

# 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

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#### Postal code

#### Phone

+98 21 8804 8770

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#### 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

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**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*