

# 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

00982166935848-00982161475

##### Email address

f-sayarifard@tums.ac.ir

##### 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

Before 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**

Pediatric Endocrinologist/Assistant Professor

**Other areas of specialty/work****Street address**

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**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences, Children  
Medical Center

**Full name of responsible person**

Dr. Fatemeh Sayarifard

**Position**

Pediatric Endocrinologist/Assistant Professor

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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences, Children  
Medical Center

**Full name of responsible person**

Dr. Fatemeh Sayarifard

**Position**

Pediatric Endocrinologist/Assistant Professor

**Other areas of specialty/work****Street address**

Gharib Ave, Keshavarz Blvd

**City**

Tehran

**Postal code****Phone**

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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*