Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of vitamin D administration on treatment of anemia in ESRD patients with vitamin D deficiency on hemodialysis

Protocol summary

Summary

Objectives: Patients with end stage renal disease suffer from anemia and chronic renal failure is a risk factor for vitamin D deficiency. The aim of this study is to investigate the effect of vitamin D prescription on Erythropoietin requirement - anemia treatment drug- in vitamin D deficient patients. Design: In this study 64 patients with end stage renal disease with at least 3 months hemodialysis will enter in study Major Inclusion and Exclusion criteria: hemoglobin level less than 12g/dL and vitamin D level less than 30ng/dL but if their calcium level is more than 9.5mg/dL or phosphate level more than 5.5mg/dL or noncompliant patients will exclude from study. Setting and conduct: In drug group (32 patients) they will receive pearl vitamin D, 50000 unit, manufactured by Zahravi company, for 12 weeks, weekly and then 3 weeks after that with cumulative dose 650000 units. In placebo group (32 patients) placebo pearl will give with the same route. Main outcome measures : In the beginning, we will checke vitamin D level, hemoglobin, ferritin, calcium and albumin. In the end of month 2 and 4 we will checke vitamin D level, and other variables will checke monthly. We will evaluate Erythropoietin requirement weekly and will calculate cumulative dose of Erythropoietin.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201505152417N17**
Registration date: **2016-08-11, 1395/05/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-08-11, 1395/05/21

Registrant information

Name
Firouzeh Moeinzadeh
Name of organization / entity
Isfahan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

Expected recruitment start date

2014-10-22, 1393/07/30

Expected recruitment end date

2015-03-21, 1394/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D administration on treatment of anemia in ESRD patients with vitamin D deficiency on hemodialysis

Public title

The effect of vitamin D administration on treatment of anemia in ESRD patients with vitamin D deficiency on hemodialysis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with renal failure on

hemodialysis for 3 months at least; Patients with hemoglobin concentration Lower than 12 g/dl; Patients with vitamin D deficiency (25(OH) vit D < 30 ng/ml); Exclusion criteria: Patients with serum calcium level more than 9.5mg/dL; Patients with serum Phosphate level more than 5.5mg/dL; Non-compliant patients; Patients who were treated by medications that could affect their Hb level such as immunosuppressants.

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **64**

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
Ethics committee of "Vice Chancellor for Research, Isfahan University of Medical Sciences"

Street address
Hezar Jarib Ave.

City
Isfahan

Postal code

Approval date
2014-09-23, 1393/07/01

Ethics committee reference number
292280

Health conditions studied

1

Description of health condition studied
End Stage Renal Disease

ICD-10 code
N18.0

ICD-10 code description
End Stage Renal Disease

Primary outcomes

1

Description
Serum 25 OH vitamin D level

Timepoint
At begining, end of 2 and 4 months

Method of measurement
ELISA, ng/mL

2

Description
Serum ferritin level

Timepoint
Monthly

Method of measurement
ELISA, mg/dL

3

Description
Serum Hemoglobin level

Timepoint
Monthly

Method of measurement
Cell counter, g/dL

4

Description
Erythropoietin dose requirement

Timepoint
Weekly

Method of measurement
Mathematically

Secondary outcomes

1

Description
Serum calcium level

Timepoint
Monthly

Method of measurement
ELISA, mg/dL

2

Description
Serum albumin level

Timepoint
Monthly

Method of measurement
ELISA, g/dL

3

Description
Serum adiponectin level
Timepoint
Begining and after 4 months
Method of measurement
ELISA

4

Description
Serum leptin level
Timepoint
Begining and after 4 months
Method of measurement
ELISA

5

Description
Serum ICAM level
Timepoint
Begining and after 4 months
Method of measurement
ELISA

6

Description
Serum VCAM level
Timepoint
Begining and after 4 months
Method of measurement
ELISA

Intervention groups

1

Description
Intervention group: Pearl vitamin D 50000 IU, weekly for 12 weeks and after 3 weeks, manufactured by Zahravi company
Category
Treatment - Drugs

2

Description
Control group: Pearl placebo, weekly for 12 weeks and after 3 weeks, manufactured by Zahravi company
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Nour Hospital, Hemodialysis centre
Full name of responsible person
Dr. Afsoon Emami
Street address
City
Isfahan

2

Recruitment center
Name of recruitment center
Amin Hospital, Hemodialysis center
Full name of responsible person
Dr. Zahraparin Hedayati
Street address
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Isfahan University of Medical Sciences
Full name of responsible person
Dr. Peyman Adibi
Street address
Hezar Jarib street
City
Isfahan
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, Isfahan 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
Isfahan University of Medical Sciences
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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