

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 31 1625 5555

Email address

moinzade@resident.mui.ac.ir

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 beginning, 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

Beginning and after 4 months

Method of measurement

ELISA

4

Description

Serum leptin level

Timepoint

Beginning and after 4 months

Method of measurement

ELISA

5

Description

Serum ICAM level

Timepoint

Beginning and after 4 months

Method of measurement

ELISA

6

Description

Serum VCAM level

Timepoint

Beginning 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. Zahrparin 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

Full name of responsible person

Dr. Firouzeh Moeinzadeh

Position

Nephrologist

Other areas of specialty/work**Street address**

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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*