Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 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

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Iran (Islamic Republic of)

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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

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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

Befor and after 8 weeks treatment

Method of measurement

Brain mapping

2

Description

Vitamin D

Timepoint

Befor 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

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Imam Hossein Psychological Center, Shahid Beheshti Blv, Yazd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

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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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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

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Latest degree
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Person responsible for updating data

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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