

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Memantine versus placebo as an adjunct in the treatment of children with Attention Deficit Hyperactivity Disorder: a double-blind randomized, placebo-controlled study

Protocol summary

Study aim

This study investigates the effect of combined administration of memantine and methylphenidate in the treatment of children with attention deficit hyperactivity disorder.

Design

This study is a randomized double-blind placebo-controlled trial

Settings and conduct

200 Children with ADHD aged between 6 and 12 years, referred to the Child and Adolescent Psychiatric Clinic of Shahid Beheshti Hospital and the Child and Adolescent Psychiatric Clinic of Shafieieh Clinic in Zanjan, will randomly be divided into two groups. The first group will receive methylphenidate and memantine and the second group will receive methylphenidate and placebo. The response to treatment will be assessed. This will be a double-blind study

Participants/Inclusion and exclusion criteria

Admission requirements: 6 to 12 years old Lack of other accompanying psychiatric disorders No mental retardation No neurological diseases, especially seizures
Exclusion criteria: Concomitant treatment with lamotrigine, amantadine, acetylcysteine, dicyclo-serine Concomitant use of hydrochlorothiazide, triamterene, metformin, cimetidine, ranitidine, quinidine Starting a new psychological intervention thirty days before the start of the study History of non-febrile seizures without a definite etiology Simultaneous kidney or liver disease Urinary-genital disorders that increase urinary pH (infections and RTA) No further referral to the clinic

Intervention groups

This study is a double-blind clinical trial. 200 Children with Attention Deficit Hyperactivity Disorder are randomly divided into two groups. The first group receives methylphenidate and memantine and the second group receives methylphenidate and placebo.

The response to treatment is assessed based on the Conners scale and the side effects of the drugs at the beginning of the study and at weeks 1, 2 and 4.

Main outcome variables

Coners scale for Attention Deficit Hyperactivity Disorder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200427047221N1**

Registration date: **2021-04-19, 1400/01/30**

Registration timing: **retrospective**

Last update: **2021-04-19, 1400/01/30**

Update count: **0**

Registration date

2021-04-19, 1400/01/30

Registrant information

Name

Seyed Yaser Mousavi Nodoushan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6147 9000

Email address

mousavinodoushan@zanjan.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-04, 1399/03/15

Expected recruitment end date

2020-10-06, 1399/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Memantine versus placebo as an adjunct in the treatment of children with Attention Deficit Hyperactivity Disorder: a double-blind randomized, placebo-controlled study

Public title

Memantine versus placebo as an adjunct in the treatment of children with Attention Deficit Hyperactivity Disorder: a double-blind randomized, placebo-controlled study

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

6 -12 years old ADHD No other psychiatric disorders No mental retardation No neurological disorders Not using other medications

Exclusion criteria:

Concomitant treatment with lamotrigine, amantadine, acetylcysteine, dicyclo-serine Concomitant use of hydrochlorothiazide, triamterene, metformin, cimetidine, ranitidine, quinidine Starting a new psychological intervention thirty days before the start of the study History of non-febrile seizures without a definite etiology Simultaneous kidney or liver disease Urinary-genital disorders that increase urinary pH (infections and RTA) No further referral to the clinic

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

a double-blind randomized, placebo-controlled study

Placebo

Used

Assignment

Factorial

Other design features**Secondary Ids**

empty

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

Ethics committee of Zanjan University of Medical Sciences

Street address

mahdavi blvd , Zanjan University of Medical Sciences

City

Zanjan

Province

Zanjan

Postal code

4513914500

Approval date

2020-01-14, 1398/10/24

Ethics committee reference number

IR.ZUMS.REC.1398.406

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**

Conner tests scores

Timepoint

1th, 2th, 4th month

Method of measurement

Conner test

Secondary outcomes

empty

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

Intervention group:The amount of prescription methylphenidate in the group receiving memantine is at least 10 mg and at most 50 mg, and the amount of prescription memantine in the group receiving memantine is at least 2.5 mg and at most 5 mg.

Category

Treatment - Drugs

2

Description

Control group:The prescription drug methylphenidate in the placebo group is at least 10 mg and at most 50 mg.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti hospital

Full name of responsible person

Moein Kiani

Street address

Beheshti hospital, Sadi Intersection

City

Zanjan

Province

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Postal code

4513914500

Phone

+98 21 6147 9000

Email

drsymousavi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Seyd Yaser Mousavi Nodoushan

Street address

No.1074, East Karmandan Ave, Mahdavi Blvd

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Seyd Yaser Mousavi Nodoushan

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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

Undecided - It is not yet known if there will be 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

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

Title and more details about the data/document

full content

When the data will become available and for how long

6 month after publication

To whom data/document is available

university researchers

Under which criteria data/document could be used

same subject

From where data/document is obtainable

seyd yaser mousavi nodoushan

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

by mailing to researcher

Comments

by mailing to researcher