

# 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

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**Full name of responsible person**

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nephrologist

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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*