Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

An oral vitamin D regimen for hypovitaminosis D in obese children and adolescents

Protocol summary

Summary

The study is conducted as a clinical trial on the obese and overweight children and adolescents with vitamin D deficiency or insufficiency patients are between the ages of 2 and 18year. Inclusion criteria: children 2- 18 year, Exclusion criteria :recent use of vitamin D preparations(for last six months); the disorders of the calcium ,phosphorus and vitamin D metabolism; the use of medication affecting vitamin D metabolism such as antiepileptics and estrogens ;malabsorbtion disorders such as celiac disease, cystic fibrosis, etc.; endocrine disorders such as cushing's disease, hypothyroidism, pseudohypoparathyroidism, etc; any acute or chronic illness; or the use of alcohol or tobacco. The subjects will divided upon BMI: 1) Obese: BMI at or above the 95th percentile for age and gender, 2) Overweight: BMI at or above the 85th percentile and lower than 95th percentile for age and gender, 3) Normal weight: BMI lower than 85th percentile for age and gender. Serum level of 25OHD level will measured. Vitamin D deficiency was defined as a 25OHD level of <15 ng/ml and vitamin D insufficiency as a 25OHD level of 15–20 ng/ml(26, 27).Vitamin D sufficiency considered as 25OHD level of ≥20 ng/mL(26). Subjects with vitamin D deficiency or insufficiency will treat with one pearl of vitamin D (50,000 IU) once a week for 6 weeks. Vitamin D3 pearls were provided by Alhavi Company Iran. A second blood sample for the measurement of 25OHD level will obtain 2-6 months later.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014090812421N2**
Registration date: **2014-10-01, 1393/07/09**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2014-10-01, 1393/07/09

Registrant information

Name
Kobra Shiasi arani
Name of organization / entity
Kashan University of Medical Sciences and Health Services
Country
Iran (Islamic Republic of)
Phone
+98 31 5557 4430
Email address
shiasi_k@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2014-10-01, 1393/07/09

Expected recruitment end date

2015-04-01, 1394/01/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

An oral vitamin D regimen for hypovitaminosis D in obese children and adolescents

Public title

An oral vitamin D regimen for hypovitaminosis D in obese children and adolescents

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:children 2- 18 year Exclusion criteria :recent use of vitamin D preparations(for last six months); the disorders of the calcium ,phosphorus and vitamin D metabolism;the use of medication affecting vitamin D metabolism such as antiepileptics and estrogens;malabsorbtion disorders such as celiac disease, cystic fibrosis, etc.;endocrine disorders such as cushing's disease, hypothyroidism, pseudohypoparathyroidism, etc; any acute or chronic illness; or the use of alcohol or tobacco.

Age

From **2 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethical committees of Kashan University of Medical Sciences

Street address

Kashan university of medical sciences

City

kashan

Postal code

Approval date

2014-09-23, 1393/07/01

Ethics committee reference number

29/5/1/1506/ب

Health conditions studied

1

Description of health condition studied

vitamin D deficiency

ICD-10 code

E55.9

ICD-10 code description

Vitamin D deficiency, unspecified

Primary outcomes

1

Description

serum vitamin D level>= 20 ng/ml

Timepoint

0, 2 ,4 month

Method of measurement

the chemiluminescence assay

Secondary outcomes

empty

Intervention groups

1

Description

one pearl of vitamin D (50,000 IU) once a week for 6 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

pediatric endocrinology clinic of Kashan University of Medical Sciences

Full name of responsible person

Kobra Shiasi Arani

Street address

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr Hamidi

Street address

Kashan University of Medical Sciences

City

Kashan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Kashan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty