

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 into 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 (Colecalciferol) 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 patient's 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

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Mohammad Hossein Dabbaghmanesh

Name of organization / entity

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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

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Zand Street central department of Shiraz University
of Medical Sciences

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Postal code

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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 phoaphatase, were checked .

Category

Treatment - Drugs

2

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Hashemi Seyed Basir MD

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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

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Position

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Person responsible for updating data

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Namazi hospital Shiraz University of Medical Sciences

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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