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
Isfehan
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
Isfehan

Postal code
8195163381

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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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8148653141

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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.

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8174673461

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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
Assisstance professor

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

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Department of Psychiatry; Imam Hossein (S) Hospital; Imam Khomeini street

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Farnaz Golmohammadi

Position
Assisstance professor

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Person responsible for updating data

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Full name of responsible person
Mona Rezvani

Position
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Latest degree
Specialist

Other areas of specialty/work
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Monarezvani77@gmail.com

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