Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Effect of vitamin D supplementation on core symptoms and serum biomarkers (serotonin and IL-6) in children with autism spectrum disorders

Protocol summary

Study aim
The effect of vitamin D supplementation on behavioral disorders, serum serotonin and enteroquin-6 in children with autism spectrum disorders

Design
A parallel, double-blind, placebo controled, randomized clinical trial

Settings and conduct
This study will be conducted on 48 children with autism spectrum disorders who are referred to an outpatient clinic of Mohammad Kermanshahi Hospital and the exceptional school of Kermanshah. Dietary intake, anthropometric data and blood biomarkers of children will be measured at the beginning and at the end of study. Participants were randomly assigned into vitamin D and placebo groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: the desire for parental collaboration, the age range of 3 to 13 years, the diagnosis of autism disorder based on DSM-5 criteria Exclusion criteria: reluctance to continue cooperation, children with significant hearing loss and vision loss, other neurological disorders such as cerebral palsy, phenylketonuria, seizure disorders. History of head trauma, genetic abnormalities, premature children, children with nutritional and malnutrition problems, children with digestive problems, immune disorders, children with endocrine diseases, cardiovascular, pulmonary, kidney, liver and children two months prior to study Supplements or the following medications: vitamin A, vitamin D, omega3, steroids, cimetidine, heparin, diuretics, digoxin, diltiazem and verapamil, children with serum vitamin D levels above 80ng/ml

Intervention groups
Vitamin D group: receiving 300 units per kilogram of body weight of vitamin D drop to a maximum of 6000 units per day and the placebo group receiving the placebo drop

Main outcome variables
Evaluatation of behavioral changes (Aberrant Behavior Checklist-Community, Autism Treatment Evaluation Checklist and Childhood Autism Rating Scales) Vitamin D, interleukin 6 and serotonin biomarkers

General information

Reason for update
Entering additional information

Acronym

IRCT registration information
IRCT registration number: **IRCT20131013014994N5**
Registration date: **2018-04-18, 1397/01/29**
Registration timing: **prospective**

Last update: **2020-06-20, 1399/03/31**
Update count: **1**

Registration date
2018-04-18, 1397/01/29

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 1335 7580

Email address
abdollahzad@kums.ac.ir

Recruitment status
Recruitment complete

Funding source
Deputy of Research of Kermanshah University of Medical Sciences

Expected recruitment start date

2018-04-20, 1397/01/31

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

2018-04-20, 1397/01/31

Actual recruitment end date

2018-08-23, 1397/06/01

Trial completion date

2018-11-22, 1397/09/01

Scientific title

Effect of vitamin D supplementation on core symptoms and serum biomarkers (serotonin and IL-6) in children with autism spectrum disorders

Public title

effect of vitamin D on Autism Spectrum Disorders

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The desire for parental collaboration The age range of 3 to 13 years The diagnosis of autism disorder based on DSM-5 criteria

Exclusion criteria:

Reluctance to continue cooperation Children with significant hearing loss and vision loss Other neurological disorders such as cerebral palsy, phenylketonuria, seizure disorders History of head trauma, genetic abnormalities, premature children, children with nutritional and malnutrition problems, children with digestive problems, immune disorders, children with endocrine diseases, cardiovascular, pulmonary, kidney, liver Children two months prior to study Supplements or the following medications: vitamin A, vitamin D, fish liver oil, steroids, cimetidine, heparin, diuretics, digoxin, diltiazem and verapamil Children with serum vitamin D levels above 80 ng / ml

Age

From **3 years** old to **13 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **48**

Actual sample size reached: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to prevent the bias before the time of the intervention, it is better to use the random allocation method to each of the two groups of intervention and random control. In this study, a simple randomization method will be used to carry out random allocation (allocation hiding). Became In this way, 50 cards that are identical in appearance are prepared on 25 numeric cards or code that identifies the intervention group, and on 25 other cards, the number or the two code that specifies the control group. Then, each eligible entry student will randomly pick one of these cards, with codes coded, which will determine the random allocation of patients to each of the groups (without the participants in the testing of the nature of the numbers one or two in The type of intervention that will be assigned will be notified.)

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, nine individuals, not scholars, are aware of the allocation to the groups. For this purpose, the information gathered in the questionnaires is encoded by people other than the researcher or other key collaborators, so that the researcher and the participants in the plan do not encode and enter the computer during the categorization and placement of each individual in the intervention or control group.

Placebo

Used

Assignment

Parallel

Other design features

In this study, patients and researchers of type of intervention (complementary to vitamin D drops or placebo) are unaware of the groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Deputy of Research of Kermanshah University of Medical Sciences

Street address

Shahid Beheshti St., Oil Field, Facing Taleghani Hospital, Building No. 2 of Kermanshah University of Medical Sciences, Research and Research Branch

City

Kermanshah

Province

Kermanshah

Postal code

6719851351

Approval date

2018-02-28, 1396/12/09

Ethics committee reference number

IR.KUMS.REC.1396.646

Health conditions studied

1

Description of health condition studied

autism spectrum disorders

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes

1

Description

Severity of autism

Timepoint

At the beginning of the study and 12 weeks after the start of treatment

Method of measurement

By Childhood Autism Rating Scale (CARS) - Aberrant Behavior Checklist-Community (ABC-C) Rating Scale

2

Description

Evaluation of autism treatment

Timepoint

At the beginning of the study and 12 weeks after the start of treatment

Method of measurement

By Autism Treatment Evaluation Checklist

3

Description

Vitamin D serum level

Timepoint

First and twelfth week of study

Method of measurement

Eliza

4

Description

Serotonin serum level

Timepoint

First and twelfth week of study

Method of measurement

Eliza

5

Description

Interleukin 6 serum level

Timepoint

First and twelfth week of study

Method of measurement

Eliza

Secondary outcomes

empty

Intervention groups

1

Description

15 drops of placebo are administered daily for three months.

Category

Placebo

2

Description

Daily vitamin D supplements, 300 units per kilogram of body weight, up to a maximum of 6,000 units for three months are consumed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Mentally Retarded Besharat

Full name of responsible person

Saberi Leila

Street address

Alley 210,Next to the gas station,Ashrafi Esfahani Street

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6713933987

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Email

besharat.autism@gmail.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

Vice– Chancellery of Research & Technology Affairs, Building No. 2 of Kermanshah University of Medical Sciences, Naft Square, Shahid Beheshti blvd

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farid_n32@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Zohreh Javadfar
Position
MS.c student in Nutrition Sciences/chief cooperator of plan
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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Position
MS.c student in Nutrition Sciences/ chief cooperator of plan
Latest degree
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Other areas of specialty/work
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zohreh.javadfar@kums.ac.ir
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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
Triales that began to fall ill on January 11, 1397 should have a release plan when registering their study protocol.
Study Protocol
No - There is not 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