

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

A Comparison of the Effect of Memantine added to Ritalin and Ritalin alone on cognitive Functions (Selective Attention, Sustained Attention, and Reverse Shot-term Memory) of Children with Attention Deficit and Hyperactivity Disorder (ADHD): A Clinical Trial

Protocol summary

Summary

The present research aimed to examine the effect of Memantine on cognitive symptoms in children with attention deficit and hyperactivity disorder (ADHD). This clinical trial was carried out on 76 patients aged between 7-12 years old (no gender restrictions) with Attention Deficit and Hyperactivity Disorder (ADHD) who referred to Pediatric Psychiatry Clinic of Amirkabir Hospital of Arak. Randomization was performed using random number table. The inclusion criteria were the presence of hyperactivity disorder for both groups in terms of Statistical Manual of Mental Disorders, Fourth Edition (DSMIV) in children aged between 7-12 years old. The Exclusion criteria were the presence of neurological disorders, mental retardation disorders, disorders causing a decreased level of consciousness at the testing time, autism disorder, bipolar disorders, psychosis, depression and anxiety in terms of interviews with pediatric psychiatrist. Initially, the two groups were asked to complete Conners' teacher and parent rating scales to determine the level of attention deficit/hyperactivity disorder (ADHD). After performing the tests, the children in control group received 10 mg Ritalin produced by Novartis Pharmaceuticals Corporation with a dosage of 5mg, ½ pill twice a day. If well-tolerated, this dosage increased to 10mg twice a day. The children in intervention group were administered Memantine Tablet (Alzantin 5mg TAB produced by Sobhan Pharmaceuticals Corporation) concurrent with Ritalin (with a dosage similar to control group) according to the child's weight. The maximum daily dosage for children weighed more than 60 kg, 39-60 kg, 20-30 kg and less than 20 kg was 15 mg, 9mg, 6mg and 3mg respectively. In all cases, the starting dosage of Memantine will be 2.5 mg (½ Memantine 5mg Tab). If the previous dosage was well-tolerated, 5 mg

was added weekly to this until the target dosage was achieved and Memantine should be consumed for one month at the target dosage. After one month, the cognitive tests were repeated and the two groups were asked again to complete Conners' teacher and parent rating scales. The cognitive tests were performed prior to these drugs administration and after one-month Memantine consumption. Then, the two groups were compared in terms of the effect of Memantine on cognitive symptoms (selective attention, sustained attention, and reverse shot-term memory) in children with attention deficit and hyperactivity disorder (ADHD).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080829268N1**

Registration date: **2017-06-11, 1396/03/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-11, 1396/03/21

Registrant information

Name

Fahimeh Omid

Name of organization / entity

Arak University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3645

Email address

farahani.re@arpc.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Arak University of Medical Sciences

Expected recruitment start date

2016-04-25, 1395/02/06

Expected recruitment end date

2016-11-26, 1395/09/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison of the Effect of Memantine added to Ritalin and Ritalin alone on cognitive Functions (Selective Attention, Sustained Attention, and Reverse Shot-term Memory) of Children with Attention Deficit and Hyperactivity Disorder (ADHD): A Clinical Trial

Public title

Evaluation of the efficacy of memantine in children with attention deficit hyperactivity disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: The presence of hyperactivity disorder for both groups in children aged between 7-12 years old according to Statistical Manual of Mental Disorders, Fourth Edition (DSMIV). Exclusion Criteria: The presence of neurological disorders; mental retardation disorders; disorders causing a decreased level of consciousness at the testing time; autism disorder; bipolar disorders; psychosis; depression and anxiety in terms of interviews with pediatric psychiatrist as well as drug side effects which led to drug intolerance.

Age

From 7 years old to 12 years old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 76

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Arak university of medical sciences ,Basij Sq,Sardasht,Arak

City

Arak

Postal code

۳۸۴۸۱-۷-۶۹۴۱

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.ARAKMU.REC.1395.10

Health conditions studied

1

Description of health condition studied

Attention deficit hyperactivity disorder

ICD-10 code

F90-F98

ICD-10 code description

mental and behavioural disorders

Primary outcomes

1

Description

Symptoms of hyperactivity and impulsivity

Timepoint

Before and one month after intervention

Method of measurement

Conners questionnaire for parents and teachers

2

Description

sustained attention

Timepoint

Continuous Performance Test (CPT)

Method of measurement

Before and one month after intervention

3

Description

selective attention

Timepoint

stroop test

Method of measurement

Before and one month after intervention

4

Description

Reverse short-term memory

Timepoint

Wechsler Digit Span Test

Method of measurement

Before and one month after intervention

Secondary outcomes

1

Description

Adverse effect of Memantine

Timepoint

During the intervention and one month after intervention

Method of measurement

Observation and parents' narration

Intervention groups

1

Description

Intervention Group: The research variables including severity of disorder, sustained attention, selective attention and reverse short-term memory were measured using Conners' teacher and parent rating scales to measure attention deficit/hyperactivity disorder (ADHD), Conners' Continuous Performance Test (Conners' CPT Test), Stroop Test and Wechsler Test, respectively. All these tests were done in the morning and, if possible, at a specific time. After the tests, Ritalin tablet was prescribed according to a pediatric psychiatrist based on a dosage mentioned in a comprehensive and evidence-based listing book of dosage recommendations (Ritalin 10mg of Novartis Pharmaceuticals Corporation) at a dosage of 5 mg twice a day (½ tablet twice a day). If it has been well-tolerated, this dosage was increased to 10 mg twice a day and the Memantine Tablet (Alzantin 5mg TAB produced by Sobhan Pharmaceuticals Corporation) was administered simultaneously based on child's weight (According to previous studies, Memantine dosage is set in terms of children's weight). If the child weighs more than 60 kg, 39-60 kg, 20-30 kg, less than 20 kg, a maximum daily dosage of 15 mg, 9mg, 6mg and 3mg is prescribed, respectively. The starting dosage of Memantine is 2.5 mg (½ Memantine 5mg Tab). If the previous dosage has been well-tolerated, 5 mg is added weekly to this dosage in terms of the target dosage and Memantine should be consumed for one month based on target dosage. After one month, the cognitive tests are repeated and the two groups are asked again to complete Conners' teacher and parent rating scales.

Category

Treatment - Drugs

2

Description

Control Group: After obtaining informed consents from parents, The research variables including severity of disorder, sustained attention, selective attention and reverse short-term memory were measured using Conners' teacher and parent rating scales to measure attention deficit/hyperactivity disorder (ADHD), Conners' Continuous Performance Test (Conners' CPT Test), Stroop Test and Wechsler Test, respectively. All these tests were done in the morning and, if possible, at a specific time. After the tests, Ritalin tablet was prescribed according to a pediatric psychiatrist based on a dosage mentioned in a comprehensive and evidence-based listing book of dosage recommendations (Ritalin 10mg of Novartis Pharmaceuticals Corporation) at a dosage of 5 mg twice a day (½ tablet twice a day). If it has been well-tolerated, this dosage was increased to 10 mg twice a day. After one month, the cognitive tests are repeated and Conners' rating scales are completed by parents and teachers again.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Kabir Hospital

Full name of responsible person

Dr. Ali Arjmand

Street address

Arak, Street RahAhan, Amir Kabir Hospital

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research , Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Rafiee

Street address

Arak University of Medical Sciences

City

Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research , Arak University of Medical Sciences

Proportion provided by this source

100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Postal code
3819693345
Phone
+98 33 1360 5558
Fax
+98 33133147
Email
amoozesh@arakmu.ac.ir
Web page address
<http://arakmu.ir>

Person responsible for general inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Omid Fahimeh
Position
Psychiatric Asistant
Other areas of specialty/work
Street address
Postcode 3819693345, A'lām-Al-Hoda Street, Shahid
Shiroodi Street, Arak, Markazi Province, Iran
City
Arak
Postal code
3819693345
Phone
+98 33 1360 5558
Fax
+98 33133147
Email
f.omidi@arakmu.ac.ir
Web page address
<http://arakmu.ir>

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Omid Fahimeh
Position
Psychiatric Asistant
Other areas of specialty/work
Street address
Postcode 3819693345, A'lām-Al-Hoda Street, Shahid
Shiroodi Street, Arak, Markazi Province, Iran
City
Arak

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Fahimeh Omid
Position
Psychiatry Resident
Other areas of specialty/work
Street address
Postcode 3819693345, A'lām-Al-Hoda Street, Shahid
Shiroodi Street, Arak, Markazi Province, Iran
City
Arak
Postal code
3819693345
Phone
+98 33 1360 5558
Fax
+98 33133147
Email
amoozesh@arakmu.ac.ir
Web page address
<http://arakmu.ir>

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty