

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Assessment of the efficacy of Vitamin D supplementation comparing to placebo on antioxidant capacity and symptoms ADHD in Students 6-13 years old whit ADHD

Protocol summary

Summary

This study is randomized, clinical trial, single center and double-blind for patients and researchers. The aim of this study is to evaluate the effects of treatment with vitamin D on antioxidant capacity and ADHD symptoms in Students 6-13 years with ADHD that is controlling by Placebo. Inclusion criteria: Age group participants is 6-13 years; Non-having other chronic diseases; Lack of consumption of Vitamin D supplementation from two months before the intervention; Lack of consumption of Selenium, Calcium, Vitamin C, Vitamin E, Omega3 and Zinc supplementations from one month before the intervention. Exclusion criteria: The use of methods such as Neurofeedback, Play-therapy and parenting education during the intervention; nonconsent of parents for the continued cooperation During the study. Sample of the study includes 84 of Patients (42 patients in the Vitamin D group and 42 patients in the Placebo group). The intervention group consume 1000 IU of Vitamin D3 daily for 12 weeks and control group in the same period, consume Placebo. ADHD symptoms in both groups, with the score SDQ (Strengths and Difficulties Questionnaire), CPQ (Conners Parent Questionnaire) and CPT (Continue performances Test) are evaluated before and after the intervention. 25(OH) vitamin D, total Antioxidant Capacity, Malon Di Aldehyde, Glutathione and Catalase of participants serum in two groups before and after intervention measured by Elisa and Spectrophotometry methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120331212N1**

Registration date: **2017-02-09, 1395/11/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-09, 1395/11/21

Registrant information

Name

Forugh Fasihi

Name of organization / entity

Isfahan University of Medical Sciences, School of Nutrition and Food Sciences, Dept

Country

Iran (Islamic Republic of)

Phone

+98 21 4426 7331

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research Isfahan University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the efficacy of Vitamin D supplementation comparing to placebo on antioxidant capacity and symptoms ADHD in Students 6-13 years old whit ADHD

Public title

The effects of Vitamin D supplementation on ADHD symptoms and antioxidant capacity in Students 6-13 years old whit ADHD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age group participants is 6-13 years; Non-having other chronic diseases; Lack of consumption of Vitamin D supplementation from two months before the intervention; Lack of consumption of Selenium, Calcium, Vitamin C ,Vitamin E, Omega3 and Zinc supplementations from one month before the intervention. Exclusion criteria: The use of methods such as neurofeedback, play-therapy and parenting education during the intervention; nonconsent of parents for the continued cooperation During the study .

Age

From **6 years** old to **13 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

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

Postal code

8174673461

Approval date

2016-02-21, 1394/12/02

Ethics committee reference number

ir.mui.rec.1394.3.886

Health conditions studied

1

Description of health condition studied

Attention Deficit Hyperactivity Disorder

ICD-10 code

f90

ICD-10 code description

Hyperkinetic disorders

Primary outcomes

1

Description

25(OH)Vitamin D3

Timepoint

before entering to the study and 12 weeks after Vitamin D or placebo consumption

Method of measurement

serum level measurement

2

Description

Attention

Timepoint

before entering to the study and 12 weeks after Vitamin D or placebo consumption

Method of measurement

continue performance test score

3

Description

Impulsive

Timepoint

before entering to the study and 12 weeks after Vitamin D or placebo consumption

Method of measurement

continue performance test score

4

Description

behaviral disorder

Timepoint

before entering to the study and 12 weeks after Vitamin D or placebo consumption

Method of measurement

Strengths and Difficulties Questionnaire score

5

Description

Antioxidant Capacity of serum

Timepoint

before entering to the study and 12 weeks after Vitamin D or placebo consumption

Method of measurement

serum level measurement

Secondary outcomes

1

Description

Body Mass Index

Timepoint

before entering to the study and 12 weeks after vitamin D or Placebo consumption

Method of measurement

Digital scale and meter

2

Description

Food receives

Timepoint

before entering to the study & 12 weeks after drug or placebo consumption

Method of measurement

Food record

Intervention groups

1

Description

The intervention group consume 1000 IU Vitamin D3 supplementation daily in during 12 weeks.

Category

Treatment - Other

2

Description

The control group consume Placebo daily in during 12 weeks intervention.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Behavioral Sciences Research Center, Isfahan University of Medical Sciences

Full name of responsible person

Amir Mansuor Alavi

Street address

Khorshid Psychiatry Center, Darvazehdolat Street, Isfahan

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Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Isfahan University of Medical Sciences

Full name of responsible person

Prof Mehdy Nematbakhsh

Street address

Vice chancellor for research, No 4 Bulding, Isfahan University of Medical Sciences, Hezarjerib 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, School of Nutrition and Food Sciences

Full name of responsible person

Dr Amir Mansour Alavi Naiini

Position

Nutrition Science PHD

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