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 tissues as the 1-α hydroxylase enzyme has been found in parts of the body outside the kidney. A recent study in hemodialysis patients showed that 1,25-dihydroxyvitamin-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 disease. 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 trial. 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 respectively. 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) 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
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04299231320
Email address
med-2009-5529@cpsp.edu.pk
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. Calcium (Ca)

**Timepoint**
At baseline and 2 months after the date of intervention

**Method of measurement**
Standard chemical analyzer

5. Phosphorus (P)

**Timepoint**
At baseline and 2 months after the date of intervention

**Method of measurement**
Standard chemical analyzer

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. C Reactive Protein

**Timepoint**
At baseline and 2 months after the date of intervention

**Method of measurement**
ELISA Kit

2. Chronic musculoskeletal symptoms

**Timepoint**
At baseline and 2 months after the date of intervention

**Method of measurement**
Visual Analog Scale

3. White blood cell count

**Timepoint**
At baseline and 2 months after the date of intervention

**Method of measurement**
Automated counter

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### Intervention groups

1. Description

Intervention /group A Supplementation with cholecalciferol will be done in 25 hydroxyvitamin D deficiency 35 patients on thrice weekly maintenance 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 B Similar 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

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### 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
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
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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Sumit Acharya
Position
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Fax
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sumitacharya2@gmail.com
Web page address
Person responsible for updating data
Contact
Name of organization / entity
College of Physician and Surgeon of Pakistan
Full name of responsible person
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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