

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Evaluation of the effects of vitamin D supplementation on vitamin status and brain mapping in children with ADHD

#### Protocol summary

##### Study aim

Evaluation of the effects of vitamin D supplementation on brain mapping in children with ADHD

##### Design

40 children aged 7-13 years are randomly assigned by computer random numbers in case and control groups. This intervention is parallel and double-blind.

##### Settings and conduct

This study is performed in Imam Hossein Psychological Center in Yazd. The subjects according to the inclusion and exclusion criteria, are entered in one of the two groups randomly. They are given vitamin D and placebo, which is olive oil. In this study, the researchers and participants are blind, which is completely identical in packaging and shape and pre-determined codes by the factory.

##### Participants/Inclusion and exclusion criteria

1. Being 7-13 years old 2. Resident of Yazd 3. If IQ is more than 80 4. If theta wave is more than 7 hz and beta is less than 13 hz 1. Having cognitive impairments or other psychotic illnesses 2. Starting medication for hyperactivity from last year 3. Hormonal disorders including Edison's disease, Cushing's disease, hyperparathyroidism, hypo or hyperthyroidism 4. Chronic diseases including cancer, heart disease, diabetes, stroke, fibromyalgia, kidney or liver defects, multiple sclerosis and Parkinson's 5. Being premature at birth 6. Take a multivitamin or mineral multivitamin more than twice in a month for at least 6 months in last year 7. Using vitamin D supplementation more than two pearls in the last year 8. Taking more than 2 pearls of calcium-D supplements in a week, for at least 6 months in the last year

##### Intervention groups

Prescribing one vitamin D perl every week for 8 weeks to intervention group and one placebo perl contains olive oil every week to control group.

##### Main outcome variables

Vitamin D, Ca, P, brain map

#### General information

##### Reason for update

To complete the protocol, we added the ADHD symptoms severity as the secondary outcome. In addition, inflammation and oxidative stress are the main factors in the pathogenesis of ADHD. Therefore, the C-reactive protein, malondialdehyde and nitric oxide were added as the secondary outcomes. new ethical number was added.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200922048802N1**  
Registration date: **2020-11-05, 1399/08/15**  
Registration timing: **registered\_while\_recruiting**

Last update: **2021-09-26, 1400/07/04**

Update count: **1**

##### Registration date

2020-11-05, 1399/08/15

##### Registrant information

###### Name

Hadis Hooshmandi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 3820 9100

###### Email address

hadis.july.1994@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-10-05, 1399/07/14

##### Expected recruitment end date

2020-12-04, 1399/09/14

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Evaluation of the effects of vitamin D supplementation on vitamin status and brain mapping in children with ADHD

**Public title**  
Evaluation of the effects of vitamin D brain mapping in children with ADHD

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
7-13 years Resident of Yazd Increase theta wave above 7 hz and decrease beta below 13 hz

**Exclusion criteria:**  
IQ less than 80

**Age**  
From **7 years** old to **13 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **40**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Randomization: Simple random unit: Individual Tool: Computer-generated random number table.  
Randomization lists are computer-generated by a statistician, then, participants will assign to the groups of the study. A trained person, randomly will allocate and assign the participants to study groups. In order to apply the concealment in the randomization process will be used on the supplement and placebo boxes.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Supplements of vitamin D and placebo in the same capsules in terms of size, color and shape Encodes A and B on supplements and placebo.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Shahid Sadoughi University of Medical Sciences

##### Street address

Campus of Sadoughi University of Medical Sciences, Shohadaye Gomnam Blv, Yazd

##### City

Yazd

##### Province

Yazd

##### Postal code

8915173160

##### Approval date

2016-10-08, 1395/07/17

##### Ethics committee reference number

IR.SSU.SPH.REC.1395.97

### 2

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Sadoughi University of Medical Sciences

##### Street address

Campus of Sadoughi University of Medical Sciences, Shohadaye Gomnam Blv, Yazd

##### City

Yazd

##### Province

Yazd

##### Postal code

8915173160

##### Approval date

2021-05-30, 1400/03/09

##### Ethics committee reference number

IR.SSU.SPH.REC.1400.028

## Health conditions studied

### 1

#### Description of health condition studied

Attention-deficit hyperactivity disorder

#### ICD-10 code

F90

#### ICD-10 code description

Attention-deficit hyperactivity disorders

## Primary outcomes

### 1

#### Description

Brain map

**Timepoint**

Before and after 8 weeks treatment

**Method of measurement**

Brain mapping

**2**

**Description**

Vitamin D

**Timepoint**

Before and after 8 weeks treatment

**Method of measurement**

Using ELISA

**Secondary outcomes**

**1**

**Description**

weight

**Timepoint**

Before and after 8 weeks treatment

**Method of measurement**

Scale

**2**

**Description**

ADHD symptoms severity

**Timepoint**

Before and after 8 weeks treatment

**Method of measurement**

Conners parent rating scale checklist

**3**

**Description**

C reactive protein

**Timepoint**

Before and after 8 weeks treatment

**Method of measurement**

ELISA Kit

**4**

**Description**

Malondialdehyde

**Timepoint**

Before and after 8 weeks treatment

**Method of measurement**

ELISA Kit

**5**

**Description**

Nitric Oxide

**Timepoint**

Before and after 8 weeks treatment

**Method of measurement**

ELISA Kit

**Intervention groups**

**1**

**Description**

The intervention group consumes a 50,000 IU pearl of vitamin D belonging to Zahravi Company every week for 8 weeks.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: They consume one pearl of olive oil every week, which is quite similar to the pearl of vitamin D, for 8 weeks.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Imam Hossein Psychological Center of Yazd

**Full name of responsible person**

seyed Hamid Mirhoseini

**Street address**

Imam Hossein Psychological Center, Shahid Beheshti Blv, Yazd

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mirhoseini.h@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Azadeh Najarzadeh

**Street address**

Nutrition and Food Security Research Center, First Floor, Faculty of Health, Imam Reza Educational and Research Complex, Daneshjoo Blv, Imam Hossein Square, Yazd

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**Email**

Azadehnajarzadeh@gmail.com

**Web page address**

https://ssu.ac.ir/

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Yazd University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Mahdieh Hoseinzadeh

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

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## Person responsible for scientific inquiries

**Contact**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Hadis Hooshmandi

**Position**

Master Student of Health Sciences in Nutrition

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available