

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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)

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+98 21 8897 4461

Email address

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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

City

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Postal code**Phone**

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Fax**Email**

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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

Position

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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