

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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

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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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Person responsible for scientific inquiries

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Isfahan University of Medical Sciences

Full name of responsible person

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Position

MD & PhD (Nutritionist)

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Person responsible for updating data

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Full name of responsible person

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Position

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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