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,singlecenter 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 controling 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 Pelasibo 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 metods.

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
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Name of organization / entity
Isfahan University of Medical Sciences, School of Nutrition and Food Sciences, Dept

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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 during12 weeks.
Category
Treatment - Other

2

Description
The control group consume Plasebo daily in during12 weeks intervention.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Behavioral Sciences Research Center, Isfahan Univercity of Medical Sciences
Full name of responsible person
Amir Mansuor Alavi
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Khorshid Psychiatry Center, Darvazehdolat Street, Isfahan
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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
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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
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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