their usual treatment. In addition, they will be prescribed the same as the placebo intervention group.

##### Main outcome variables

Conners scale dimensions; Brief scale dimensions

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200825048515N58**

Registration date: **2022-09-05, 1401/06/14**

Registration timing: **prospective**

Last update: **2022-09-05, 1401/06/14**

Update count: **0**

##### Registration date

2022-09-05, 1401/06/14

##### Registrant information

##### Name

Asieh Maghami Mehr

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 0000 0000

##### Email address

asimaghami@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-09-23, 1401/07/01

##### Expected recruitment end date

2023-03-21, 1402/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of therapeutic effects of adding memantine to stimulants in children with attention deficit hyperactivity disorder

### Public title

Evaluation of therapeutic effects of adding memantine to stimulants in children with attention deficit hyperactivity disorder

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Children with attention deficit hyperactivity disorder (ADHD) Age range 6 to 12 years Treated with methylphenidate Parents' consent to participate in the study

#### Exclusion criteria:

Having major medical disorders (diabetes, asthma, heart disease, seizures) Having a concomitant psychiatric disorder (mood and anxiety disorders and behavioral and confrontational disorders - disobedience) Taking another drug in addition to a long-acting stimulant Mental retardation Drug sensitivity

### Age

From **6 years** old to **12 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

### Sample size

Target sample size: **80**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The method is permuted block randomization. In this way, first using online software (sealed envelope), a sequence of random numbers will be created and by the same software, the generated numbers will be divided into 40 blocks of 2. An equal number in each block will be 1 item from the intervention group and 1 item from the control group. So by doing each block, 2 patients (equally) will be assigned to each group.

### Blinding (investigator's opinion)

Triple blinded

### Blinding description

In this study, two drugs, memantine, and placebo are pre-prepared by the pharmacist in the same shape and color, placed in coded packages, and delivered to the researcher. She prescribes them without knowing the type of each drug. Also, the patients, the investigator, the person recording the clinical and basic information of the patients as well as the statistical analyst will not be aware of the type of intervention.

### 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

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

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8179964167

#### Approval date

2022-08-12, 1401/05/21

#### Ethics committee reference number

IR.MUI.MED.REC.1401.193

## Health conditions studied

### 1

#### Description of health condition studied

Attention-deficit hyperactivity disorder (ADHD)

#### ICD-10 code

F90.9

#### ICD-10 code description

Attention-deficit hyperactivity disorder, unspecified type

## Primary outcomes

### 1

#### Description

Cognitive Problems

#### Timepoint

Before and after the intervention

#### Method of measurement

The Conners' Parent Rating Scale (CPRS)

### 2

#### Description

Social problems

#### Timepoint

Before and after the intervention

#### Method of measurement

The Conners' Parent Rating Scale (CPRS)

### 3

**Description**

Psychosomatic problems

**Timepoint**

Before and after the intervention

**Method of measurement**

The Conners' Parent Rating Scale (CPRS)

### 4

**Description**

Anxiety-shyness

**Timepoint**

Before and after the intervention

**Method of measurement**

The Conners' Parent Rating Scale (CPRS)

### 5

**Description**

Inhibitory control

**Timepoint**

Before and after the intervention

**Method of measurement**

BREIF scale

### 6

**Description**

emotional modulation

**Timepoint**

Before and after the intervention

**Method of measurement**

BREIF scale

### 7

**Description**

Ability to shift set

**Timepoint**

Before and after the intervention

**Method of measurement**

BREIF scale

### 8

**Description**

Working memory

**Timepoint**

Before and after the intervention

**Method of measurement**

BREIF scale

### 9

**Description**

initiating

**Timepoint**

Before and after the intervention

**Method of measurement**

BREIF scale

### 10

**Description**

Planning

**Timepoint**

Before and after the intervention

**Method of measurement**

BREIF scale

### 11

**Description**

Organizing

**Timepoint**

Before and after the intervention

**Method of measurement**

BREIF scale

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: Patients in this group receive their routine treatment. In addition, they will be treated with memantine. The prescribed dose in children is based on weight, so that for children weighing more than 60 kg, the maximum dose is 15 mg/day, and for children weighing 39 to 60 kg, the maximum dose is 9 mg/day, and for children weighing 20 to 39 kg, the maximum dose is 6 mg/day and with a weight of less than 20 kg, a maximum dose of 3 mg/day is prescribed. The duration of the study will be one month after stabilizing the dose of memantine based on weight or the maximum dose tolerated by the patient.

**Category**

Treatment - Drugs

### 2

**Description**

Control group: patients in this group receive their routine treatment. In addition, they will be prescribed the same as the placebo intervention group.

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Imam Hossein Hospital in Isfahan

**Full name of responsible person**

Farnaz Golmohammadi

**Street address**

Imam Khomeini street

**City**

Isfahan  
**Province**  
Isfahan  
**Postal code**  
8195163381  
**Phone**  
+98 31 3386 6266  
**Email**  
Farnazgolmohammadi@gmail.com

## 2

### Recruitment center

**Name of recruitment center**  
Amin Hospital of Isfahan  
**Full name of responsible person**  
Farnaz Golmohammadi  
**Street address**  
Sanbolistan Alley, Ibn Sina Street  
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Farnazgolmohammadi@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Mansour Siavash  
**Street address**  
Vice Chancellor for Research, School of Medicine,  
Hezar Jarib Street, Isfahan.  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
8174673461  
**Phone**  
+98 31 3668 8597  
**Email**  
dean@med.mui.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
No  
**Title of funding source**  
Isfahan 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**  
Assistance professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Psychiatrics  
**Street address**  
Department of Psychiatry; Imam Hossein (S) Hospital;  
Imam Khomeini street  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
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**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mona Rezvani

**Position**

Non-faculty specialist doctor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

Department of Psychiatry; Imam Hossein (S) Hospital;  
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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**

There is no further information

**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