Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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

2017-07-22, 1396/04/31

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

Ziaeian 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
Tehran
Postal code
Phone
+98 21 8897 4461
Fax
Email
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
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
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