Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 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
his 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

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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
Khouzestan

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
Befor 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
Forugh Riahi

Street address
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

Street address
Ahvaz Junishapur University of Medical Science,Farvardin Blvd,Ahvaz ,Khoozestan

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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
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Full name of responsible person
Maryam Enayatollahi

Position
resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data

Contact

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Position

Resident

Latest degree

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Other areas of specialty/work

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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