

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of vitamin D deficiency correction on serum Fibroblast growth factor 23 level in vitamin D deficient patients and comparison with vitamin D deficient patients

#### Protocol summary

##### Summary

Goal: investigating the effect of vitamin D supplement on serum Fibroblast growth factor 23 level in vitamin D deficient patients. Inclusion and exclusion criteria: The study was performed on vitamin D deficient patients. Vitamin D deficiency is defined as serum vitamin D level below 20 ng/ml. vitamin D deficient patients were treated with 50000 unit vitamin D per week for 12 weeks. level of Calcium; Phosphorous; Alkaline phosphatase; PTH; FGF23; 25-hydroxy vitamin D and 1,25-dihydroxy vitamin D after therapy were assessed. Society of the study: Vitamin D deficient patients in both sexes and in range 15-90 years old were included in this study. Volume of the Sample: Study was enrolled 119 vitamin D deficient patients who were divided in to case and control groups. Intervention, duration and result: The patients were enrolled through a simple random sampling and were also blindly divided in two groups. "First group, patients were given 50,000 IU of vitamin D3 (Calciferol) once a week for 12 weeks, manufactured by Roche pharmaceutical, Tehran, Iran" and "the controls were given olive oil capsules as placebo". After 12 weeks of therapy, second samples were taken from the patients. Only one physician knew each patients codes that had received vitamin D, and was not in contact with patients. Both the physician and the patients were blind to what each patient had received. After termination of the study, all the patients in the control group received proper dose of vitamin D3.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138707171312N1**

Registration date: **2017-05-16, 1396/02/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-05-16, 1396/02/26

##### Registrant information

###### Name

Mohammad Hossein Dabbaghmanesh

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1230 8728

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##### Recruitment status

###### Recruitment complete

##### Funding source

Endocrinology and Metabolic Department of "Shiraz University of Medical Sciences"

##### Expected recruitment start date

2015-12-06, 1394/09/15

##### Expected recruitment end date

2016-06-07, 1395/03/18

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of vitamin D deficiency correction on serum Fibroblast growth factor 23 level in vitamin D deficient patients and comparison with vitamin D deficient patients

**Public title**

Effect of vitamin D deficiency correction on serum Fibroblast growth factor 23 level

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Vitamin D deficient patients (serum vitamin D level under 20 ng/ml) in both sexes and in range 15-90 years old were included in this study. patients who had underlying diseases such as osteomalacia, renal failure, hyperparathyroidism; hypoparathyroidism; osteoporosis; hereditary bone disease such as autosomal dominant hypophosphatemic rickets; autosomal recessive hypophosphatemic rickets, vitamin D resistant rickets; vitamin D dependent rickets; X- linked hypophosphatemia autosomal recessive hypophosphatemia and fibrous dysplasia; recent consumption of calcium supplement; concurrent use of drugs that interfere with vitamin D such as iron supplement; Aluminum and Magnesium admixture such as anti acid drugs; proton pump inhibitors (PPI) like Omeprazole or pantoprazole; bile acid binding resins like cholestyramine; cardiac glycosides such as Digoxin; Danazole; Multi vitamin and minerals; Sucralfate; Orlistat; Thiazide diuretic; alcohol consumption; consumption of other analogs of vitamin D; Herbal drugs; use of Olive; pregnant and lactating women were excluded from the study.

**Age**

From **15 years** old to **90 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features**

none

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Shiraz University of Medical Sciences

**Street address**

Zand Street central department of Shiraz University of Medical Sciences

**City**

Shiraz

**Postal code**

7193711351

**Approval date**

2016-04-24, 1395/02/05

**Ethics committee reference number**

IR.SUMS.REC.1395.17

**Health conditions studied****1****Description of health condition studied**

Vitamin D deficiency

**ICD-10 code**

E55

**ICD-10 code description**

Vitamin D deficiency

**Primary outcomes****1****Description**

FGF23

**Timepoint**

Basal and 3 month after

**Method of measurement**

blood sample

**Secondary outcomes****1****Description**

calcium

**Timepoint**

Basal and 3 month after

**Method of measurement**

blood sample

**Intervention groups****1****Description**

In case group patients with vitamin D deficiency were treated with 50000 unit vitamin D on Fridays for 3 months and at the end of 3 months level of Calcium, Phosphorous, Fibroblast growth factor 23, Parathormon, 1,25- hydroxyl vitamin D, 25-hydroxy vitamin D, and Alkaline phosphatase, were checked.

**Category**

Treatment - Drugs

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### Description

In control group patients were treated with placebo( olive oil capsule) on fridays for 3 months and at the end of 3 months, level of Calcium , Phosphorous, fibroblast growth factor 23, parathormon , 1,25- hydroxy vitamin D, 25- hydroxy vitamin D , and Alkaline phoaphatase were checked .

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Endocrinology & Metabolism Department of Shiraz University of Medical Sciences

##### Full name of responsible person

Gholamhossein Ranjbar Omrani

##### Street address

Endocrinology & Metabolism Department of Shiraz University of Medical Sciences

##### City

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Hashemi Seyed Basir MD

##### Street address

Shiraz University of Medical Sciences

##### City

Shiraz

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shiraz 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

Shiraz University of Medical Science

#### Full name of responsible person

Forugh Saki

#### Position

Assistant Professor Shiraz University of Medical Science

#### Other areas of specialty/work

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Endocrinology & Metabolism Department of Shiraz University of Medical Sciences

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Namazi hospital Shiraz University of Medical Sciences

#### Full name of responsible person

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Fellow of adult Endocrinolgy & Metabilic disease

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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*