Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of therapeutic response to identical oral Vitamin D between obese and non-obese children with vitamin D deficiency

Protocol summary

Summary

This study is a clinical trial to compare the prevalence of Vitamin D deficiency and therapeutic response to identical oral vitamin D therapy between obese and non-obese children. Inclusion criteria include: Ages between 2 to 14 years and Exclusion criteria include: Body Mass Index between 85 to 95 percentile for age, Ingestion of vitamin D, Multivitamin supplements usage, Anticonvulsants usage, Systemic corticosteroids usage, and chronic diseases. Study participants are children 2 to 14 years age, referring to endocrine clinic, vaccination clinic and general clinic. The sample size is 90 (45 in each group). After blood sampling, children with serum 25 hydroxy Vitamin D less than 30 Nano gram per milliliter of both groups, will be treated by 300,000 IU oral Vitamin D in 6 weeks (50,000 IU as a pearl, once a week).2-6 weeks after the treatment, Serum 25 hydroxy Vitamin D will be measured again. Assessment of differentiation in response to therapy between obese and non-obese groups is due to comparing their means of Vitamin D status before and after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012100210988N1**
Registration date: **2012-11-14, 1391/08/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-11-14, 1391/08/24

Registrant information

Name

Fatemeh Sayarifard

Name of organization / entity

Tehran University of Medical Sciences,children medical center

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic response to identical oral Vitamin D between obese and non-obese children with vitamin D deficiency

Public title

Efficacy of oral Vitamin D therapy in children with Vitamin D deficiency

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Child ; Ages 2-14 years Exclusion criteria: Body Mass Index between 85-95 percentile for age ; Ingestion of vitamin D ; Multivitamin supplements usage ; Anticonvulsants usage ; Systemic corticosteroids

usage ; Presence of hepatic disease ; Presence of renal disease ; Presence of Endocrine disorders ; Presence of malabsorptive disorders ; Presence of cancer

Age
From **2 years** old to **14 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Not randomized

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
Tehran University of Medical Sciences

Street address
Central Orgaznization of Tehran University of Medical Sciences, Qods Ave, Keshavarz Blvd

City
Tehran

Postal code
1417653761

Approval date
2012-09-25, 1391/07/04

Ethics committee reference number
18226.65719

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

2

Description of health condition studied
obesity

ICD-10 code
E66.9

ICD-10 code description
Obesity, unspecified

Primary outcomes

1

Description
Primary 25-Hydroxy Vitamin D

Timepoint
Befor treatment

Method of measurement
ng/dl-laboratory kit

2

Description
Secondary 25-Hydroxy Vitamin D

Timepoint
2-6 weeks after the end of treatment

Method of measurement
ng/dl-laboratory kit

Secondary outcomes

1

Description
Secondary serum calcium

Timepoint
2-6 weeks after end of treatment

Method of measurement
mg/dl-laboratory kit

2

Description
Primary urine calcium-creatinin ratio

Timepoint
before treatment

Method of measurement
laboratory kit

3

Description
Secondary urine calcium-creatinin ratio

Timepoint
2-6 weeks after end of treatment

Method of measurement
laboratory kit

4

Description
Primary serum PTH

Timepoint

before treatment

Method of measurement

Pg/dl-laboratory kit

5

Description

Secondary serum PTH

Timepoint

2-6 weeks after end of treatment

Method of measurement

Pg/dl-laboratory kit

6

Description

Primary serum calcium

Timepoint

before treatment

Method of measurement

mg/dl-laboratory kit

7

Description

Secondary serum phosphorus

Timepoint

2-6 weeks after end of treatment

Method of measurement

mg/dl-laboratory kit

8

Description

primary serum phosphorus

Timepoint

before treatment

Method of measurement

mg/dl-laboratory kit

9

Description

primary serum alkaline phosphatase

Timepoint

before treatment

Method of measurement

Unit/l-laboratory kit

10

Description

secondary serum alkaline phosphatase

Timepoint

2-6 weeks after end of treatment

Method of measurement

Unit/l-laboratory kit

Intervention groups

1

Description

300,000 IU oral Vitamin D in 6 weeks(50,000 IU once a week) in Obese children with Vitamin D deficiency

Category

Treatment - Drugs

2

Description

300,000 IU oral Vitamin D in 6 weeks(50,000 IU once a week) in Non obese children with Vitamin D deficiency

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children Medical Center

Full name of responsible person

Dr. Fatemeh Sayarifard

Street address

Gharib Ave, Keshavarz Blvd

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Central Orgaznization of Tehran University of Medical Sciences, Qods Ave, Keshavarz Blvd

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tehran 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
Name of organization / entity
Tehran University of Medical Sciences, Children Medical Center
Full name of responsible person
Dr. Fatemeh Sayarifard
Position
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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