Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Nov 2026

The Effect of Vitamin D Supplementation on Superoxide Dismutase Antioxidant Enzyme and Inflammatory Factors in Students 6-13 Years of Age with Attention Deficit Hyperactivity Disorder (ADHD)

Protocol summary

Study aim

The aim of this randomized controlled trial is to determine the effect of vitamin D supplementation on superoxide dismutase (antioxidant enzyme) and inflammatory factors in students 6-13 years of age with attention deficit hyperactivity disorder (ADHD).

Design

In this research, 84 patients with ADHD referring to the Behavioral Sciences Research Center are selected based on the inclusion and the non-inclusion criteria. Then they are randomly divided into intervention and control groups and each participant is assigned a code.

Settings and conduct

The study is conducted at the Behavioral Sciences Research Center, and the participants are ADHD patients diagnosed by the child and adolescent psychiatrist. Patients are selected after obtaining informed consent for research participation from their parents. The patients are not aware of the type of intervention they receive. The placebo, used in the control group, is similar in appearance to the vitamin D supplement in the intervention group. Data collectors and outcomes assessors do not know the type of intervention assigned to patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: In the age group of 13-6 years; Attention deficit hyperactivity disorder has been diagnosed and taken appropriate medications by the child and adolescent psychiatrist; Both groups take the same drugs at the same dose; Resident in Isfahan city Non-inclusion criteria: Use of any non-pharmaceutical treatment; Use of vitamin D and multivitamins supplement, foods rich in vitamin D or any supplementation of vitamin D received three months before the start of the study; Patients with other chronic diseases except ADHD

Intervention groups

The patients in the intervention group receive an oral pearl of 1000 IU vitamin D3 daily for 12 weeks; The patients in the control group receive placebo similar in appearance to the vitamin D supplement daily for 12 weeks.

Main outcome variables

Serum Levels of 25-hydroxy Vitamin D3; Serum Levels of C-reactive protein; Serum Levels of interleukin-6; Serum Levels of homocysteine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161104030698N1**
Registration date: **2017-12-21, 1396/09/30**
Registration timing: **prospective**

Last update: **2017-12-21, 1396/09/30**
Update count: **0**

Registration date

2017-12-21, 1396/09/30

Registrant information

Name

Iman Namjoo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2017-12-22, 1396/10/01
Expected recruitment end date
2018-03-20, 1396/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Vitamin D Supplementation on Superoxide Dismutase Antioxidant Enzyme and Inflammatory Factors in Students 6-13 Years of Age with Attention Deficit Hyperactivity Disorder (ADHD)

Public title
Effect of Vitamin D on Management of Attention Deficit Hyperactivity Disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1- In the age group of 13-6 years 2- Attention deficit hyperactivity disorder has been diagnosed and taken appropriate medications by the child and adolescent psychiatrist 3- Both groups take the same drugs at the same dose. Due to various psychiatric problems in this disorder and the ethical abnormal use of Ritalin, patients in the two groups take other drugs other than Ritalin according to the needs of the psychiatrist, but the range of medications used in the two groups is the same 4- Resident in Isfahan city
Exclusion criteria:
1. Use of any non-pharmaceutical treatment 2. Use of vitamin D and multivitamins supplement, foods rich in vitamin D or any supplementation of vitamin D received three months before the start of the study 3. Patients with other chronic diseases except for ātention deficit hyperactivity disorder
Age
From **6 years** old to **13 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **84**
More than 1 sample in each individual
Number of samples in each individual: **2**
After overnight fasting, the samples (5 ml) of blood was drawn from each patient in both the intervention and control groups for two times: the first blood sample at the beginning of the study and the second one after 12 weeks of the intervention

Randomization (investigator's opinion)
Randomized
Randomization description
The patients are selected according to the inclusion and the non-inclusion criteria by simple sampling and then they are randomly divided into intervention and control groups. (Simple Randomization)
Blinding (investigator's opinion)
Double blinded
Blinding description
The patients are not aware of the type of intervention they receive. The placebo, used in the control group, is similar in appearance to the vitamin D supplement in the intervention group. Data collectors and outcomes assessors do not know the type of intervention assigned to patients.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezarjerib Street, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2017-03-02, 1395/12/12
Ethics committee reference number
IR.MUI.REC.1395.3.370

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
25-hydroxy Vitamin D3
Timepoint
At the beginning of the study and after 12 weeks of the intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) kit

2

Description
Serum levels of C-reactive protein
Timepoint
At the beginning of the study and after 12 weeks of the intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) kit

3

Description
Serum levels of interleukin-6
Timepoint
At the beginning of the study and after 12 weeks of the intervention
Method of measurement
enzyme-linked immunosorbent assay (ELISA) kit

4

Description
Serum levels of homocysteine
Timepoint
At the beginning of the study and after 12 weeks of the intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) kit

5

Description
Serum levels of superoxide dismutase
Timepoint
At the beginning of the study and after 12 weeks of the intervention
Method of measurement
Spectrophotometric method

Secondary outcomes

1

Description
Food intake
Timepoint
At the beginning of the study
Method of measurement
Food Frequency Questionnaire

2

Description
Sunlight exposure
Timepoint
At the beginning of the study
Method of measurement
Questionnaire

3

Description
Physical activity
Timepoint
At the beginning of the study
Method of measurement
Baecke Physical Activity Questionnaire

Intervention groups

1

Description
Intervention group: an oral pearl of 1000 IU vitamin D3 daily for 12 weeks
Category
Treatment - Drugs

2

Description
Control group: a placebo similar in appearance to the vitamin D supplement daily for 12 weeks
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Behavioral Sciences Research Center, Isfahan University of Medical Sciences
Full name of responsible person
Amirmansour Alavi Naeini
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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Web page address
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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
Esfahan University of Medical Sciences
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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Person responsible for updating data

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available