

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of supplementation with vitamin D and magnesium compared with placebo on cognitive function and behavior in children with attention deficit hyperactivity disorder

#### Protocol summary

##### Summary

This study aimed to evaluate the Effect of magnesium and vitamin D supplementation on cognitive and behavioral function in children with ADHD. .In this double blind randomized controlled trial 64 out patients with ADHD be selected based on Inclusion criteria 1) age between 6-12 year 2) signing informed written consents to participate in the study 4) serum 25-OH-vitamin D level less than 30 ng/dl 5) serum Mg level less than 2.3 mg/dl and exclusion criteria 1) ages outside the above range 2) unwillingness to participate in the study 3) having any other chronic medical diseases 4) serum 25-OH-vitamin D level more than 30 ng/dl and serum Mg level more than 2.3 mg/dl. Then patients will be randomly assigned in 2 groups, the first group received vitamin D(50000 IU/week) plus magnesium(6 mg/day depending on weight) and the second group received placebo. The participants will be blinded to their allocations. The cognitive and behavioral function will be assessed at the base line and week 4 and 8 after the medication started. The level of 25-OH-vitamin D and Mg will be measured at the base line and week 8 after the medication started.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016030326886N1**  
Registration date: **2016-03-24, 1395/01/05**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-03-24, 1395/01/05

#### Registrant information

##### Name

Mostafa Hemamy

##### Name of organization / entity

Isfahan university of medical science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 2110

##### Email address

mostafa.hemamy@nutr.mui.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Isfahan university of medical science

#### Expected recruitment start date

2016-03-10, 1394/12/20

#### Expected recruitment end date

2016-05-09, 1395/02/20

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of supplementation with vitamin D and magnesium compared with placebo on cognitive function and behavior in children with attention deficit hyperactivity disorder

#### Public title

Effect of magnesium and vitamin D supplementation in the treatment of ADHD

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: 1) age between 6-12 year 2) signing informed written consents to participate in the study 4) serum 25-OH-vitamin D level less than 30 ng/dl 5) serum Mg level less than 2.3 mg/dl. Exclusion criteria: 1) Ages outside the above range 2) Unwillingness to participate in the study 3) having chronic medical diseases 4) serum 25-OH-vitamin D level more than 30 ng/dl and serum Mg level more than 2.3 mg/dl.

#### Age

From **6 years** old to **12 years** old

#### Gender

Both

#### Phase

1-2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **74**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

Subjects will be assigned randomly (block randomization) in two groups. The intervention group will receive magnesium (magnesium sulfate tablet) at a dose of 6 milligram per day and vitamin D (pearl) at a dose of 50000 international unit per week for 8 week. The control group will receive placebo. Blinding: the participants are blind to their allocations

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

##### Street address

Hezargerib street, Isfahan

##### City

Isfahan

##### Postal code

#### Approval date

2016-02-21, 1394/12/02

#### Ethics committee reference number

IR.MUI.REC.1394.3.961

## Health conditions studied

### 1

#### Description of health condition studied

attention deficit-hyperactivity disorder

#### ICD-10 code

F 90.0

#### ICD-10 code description

Disturbance of activity and attention

## Primary outcomes

### 1

#### Description

cognitive and behavioral function

#### Timepoint

before, 4 weeks and 8 weeks after intervention

#### Method of measurement

Conner's Parent Rating Scale (CPRS)

### 2

#### Description

cognitive and behavioral function

#### Timepoint

before, 4 weeks and 8 weeks after intervention

#### Method of measurement

Strength and Difficulties Questionnaire (SDQ)

## Secondary outcomes

### 1

#### Description

Serum vitamin D level

#### Timepoint

First and end of intervention(2 month)

#### Method of measurement

ELISA

### 2

#### Description

Serum magnesium level

#### Timepoint

First and end of intervention(2 month)

#### Method of measurement

spectrophotometry

## Intervention groups

### 1

#### Description

The intervention group will receive magnesium (magnesium sulfate tablet) at a dose of 6 milligram per day and vitamin D (pearl) at a dose of 50000 international unit per week

#### Category

Treatment - Drugs

## 2

### Description

Control group will receive placebo.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Khorshid clinic

##### Full name of responsible person

Dr. Gholamreza Askari

##### Street address

Ostandari Street, Isfahan

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

##### Full name of responsible person

Dr. Gholamreza Askari

##### Street address

Hezargerib Street, Isfahan

##### City

Isfahan

#### 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, Isfahan 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

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Full name of responsible person

Mostafa Hemamy

#### Position

MSc of Nutrition & Dietetics

#### Other areas of specialty/work

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Dr. Gholamreza Askari

##### Position

MD & PhD (Nutritionist)

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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*