

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 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 Ziaei 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 groups 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, Pharmaceutical sciences branch

Country

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
Tehran

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

Ziaeeian hospital

Full name of responsible person

Fatemeh Ajorloo

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Abouzar St, District 17, Tehran, Iran

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Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Farshad Hashemian

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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

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ramin Abrishami

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Tehran University of Medical Sciences

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Latest degree

Subspecialist

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Person responsible for updating data

Contact

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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

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