Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of vitamin D deficiency correction on serum Fibroblast growth factor 23 level in vitamin D deficient patients and comparision 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 phosaphatase; 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 (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 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

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Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

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

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 comparision 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; osteoporesis; 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; Alluminum 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 exclude 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 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

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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