

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Effects of different dosages of vitamin D3 on anthropometric indices, metabolic, bone, and vascular parameters and body composition in overweight or obese children and adolescents

Protocol summary

Study aim

determine the effect of different doses of vitamin D3 supplementation on anthropometric indexes, parameters of metabolic, bone, vascular and body composition in children and adolescents with overweight or obesity

Design

parallel group, single blind, randomized placebo-controlled clinical trial.

Settings and conduct

overweight and obesity children and adolescents of Tehran, Iran

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Willingness to cooperate - Age 6-13 years - Overweight or obesity Exclusion criteria: - Reluctance to cooperate in any stage of study - Use of any vitamin D supplements - Use of any drugs, affecting metabolism of vitamin D including glucocorticoids, steroids and anticonvulsants such as carbamazepine, phenytoin and phenobarbital

Intervention groups

Three intervention groups as follows: oral 2000 IU of vitamin D3 supplement, 1000 IU vitamin D3 supplement, and the control group (600 IU vitamin D3 supplement) for 12 months.

Main outcome variables

carotid intima media thickness (cIMT), 25 hydroxy vitamin D, parathormone, lipid profile, glucose, insulin, body mass index, fat mass, lean mass, systolic and diastolic blood pressure, calcium, phosphorus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180805040703N1**

Registration date: **2018-10-20, 1397/07/28**

Registration timing: **retrospective**

Last update: **2018-10-20, 1397/07/28**

Update count: **0**

Registration date

2018-10-20, 1397/07/28

Registrant information

Name

Golaleh Asghari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2240 9309

Email address

g_asghari@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-06-20, 1395/03/31

Expected recruitment end date

2017-03-12, 1395/12/22

Actual recruitment start date

2016-06-20, 1395/03/31

Actual recruitment end date

2017-03-12, 1395/12/22

Trial completion date

2018-08-21, 1397/05/30

Scientific title

Effects of different dosages of vitamin D3 on anthropometric indices, metabolic, bone, and vascular parameters and body composition in overweight or obese children and adolescents

Public title

Effects of different dosages of vitamin D3 on anthropometric indices, metabolic, bone, and vascular parameters and body composition

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Willingness to cooperate Age 6-13 years Overweight or obesity (BMI $\geq$ 85th percentile national scale by age and sex)
Exclusion criteria:
 Reluctance to cooperate in any stage of study Use of any vitamin D supplements during the last six months Identifying any types of liver diseases, kidney, cardiovascular and metabolic bone Use of any drugs, affecting metabolism of vitamin D including glucocorticoids, steroids and anticonvulsants such as carbamazepine, phenytoin and phenobarbital Following any weight loss diets during the past one year

Age
From **6 years** old to **13 years** old

Gender
Both

Phase
3

Groups that have been masked

- Investigator

Sample size
 Target sample size: **327**
 Actual sample size reached: **378**

Randomization (investigator's opinion)
Randomized

Randomization description
 Children and adolescents will be randomized using stratified block randomization method in each intervention group (2000 IU vitamin D, 1000 IU vitamin D, and 600 IU vitamin D), before which important confounders including sex (boy or girl), body mass index (overweight or obesity), and pubertal stage (pre-puberty and puberty) are determined. Eight strata including 3-blocks of A, B and C (3 intervention groups) are determined (ABC, BCA, CAB, ACB, BAC, CBA). Thus, at the end of the study, the three therapeutic groups in terms of confounding factors, including sex, body mass index, and pubertal stage will be the same and with an equal number of subjects.

Blinding (investigator's opinion)
Single blinded

Blinding description
 in this study participants were aware of dosage of vitamin D supplementation they received. but, the investigator was blind for randomization of participants. so there was no awareness of the dose received by each person.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

institutional ethics committee of the Research Institute for Endocrine Sciences, affiliated to the S

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No.24, Parvaneh Ave., Yaman str., Velenjak Blvd., Chamran High way

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Approval date

2016-07-19, 1395/04/29

Ethics committee reference number

IR.SBMU.ENDOCRINE.REC.1395.213

Health conditions studied

1

Description of health condition studied

over weight and obesity, cardiovascular disease

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

2

Description of health condition studied

vitamin D deficiency

ICD-10 code

E55

ICD-10 code description

Vitamin D deficiency

Primary outcomes

1

Description

carotid intima media thickness

Timepoint

before intervention, 6 and 12 months after intervention

Method of measurement

sonography

Secondary outcomes

1

Description

25 hydroxy vitamin D
Timepoint
before intervention, 6 and 12 months after intervention
Method of measurement
Electrochemiluminescence

2

Description
para thyroid hormon
Timepoint
before intervention, 6 and 12 months after intervention
Method of measurement
Electrochemiluminescence

3

Description
plasma insulin
Timepoint
before intervention, 6 and 12 months after intervention
Method of measurement
Electrochemiluminescence

4

Description
plasma glucose
Timepoint
before intervention, 6 and 12 months after intervention
Method of measurement
colorimetry

5

Description
lipid profile
Timepoint
before intervention, 6 and 12 months after intervention
Method of measurement
colorimetry

6

Description
body mass index
Timepoint
before intervention, 6 and 12 months after intervention
Method of measurement
calculation

7

Description
fat mass
Timepoint
before intervention, 6 and 12 months after intervention
Method of measurement
bioimpedance analysis

8

Description
lean mass

Timepoint
before intervention, 6 and 12 months after intervention
Method of measurement
bioimpedance analysis

9

Description
systolic and diastolic blood pressure
Timepoint
before intervention, 6 and 12 months after intervention
Method of measurement
Sphygmomanometer

10

Description
calcium
Timepoint
before intervention, 6 and 12 months after intervention
Method of measurement
colorimetry

11

Description
phosphorus
Timepoint
before intervention, 6 and 12 months after intervention
Method of measurement
colorimetry

Intervention groups

1

Description
Intervention group1: 12 months oral vitamin D supplementation of 2000 IU/d (ZAHRAVI pharmaceutical company-Tabriz-Iran)
Category
Prevention

2

Description
Intervention group2: 12 months oral vitamin D supplementation of 1000 IU/d (ZAHRAVI pharmaceutical company-Tabriz-Iran)
Category
Prevention

3

Description
Control group: 12 months oral vitamin D supplementation of 600 IU/d (ZAHRAVI pharmaceutical company-Tabriz-Iran)
Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Institute for Endocrine Science, Shahid Beheshti
university of medical sciences

Full name of responsible person

Golaleh Asghari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Institute for Endocrine Science

Full name of responsible person

Fereidoun Azizi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Institute for Endocrine Science

Proportion provided by this source

100

Public or private sector

Private

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**

Institute for Endocrine Science

Full name of responsible person

Golaleh Asghari

Position

senior researcher

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

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Position

senior researcher

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Person responsible for updating data

Contact**Name of organization / entity**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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