Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the efficacy of the methylphenidate in combination with magnesium and methylphenidate with placebo in patients with attention deficit hyperactivity disorder

Protocol summary

Study aim
The effect of magnesium supplement as adjunctive therapy to methylphenidate in patients with attention deficit hyperactivity disorder

Design
Randomized, double-blind, placebo controlled clinical trial

Settings and conduct
The participants in the study are selected from among the referrals to Ziaeian Hospital based on inclusion criteria. Diagnosis of ADHD is performed by a child and adolescent psychiatrist.The total number of samples is 62 patients. Patients will be divided randomly in two group of 31 patients. The first group will receive methylphenidate and magnesium, the second group will receive methylphenidate and placebo, for 8 weeks. Patients are evaluated before intervention, 4 and 8 weeks after intervention. The severity of the symptoms is evaluated by the Conner's Rating Scale questionnaire of parents and ADHD Rating Scale. Side effects will be recorded in 4 and 8 weeks after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1-Age between 8-16 years old 2-Diagnosis of ADHD by the pediatric psychiatrist 3-Lack of mental retardation 4-No history of epilepsy and seizure 5-Intake methylphenidate tablet as the main method of drug therapy 6-consent of the patient and parents to participate in the research. Exclusion criteria: 1-Renal failure 2-intolerance to magnesium

Intervention groups
The first group received methylphenidate and magnesium at a dose of 125 mg/day for patients less than 35 kg and 250 mg/day for patients more than 35 kg.The second group received methylphenidate and placebo.

Main outcome variables
Decrease attention deficit, hyperactivity symptoms

General information

Reason for update

Acronym
ADHD

IRCT registration information
IRCT registration number: **IRCT20160813029327N19**
Registration date: **2020-09-07, 1399/06/17**
Registration timing: **retrospective**

Last update: **2020-09-07, 1399/06/17**
Update count: **0**

Registration date
2020-09-07, 1399/06/17

Registrant information

Name
Ramin Abrishami

Name of organization / entity
Islamic Azad University, Pharamceutical sciences branch

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-06, 1397/05/15

Expected recruitment end date
2019-07-06, 1398/04/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of the methylphenidate in combination with magnesium and methylphenidate with placebo in patients with attention deficit hyperactivity disorder

Public title

The effect of magnesium in patients with attention deficit hyperactivity disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 8-16 years old Diagnosis of ADHD by the pediatric psychiatrist Lack of mental retardation No history of epilepsy and seizure Intake methylphenidate tablet as the main method of drug therapy Consent of the patient and parents to participate in the research

Exclusion criteria:

Renal failure intolerance to magnesium

Age

From **8 years** old to **16 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

block randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and physician will be blind about drug

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University of Pharmaceutical Sciences

Street address

#99, The First of Yakhchal Ave., Gholhak, Shariati St.

City

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Province

Tehran

Postal code

19395-6466

Approval date

2018-03-03, 1396/12/12

Ethics committee reference number

IR.IAU.PS.REC.1396.236

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

Scores in Conner's Parent Rating Scale questionnaire

Timepoint

Before, 4 weeks and 8 weeks after intervention

Method of measurement

Conner's Parent Rating Scale questionnaire

2

Description

Scores in ADHD Rating Scale questionnaire

Timepoint

Before, 4 weeks and 8 weeks after intervention

Method of measurement

ADHD Rating Scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients will receive 0.3 to 2 mg/kg/day methylphenidate tablet and magnesium at a dose of 125 mg/day for patients less than 35 kg and 250 mg/day for patients more than 35 kg for 8 weeks.

Category

Treatment - Drugs

2

Description
Control group: patients will receive 0.3 to 2 mg/kg/day methylphenidate tablet and placebo for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ziaeian hospital
Full name of responsible person
Fatemeh Ajorloo
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Islamic Azad University
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
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Ramin Abrishami
Position
Assistant professor
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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
No - There is not 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
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available