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 ofattention 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

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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 mounth 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 mounth after intervention

3

Description
selective attention
Timepoint
stroop test
Method of measurement

Before and one mounth after intervention

4

Description
Reverse short-term memory
Timepoint
Wechsler Digit Span Test
Method of measurement
Before and one mounth 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

Person responsible for general inquiries

Contact

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Other areas of specialty/work

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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