Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of cholecalciferol supplementation on Bone mineral metabolism in end stage renal disease patients in comparison with placebo

Protocol summary

Summary

Abstract INTRODUCTION There is a great interest in vitamin-D supplementation that has recently grown; as the scientific community has reported extra renal production of calcitriol by cells in nearly all body systems and the presence of vitamin-D binding receptors in different tissues5 as the 1-α hydroxylase enzyme has been found in parts of the body outside the kidney1. A recent study in hemodialysis patients showed that 1,25-dihydroxvitamin-D3 levels increased after supplementation with nutritional vitamin-D, suggesting that even in ESRD there is enough extra renal 1-α hydroxylase activity to influence serum levels there by showing a role for nutritional vitamin D in patients with kidney disease6 OBJECTIVES 1. To find the effect of oral cholecalciferol supplementation on Bone Mineral Metabolism (25 hydroxyvitamin D level, Alkaline Phosphatase, intact Parathyroid Hormone (iPTH), Calcium (Ca), Phosphorus (P), calcium phosphorus product(Ca x P)) and 2. To find the effects of its supplementation on marker of inflammation (C Reactive Protein, White blood cell count) and chronic musculoskeletal symptoms (visual analog scale). MATERIAL AND METHODS: Study Design: Double blind Randomized controlled trail. Settings: The study will be carried out in the Hemodialysis Unit, Shaikh Zayad Hospital Lahore. Duration of Study: 2 months. SAMPLE SIZE: 70 , 35 in each group The sample size of 35 was estimated by using 95% confidence level, 90% power of the test with expected iPTH level at baseline and at two months 295± 90 and 249± 80 respectively24. SAMPLING TECHNIQUE: Lottery method SAMPLE SELECTION: Inclusion criteria Age more than 18 years On hemodialysis thrice per week for more than 3 months Both the gender Patients who give informed consents Exclusion criteria The patients with history of active bleeding (melena, hematemesis, hematochezia). Patients who have taken cholecalceferol or ergocholicalciferol within two months period, Patients taking cinacalcet Iv Iron in 1 month prior to enrollment Blood transfusion 1 month prior to enrollment during the study Any diagnosed malignancy, tubercular infection, sarcoidosis, pregnancy Calcitriol or activated Vitamin D3 or erythropoietin dosage adjustment 1 month prior to enrollment Patients having corrected serum calcium>10.2 mg/dl or having serum phosphorus >6mg/dl OUTCOME VARIABLES Serum level of 25 hydroxyvitamin D level, Alkaline Phosphatase, intact Parathyroid Hormone (iPTH), Calcium (Ca), Phosphorus (P), calcium phosphorus product(Ca x P)C Reactive Protein, White blood cell count) and for Chronic musculoskeletal symptoms (visual analog scale).

General information

Acronym

ESRD-end stage renal disease

IRCT registration information

IRCT registration number: **IRCT2015091323989N1**
Registration date: **2015-11-09, 1394/08/18**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-11-09, 1394/08/18

Registrant information

Name

Sumit Acharya

Name of organization / entity

College of physician and surgeon of pakistan

Country

Pakistan

Phone

04299231320

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Recruitment status

Recruitment complete

Funding source
Department of Nephrology, Shaikh Zayad Hospital

Expected recruitment start date
2015-11-10, 1394/08/19
Expected recruitment end date
2015-12-10, 1394/09/19
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of cholecalciferol supplementation on Bone mineral metabolism in end stage renal disease patients in comparison with placebo

Public title
Effect of Vitamin D (Cholecalciferol) supplementation on bone mineral metabolism in patient on Dialysis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Age more than 18 years On hemodialysis thrice per week for more than 3 months Both the gender Patients who give informed consents Exclusion criteria: The patients with history of active bleeding (melena, hematemesis, hematochezia). Patients who have taken cholecalceferol or ergocholicalciferol within two months period, Patients taking cinacalcet Iv Iron in 1 month prior to enrollment Blood transfusion 1month prior to enrollment during the study Any diagnosed malignancy, tubercular infection, sarcoidosis, pregnancy Calcitriol or active vitamin D3 or erythropoietin dosage adjustment 1 month prior to enrollment Patients having corrected serum calcium>10.2 mg/dl or having serum phosphorus >6mg/dl
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Group A and Group B will be written in 70 close envelop, 35 each . Hemodialysis staff will take the envelop out by lottery method and allocate the group.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Dr Farkandha, National Health council, Institutional Review Board, IORG0006065, Federal postgraduate
Street address
National Health Research Complex, Federal Postgraduate Medical Institute, Shaikh Zayad Hospital, Muslim Town
City
Lahore
Postal code
0092
Approval date
2015-02-11, 1393/11/22
Ethics committee reference number
1361

Health conditions studied

1

Description of health condition studied
End stage renal disease patients on hemodialysis
ICD-10 code
N18.5
ICD-10 code description
End stage kidney disease:on dialysis

Primary outcomes

1

Description
1. 25 hydroxyvitamin D level
Timepoint
At baseline and 2 months after the date of intervention
Method of measurement
ELISA kit

2

Description
2. intact Parathyroid Hormone (iPTH)
Timepoint
At baseline and 2 months after the date of intervention
Method of measurement
ELISA kit

3

Description

3. Alkaline Phosphatase

Timepoint

At baseline and 2 months after the date of intervention

Method of measurement

Standard chemical analyzer

4

Description

4. Calcium (Ca)

Timepoint

At baseline and 2 months after the date of intervention

Method of measurement

Standard chemical analyzer

5

Description

5. Phosphorus (P)

Timepoint

At baseline and 2 months after the date of intervention

Method of measurement

Standard chemical analyzer

6

Description

6. calcium phosphorus product(Ca x P)

Timepoint

At baseline and 2 months after the date of intervention

Method of measurement

calculated from calcium and phosphorus product

Secondary outcomes

1

Description

1. C Reactive Protein

Timepoint

At baseline and 2 months after the date of intervention

Method of measurement

ELISA Kit

2

Description

2. Chronic musculoskeletal symptoms

Timepoint

At baseline and 2 months after the date of intervention

Method of measurement

Visual Analog Scale

3

Description

3. White blood cell count

Timepoint

At baseline and 2 months after the date of intervention

Method of measurement

Automated counter

Intervention groups

1

Description

Intervention /group A Supplementation with cholecalciferol will be done in 25 hydoxyvitamin D deficiency 35 patients on thrice weekly maintenence hemodialysis patients according to 25-hydroxyvitamin D3 serum levels. 50,000 IU cholecalciferol once a week will be given for patients with 25-hydroxyvitamin D levels <15 ng/ml, 10,000 IU once a week when 25-hydroxyvitamin D3 level between 16 and 30 ng/ml.The supplementation with cholecalciferol capsule, once a week will be given orally, with meal during their hemodialysis session, under supervision by study staff. All the test 25-hydroxyvitamin D3 level, iPTH, alkaline phosphatase, Ca, P, albumin, Complete blood count, and CRP level will be done before intervention and repeated after two months of supplementation.

Category

Treatment - Drugs

2

Description

Control group/Group BSimilar placebo is given to group B patients on thrice weekly maintenance hemodialysis patients according to 25-hydroxyvitamin D levels . The supplementation with placebo, once a week will be given orally, with meal during their hemodialysis session, under supervision by study staff. All the test 25-hydroxyvitamin D3 level, iPTH, alkaline phosphatase, Ca, P, albumin, Complete blood count, and CRP level will be done before the intervention and repeated after two months of supplementation.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Nephrology Department, Shaikh Zayad Hospital

Full name of responsible person

Prof Waqar Ahmed

Street address

Shaikh Zayad Hospital, Nephrology Department, Khayaban-e-jamia punjab road, Block D New Muslim Town

City

Lahore

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nephrology Department, Shaikh Zayad Hospital

Full name of responsible person
Prof Waqar Ahmed
Street address
Khayaban-e-jamia punjab road, Block D New Muslim Town
City
Lahore
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Nephrology Department, Shaikh Zayad Hospital
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
Shaikh Zayad Hospital
Full name of responsible person
Prof Dr Farrukh Iqbal
Street address
Khayaban-e-jamia punjab road, Block D New Muslim Town
City
Lahore
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shaikh Zayad Hospital
Proportion provided by this source
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
College of Physician and Surgeon of Pakistan
Full name of responsible person
Sumit Acharya
Position
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Person responsible for updating data

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Email
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Web page address

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