Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jul 2026

Comparison of treatment effect of active vitamin D versus passive vitamin D on bone metabolism indexes and PTH in hemodialysis patients

Protocol summary

Summary

Objective: Comparison of treatment effect of active vitamin D versus passive vitamin D on bone metabolism indexes and PTH in hemodialysis patients. Design: In this interventional study, a total of 40 consenting patients will be selected and divided in to intervention and control groups using block randomization method (n=20 in each group). Proper counseling will be done and a written informed consent will be obtained before starting the treatment regimen. Inclusion criteria: patients with chronic kidney disease. Exclusion criteria: Multiple myeloma. Setting and conduct: At baseline, for all diseases, tests include PTH, ALK, 25-hydroxy vitamin D and calcium is requested and the results in the questionnaire containing demographic and disease information is recorded. In the intervention group, patients will be divided into three groups based on serum levels of 25-hydroxy vitamin D (mild deficient: 16 – 20 ng/Ml , moderate deficient: 10 - 15 ng/Ml and severe deficient: < 10 ng/Ml), Then patients in mild deficient group will be received oral Rocaltrol capsule (0.25 µg every 24 hours produced by Osve CO) and oral cholecalciferol 50,000 units/week for 4 weeks (produced by Caspian tamin CO). Patients in moderate deficient group will be received oral Rocaltrol capsule every 24 hours and oral cholecalciferol 50,000 units/ every week for 8 weeks and patients in severe deficient group will be received oral Rocaltrol capsule every 24 hours and oral cholecalciferol 50,000 units/ every week for 12 weeks. Also Patients in control group will be divided into three groups based on serum levels of 25-hydroxy vitamin D (mild deficient: 16 – 20 ng/Ml , moderate deficient: 10 - 15 ng/Ml and severe deficient: < 10 ng/Ml), Then patients in mild deficient group will be received oral Rocaltrol capsule (0.25 µg every24 hours produced by Osve CO) and oral Gelatin pearl every week for 4 weeks (produced by Caspian tamin CO). Patients in moderate deficient group will be received oral Rocaltrol capsule every 24 hours and oral Gelatin pearl every week for 8 weeks and patients in severe deficient group will be received oral Rocaltrol capsule every 24 hours and oral Gelatin pearl every week for 12 weeks. Level of PTH, ALK, 25-hydroxy vitamin D and calcium after the end of the intervention will be evaluated in both groups again and the results of this study are analyzed. Outcomes measure: Serum levels of ALK, PTH, 25(OH)D, calcium

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050723559N12**
Registration date: **2017-05-24, 1396/03/03**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-05-24, 1396/03/03

Registrant information

Name

Somaieh Matin

Name of organization / entity

Ardabil University of Medicine Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ardabil University of Medical Sciences

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date
2017-11-06, 1396/08/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of treatment effect of active vitamin D versus passive vitamin D on bone metabolism indexes and PTH in hemodialysis patients

Public title
Changes of metabolism indexes and PTH in hemodialysis patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: patients with chronic kidney disease; Exclusion criteria: patients with Multiple myeloma

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
rdabil University of Medicine Sciences Ethics committee

Street address
Ardabil University of Medicine Sciences, Daneshgah street, Ardabil

City
Ardabil

Postal code
53141-56198

Approval date
2017-03-05, 1395/12/15

Ethics committee reference number
IR.ARUMS.REC.1395.131

Health conditions studied

1

Description of health condition studied
Disorders of mineral metabolism

ICD-10 code
E83

ICD-10 code description
Disorders of mineral metabolism

2

Description of health condition studied
Vitamin D deficiency

ICD-10 code
E55

ICD-10 code description
Vitamin D deficiency

3

Description of health condition studied
Chronic kidney disease

ICD-10 code
N18

ICD-10 code description
Chronic kidney disease

4

Description of health condition studied
Abnormal levels of other serum enzymes

ICD-10 code
R74

ICD-10 code description
Abnormal levels of other serum enzymes

Primary outcomes

1

Description
Serum levels of 25(OH) vit D

Timepoint
At the beginning of study and 3 month after intervention

Method of measurement
Lab

Secondary outcomes

1

Description
Serum levels of PTH

Timepoint
At the beginning of study and 3 month after intervention
Method of measurement
Lab

2

Description
Calcium serum level
Timepoint
At the beginning of study and 3 month after intervention
Method of measurement
Lab

3

Description
ALP serum level
Timepoint
At the beginning of study a 3 month after intervention
Method of measurement
Lab

Intervention groups

1

Description
Intervention group: Patients in intervention groupwill be divided into three groups based on serum levels of 25-hydroxy vitamin D (mild deficient: 16 – 20 ng/Ml , moderate deficient: 10 - 15 ng/Ml and severe deficient: < 10 ng/Ml), Then patients in mild deficient group will be received oral Rocaltrol capsule (0.25 µg every 24 hours produced by Osve CO) and oral cholecalciferol 50,000 units/week for 4 weeks (produced by Caspian tamin CO). Patients in moderate deficient group will be received oral Rocaltrol capsule every 24 hours and oral cholecalciferol 50,000 units/ every week for 8 weeks and patients in severe deficient group will be received oral Rocaltrol capsule every 24 hours and oral cholecalciferol 50,000 units/ every week for 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: Patients in control group will be divided into three groups based on serum levels of 25-hydroxy vitamin D (mild deficient: 16 – 20 ng/Ml , moderate deficient: 10 - 15 ng/Ml and severe deficient: < 10 ng/Ml), Then patients in mild deficient group will be received oral Rocaltrol capsule (0.25 µg every24 hours produced by Osve CO) and oral Gelatin pearl every week for 4 weeks (produced by Caspian tamin CO). Patients in moderate deficient group will be received oral Rocaltrol capsule every 24 hours and oral Gelatin pearl every week for 8 weeks and patients in severe deficient group will be received oral Rocaltrol capsule every 24 hours and oral Gelatin pearl every week for 12 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital, Ardabil
Full name of responsible person
Dr. Zeinab Izadi
Street address
Internal Medicine Department, Imam Khomeini Hospital, Shahid Jeddi street, Ardabil
City
Ardabil

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Ardabil University of Medical Sciences
Full name of responsible person
Dr Shahram Habibzadeh
Street address
Ardabil University of Medical Science, Daneshgah street, Ardabil, Iran
City
Ardabil
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Ardabil 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
Ardabil University of Medical Sciences
Full name of responsible person
Dr. Zeinab Izadi
Position
Internal Medicine Asisstant
Other areas of specialty/work
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Position
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Other areas of specialty/work

Street address
Ardabil University of Medical Sciences update Ardabil

City

Postal code

Phone
00

Fax

Email

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