# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

31 May 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)

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**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 ≥ 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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**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

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Fereidoun Azizi

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azizi@erc-iran.com

**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**
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**Full name of responsible person**
Golaleh Asghari

**Position**
senior researcher

**Latest degree**
Master

**Other areas of specialty/work**
Nutrition

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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