

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Comparison of the effects of different doses of memantine in combination with methylphenidate in children affected by attention deficit hyperactivity disorder

Protocol summary

Study aim

Effect of different amounts of memantine with methylphenidate in children with ADHD

Design

This clinical trial has two intervention groups of 69 people, community based and pragmatic with parallel, blind, and randomized groups. The random method is the permutation block and Phase 2 is a clinical trial.

Settings and conduct

This study will be done at Ahvaz Golestan Hospital. The two-blind study will be that the patient, nurse and assessor are unaware of how the medication is given and the dose administered.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of children aged 6 to 12 years, Having diagnostic criteria based on IV-IRDSM and Conners test exclusion criteria: the presence of other serious psychiatric disorders, History of Complications of Ritalin, memantine allergy history

Intervention groups

Intervention group 1: This memantine group will be given at a dose of 0.1 to 0.25 milligrams per kilogram. In this group, the minimum dose of memantine, 0.1, will begin with ritalin and will increase to a maximum dose within two weeks. Ritalin is used at a constant dose.

Intervention group 2: This memantine group will be given at a dose of 0.25 to 0.50 milligrams per kilogram. In this group, the minimum dose of memantine, 0.25, will begin with ritalin and will increase to a maximum dose within two weeks. Ritalin is used at a constant dose. This drug is prescribed to patients in the form of placebo with the same form, color, smell and taste.

Main outcome variables

ADHD

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100520003979N8**

Registration date: **2018-09-22, 1397/06/31**

Registration timing: **prospective**

Last update: **2018-09-22, 1397/06/31**

Update count: **0**

Registration date

2018-09-22, 1397/06/31

Registrant information

Name

Forugh Riahi

Name of organization / entity

Ahvaz Jundishapour University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 61 3374 3038

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of different doses of memantine in combination with methylphenidate in children affected by attention deficit hyperactivity disorder

Public title

Effecting the combination of memantine and methylphenidate in children affected by attention deficit hyperactivity disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of children aged 6 to 12 years Having diagnostic criteria based on IV-IRDSM and Conners test

Exclusion criteria:

Another serious psychiatric disorder, such as schizophrenia, bipolar disorder A history of seizure and medical conditions such as cardiovascular problems and diabetes History of allergy for Memantine Failure to respond to Memantine Severe ritalin complications

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **69**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the method of the permutation 4blocks, individuals are randomly divided into two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patient, nurse, and evaluator did not know how much memantine was taken by each patient. each group did not have any information that another group exists and receive a different dose. Because medicines are packaged in the form of one and two, and delivered to the patient.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Blvd, Ahvaz, Khoozestan

City

Ahvaz

Province

Khoozestan

Postal code

6135715794

Approval date

2017-05-20, 1396/02/30

Ethics committee reference number

IR.AJUMS.REC.1396.543

Health conditions studied

1

Description of health condition studied

attention deficit hyperactivity disorder

ICD-10 code

F90.0

ICD-10 code description

Attention-deficit hyperactivity disorder, predominantly inattentive type

Primary outcomes

1

Description

Attention Deficit Hyperactivity Disorder.

Timepoint

Before intervention- the end of second, fourth and sixth,eighth, tenth,twelfth weeks of the study

Method of measurement

The Conner's parent rating scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In this group, memantine is given at a dose of 0.1 to 0.25 mg / kg. In this group, with a minimum dose of memantine 0.1, it starts with ritalin, and gradually we increase and maximize the dose within two weeks. Ritalin is given at a fixed dose. In the first week, one fourth of the pill is taken twice daily, the second week, the second one, twice a day, the third week, three quarters of the pill twice daily, and the

fourth week, once a pill twice a day, and until the end of the study, the dose remains constant.

Category

Treatment - Drugs

2**Description**

Intervention group 2: In this group, memantine is given at a dose of 0.25 to 0.50mg / kg. In this group, with a minimum dose of memantine 0.25, it starts with ritalin, and gradually we increase and maximize the dose within two weeks. Ritalin is given at a fixed dose. In the first week, one fourth of the pill is taken twice daily, the second week, the second one, twice a day, the third week, three quarters of the pill twice daily, and the fourth week, once a pill twice a day, and until the end of the study, the dose remains constant. This drug is prescribed to patients in the form of placebo with the same form, color, smell and taste.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Adolecent and child Psychiatry Clinic, Golestan Hospital

Full name of responsible person

Forough Riahi

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Ahvaz Golestan Hospital, Ahvaz

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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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

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Forough Riahi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Maryam Enayatollahi

Position

resident

Latest degree

Medical doctor
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Person responsible for updating data

Contact

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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