

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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 into 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 every 24 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 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 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 every 24 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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Person responsible for scientific inquiries

Contact

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Nephrologist

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Full name of responsible person

Dr. Zeinab Izadi

Position

Internal Medicine Asisstant

Other areas of specialty/work

Street address

Ardabil University of Medical Sciences update Ardabil

City

Postal code

Phone

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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