

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of vitamin D supplementation on inflammatory cytokines (Interleukin 6, Tumor Necrosis Factor alpha), Brain-derived neurotrophic factor (BDNF), Dopamine, Serotonin, Paroxonase-1 enzyme (PON-1), Total Antioxidant Capacity (TAC), 8-Isoprostane, Soluble intercellular adhesion molecule-1 (sICAM-1) and Soluble vascular cell adhesion molecule-1 (sVCAM-1) in school-aged children with Attention Deficit Hyperactivity Disorder

#### Protocol summary

2017-07-22, 1396/04/31

#### Summary

Objective: The effect of vitamin D supplementation in children with Attention Deficit Hyperactivity Disorder  
Study design: Randomized, double-blind, placebo-controlled, single-center, trial study (phase II) population: school-aged children (6-12 year old) with Attention Deficit Hyperactivity Disorder  
Main inclusion criteria:  
1. Children with ADHD according to DSM-V criteria  
2. Children taking Ritalin  
Main exclusion criteria:  
1. children use other supplements except vitamin D  
2. Discontinue taking Ritalin and vitamin D  
Sample size: 80 children  
Interventions: vitamin D supplementation and placebo  
Intervention period: 3 months  
Outcomes: Brain-derived neurotrophic factor (BDNF), Dopamine, Serotonin, Paroxonase-1 enzyme, Total Antioxidant Capacity, 8-Isoprostane, Interleukin 6 (IL-6), Tumor Necrosis Factor alpha (TNF-a), Soluble intercellular adhesion molecule-1 (sICAM-1), Soluble vascular cell adhesion molecule-1 (sVCAM-1)

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016102324081N2**  
Registration date: **2017-07-22, 1396/04/31**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

#### Registrant information

##### Name

Niaz Mohammadzade Honarvar

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8897 4461

##### Email address

honarvar@tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Ziaieian hospital and Tehran University Of Medical Sciences

#### Expected recruitment start date

2016-10-22, 1395/08/01

#### Expected recruitment end date

2017-01-20, 1395/11/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of vitamin D supplementation on inflammatory cytokines (Interleukin 6, Tumor Necrosis Factor alpha),

Brain-derived neurotrophic factor (BDNF), Dopamine, Serotonin, Paroxonase-1 enzyme (PON-1), Total Antioxidant Capacity (TAC), 8-Isoprostane, Soluble intercellular adhesion molecule-1 (sICAM-1) and Soluble vascular cell adhesion molecule-1 (sVCAM-1) in school-aged children with Attention Deficit Hyperactivity Disorder

#### Public title

The Effect of Vitamin D on Attention Deficit Hyperactivity Disorder

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

Inclusion criteria: The age between 6-12 year old ; Children with ADHD according to DSM-V criteria ; Children taking Ritalin  
Exclusion criteria: Children use other supplements except vitamin D3 ; Discontinue taking Ritalin and vitamin D ; Medical conditions (e.g., infectious or cardiovascular diseases, diabetes ,hypertension, Hyperthyroidism, Digestive diseases, liver or kidney diseases, respiratory diseases and allergies) ; Neurological diseases such as seizures, epilepsy and ... except ADHD ; History of severe head trauma ; BMI above the 85th percentile ; Taking any medicine except Ritalin

#### Age

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

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **80**

#### 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

Tehran University Of Medical Science

##### Street address

Central Department of University, Ghods St., Keshavarz Blvd

#### City

Tehran

#### Postal code

#### Approval date

2016-01-24, 1394/11/04

#### Ethics committee reference number

IR.TUMS.REC.1394.1719

## 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

Interleukin 6 (IL-6)

#### Timepoint

Pre-intervention/post intervention

#### Method of measurement

ELISA - pg/ml

### 2

#### Description

Tumor Necrosis Factor alpha (TNF-a)

#### Timepoint

Pre-intervention/post intervention

#### Method of measurement

ELISA-pg/ml

### 3

#### Description

Brain-derived neurotrophic factor (BDNF)

#### Timepoint

Pre-intervention/post intervention

#### Method of measurement

ELISA - pg/ml

### 4

#### Description

Dopamine

#### Timepoint

Pre-intervention/post intervention

#### Method of measurement

ELISA - pg/ml

### 5

#### Description

Serotonin

#### Timepoint

Pre-intervention/post intervention  
**Method of measurement**  
ELISA - ng/ml

## 6

**Description**  
Total Antioxidant Capacity (TAC)  
**Timepoint**  
Pre-intervention/post intervention  
**Method of measurement**  
ELISA-pg/ml

## 7

**Description**  
8-Isoprostan  
**Timepoint**  
Pre-intervention/post intervention  
**Method of measurement**  
ELISA-pg/ml

## 8

**Description**  
Paroxonase-1(PON-1)  
**Timepoint**  
Pre-intervention/post intervention  
**Method of measurement**  
ELISA-pg/ml

## 9

**Description**  
Soluble intercellular adhesion molecule-1 (sICAM-1)  
**Timepoint**  
Pre-intervention/post intervention  
**Method of measurement**  
ELISA-ng/dl

## 10

**Description**  
Soluble vascular cell adhesion molecule-1 (sVCAM-1)  
**Timepoint**  
Pre-intervention/post intervention  
**Method of measurement**  
ELISA-ng/dl

## Secondary outcomes

### 1

**Description**  
Symptoms  
**Timepoint**  
Pre-intervention/post intervention  
**Method of measurement**  
Conner's Parent Rating Scale-Revised [S], ADHD Rating scale-IV, Parent Rating of Evening and Morning Behavior-Revised

## Intervention groups

### 1

**Description**  
Intervention group: vitamin D3, 25 mcg oral tablet manufactured by Jalinous, twice a day for 3 months  
**Category**  
Treatment - Drugs

### 2

**Description**  
Control group: placebo, 25 mcg oral tablet manufactured by Jalinous, twice a day for 3 months  
**Category**  
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**  
**Name of recruitment center**  
Ziaeian hospital  
**Full name of responsible person**  
Mohammad Effatpanah  
**Street address**  
Ziaeian hospital, Abuzar Sq, 17th district, Tehran  
**City**  
Tehran

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Masoud Yunesian  
**Street address**  
Sixth Floor, Central Department of University, Ghods St., Keshavarz Blvd  
**City**  
Tehran  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Tehran 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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Niaz Mohammadzade Honarvar

**Position**

PhD Nutrition Sciences

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

Department of Nutrition and Dietetic, Hojat doost Alley, Naderi St, Keshavarz Blvd, Tehran

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**Postal code****Phone**

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honarvar@tums.ac.ir

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

Tehran University of Medical Sciences

**Full name of responsible person**

Niaz Mohammadzade Honarvar

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Tehran

**Postal code****Phone**

+98 21 8897 4461

**Fax****Email**

honarvar@tums.ac.ir

**Web page address****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*