

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effect of vitamin D supplementation on attention deficit hyperactivity disorder symptoms and stress oxidative in children

Protocol summary

Summary

1-Objectives: The aim of present study is to determine the effect of vitamin D supplementation on attention deficit hyperactivity disorder symptoms and stress oxidative in children. 2-Design: placebo controlled randomized clinical trial, double blind, phase III. 3-Setting and conduct: Sixty children with attention deficit hyperactivity disorder will be randomly allocated into two groups to receive daily either 2000IU vitamin D or placebo for 8 weeks. Ten milliliters of fasting blood samples will be collected at baseline and after intervention. 4-Inclusion criteria: signed parental consent form, diagnosis of attention deficit hyperactivity disorder in 6-12 year-old children by psychiatrist. 5-Exclusion criteria: any psychiatric, neurologic or systemic disorders based on history, consumption of any medicine or supplement. 6- Intervention: Both groups will take the standard medicine for this disease (Ritalin, 0.3-1 mg/kg/d). one group will take vitamin D3, 2000IU/d (plus Ritalin) and the second group will take placebo (plus Ritalin) for 8 weeks. 7- Primary Outcomes: Symptoms evaluation by parents Conner's questionnaire. 8- Other outcomes: Symptoms evaluation by morning-evening questionnaires, Assessment of serum levels of 25-hydroxy vitamin D, Malondialdehyde and 8-hydroxydeoxy guanosine.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404222394N10**
Registration date: **2014-08-15, 1393/05/24**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-15, 1393/05/24

Registrant information

Name

Shima Jazayeri

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 4805

Email address

sjazayeri@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Iran University of Medical Sciences

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D supplementation on attention deficit hyperactivity disorder symptoms and stress oxidative in children

Public title

Efficacy of vitamin D supplementation in children with attention deficit hyperactivity disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Signed parental (mother/father) informed consent; 6-12 years old children; Newly diagnosed attention deficit hyperactivity disorder children by child and adolescent psychiatrist; BMI percentile between 5 to 85. Exclusion criteria: History or current diagnosis of other psychiatric diseases (e.g., autism, bipolar disorder, major depression disorder, etc.) by psychiatrist; History or current diagnosis of neurological condition (e.g., epilepsy, brain tumors, etc.) by psychiatrist; History or current diagnosis of any serious systemic (e.g., diabetes, hyper/hypothyroidism, etc.); History of major head trauma ; Diagnosis of Mental retardation; Any medicine administration at least 4weeks before the initiation of the study; Any vitamin D products (enriched products with vitamin D) at least 3 months before the initiation of the study; Any supplement use containing antioxidants like multivitamin, vitamin A,C,E at least 2 months before the initiation of the study.

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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 Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Postal code**Approval date**

2014-04-14, 1393/01/25

Ethics committee reference number

92-02-27-23601-100469

Health conditions studied**1****Description of health condition studied**

attention deficit hyperactivity disorder

ICD-10 code

F90.0

ICD-10 code description

Disturbance of activity and attention

Primary outcomes**1****Description**

Symptoms of disease

Timepoint

week 0,4 and 8

Method of measurement

Parental Conners questionnaire

Secondary outcomes**1****Description**

symptoms in morning and evening

Timepoint

week 0,4 , 8

Method of measurement

Morning-evening symptoms questionnaire

2**Description**

adverse drug effects

Timepoint

week 4,8

Method of measurement

Adverse drug effects questionnaire

3**Description**

Serum level of Malondialdehyde

Timepoint

week 0,8

Method of measurement

blood test

4**Description**

Serum level of 8-hydroxydeoxyguanosine

Timepoint

week 0,8

Method of measurement

blood test

5

Description

Serum level of 25-hydroxyD

Timepoint

week 0,8

Method of measurement

blood test

Intervention groups

1

Description

intervention group: vitamin D, 2000IU, one tablet daily for 8 weeks

Category

Treatment - Drugs

2

Description

control group: placebo containing starch and lactose, one tablet daily for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Dr Mehdi Tehranidoost

Street address

Roozbeh hospital, Southern Kargar Street

City

Tehran

2

Recruitment center

Name of recruitment center

Imam Hossein hospital

Full name of responsible person

Dr Rozita Davari

Street address

Imam Hossein hospital, Shahid Madani Street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Alijavad Mousavi

Street address

Iran university of medical sciences, next to Milad tower, Hemmat Highway, Tehran

City

Tehran

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, Iran 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

Nutrition and dietetics faculty of Tehran university of medical sciences

Full name of responsible person

Nakisa Mohammadpour

Position

Student of Master of Art

Other areas of specialty/work

Street address

No 44, Hojatdost alley, Naderi street, Keshavarz boulevard, Tehran

City

Tehran

Postal code

Phone

+98 21 8804 8770

Fax

Email

mohammadpour.nakisa@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Nutrition, Faculty of public Health, Iran university of medical sciences

Full name of responsible person

Dr. Shima Jazayeri

Position

Md, Phd of nutrition

Other areas of specialty/work

Street address

Faculty of public health, Iran university of medical sciences, next to Milad tower, Hemmat Highway, Tehran

City

Tehran

Postal code**Phone**

+98 21 8670 4805

Fax**Email**

sjazayeri@razi.tums.ac.ir

Web page address

boulevard, Tehran

City

Tehran

Postal code**Phone**

+98 21 8804 8770

Fax**Email**

mohammadpour.nakisa@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Nutrition and dietetics faculty of Tehran University of medical sciences

Full name of responsible person

Nakisa Mohammadpour

Position

student

Other areas of specialty/work**Street address**

No 44, Hojatdoost alley, Naderi street, Keshavarz

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