Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Correlation between vitamin D3 and rise of hemoglobin in dialysis in hemodialysis ward

Protocol summary

Study aim
Determining the effect of vitamin D therapy on hemoglobin in hemodialysis patients in two groups of normal and low vitamin D levels

Design
A clinical trial with a control group with parallel randomized three-blind groups on 60 patients Random allocation role method will be used for randomization 30 patients are in the vitamin D group and 30 patients are in the placebo group

Settings and conduct
The study is performed on outpatients referred to the dialysis ward of the shohadaye gomnam Hospital and the treating physician and analyzer and the patient are unaware of their group type.

Participants/Inclusion and exclusion criteria
All available samples that have inclusion criteria, including Age over 18 years Patients undergoing dialysis more than or equal to 3 times a week for more than or equal to 90 days Receive standard treatment for anemia (erythropoietin and Venofer ampoules) for at least three months Life expectancy of more than 6 months Absence of gastrointestinal disease or surgery that affects the absorption of vitamin D. iPTH = 150-350pg / ml Exclude Criteria : 1- Hemoglobinopathy 2- Chronic liver disease 3- Dissatisfaction of the patient's companions 4- Patients who do not return one month later 5. Pregnancy 6- Dialysis adequacy less than 1.4 in the last three months 7- Transfusion in the last three months

Intervention groups
Intervention group: Patients' hemoglobin concentration and vitamin D levels will be checked. They will then be treated with vitamin D at a dose of 50,000 oral units once a week for three months. The patient's hemoglobin and vitamin D levels and other tests will be measured three months later. Control group: we give patients treated with placebo once a week for three months. The patient's tests will be measured three months later

Main outcome variables
Hemoglobin levels three months later

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190202042588N2**
Registration date: **2021-01-22, 1399/11/03**
Registration timing: **prospective**

Last update: **2021-01-22, 1399/11/03**
Update count: **0**

Registration date
2021-01-22, 1399/11/03

Registrant information

Name
Sara Salarian

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-18, 1399/11/30

Expected recruitment end date
2021-02-18, 1399/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Correlation between vitamin D3 and rise of hemoglobin in dialysis in hemodialysis ward

Public title
Evaluation of the relationship between vitamin D3 and hemoglobin in patients undergoing hemodialysis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 years Patients undergoing dialysis more than or equal to 3 times a week for more than or equal to 90 days Receive standard treatment for anemia (erythropoietin and Venofer ampoules) for at least three months Life expectancy of more than 6 months Absence of gastrointestinal disease or surgery that affects the absorption of vitamin D. Intact Parathyroid Hormone(IPTH)= 150-350pg/ml

Exclusion criteria:
Hemoglobinopathy Chronic liver disease Dissatisfaction of patient companions Patients who do not return one month later pregnancy Dialysis adequacy is less than 1.4 in the last three months Transfusion over the past three months Hypercalcemia over the past month (> 10) Hyperphosphatemia over the past month (> 5)

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

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
For this purpose, the random allocation role method will be used. For this purpose, the letter A (drug identifier) will be written on 30 sheets of paper and all letters B will be written on the other 30 papers. It is closed and placed inside the box, then the papers will be randomly removed from the box for each patient without replacement and the created sequence will be recorded.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The study is three-blind Drugs and placebos, which are completely similar in shape and packaging and made by Tehran Drug Company, will be written on one A and on one B, and the nurse will not know if the drug or placebo is the same, and the patient will not know about the drug and Or will not know if it is a placebo and after testing the patient information will be delivered to the analyzer in two groups with numbers one and two

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences

Street address
Imam Hossein Hospital, Madani Str, Tehran, Iran. Post Code

City
Tehran

Province
Tehran

Postal code
1617763141

Approval date
2020-08-08, 1399/05/18

Ethics committee reference number
IR.SBMU.RETECH.REC.1399.472

Health conditions studied

1

Description of health condition studied
Anemia in chronic kidney disease

ICD-10 code
D63.1

ICD-10 code description
Anemia in chronic kidney disease

Primary outcomes

1

Description
Hemoglobin level

Timepoint
One and three months after the start of the trial

Method of measurement
Complete Blood Count

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Thirty patients underwent hemodialysis for 6 months, and for the treatment of anemia during these six months, they were treated with Aprex 4000 ampoules three times a week subcutaneously with 100 mg Venofer ampoules from soha daroo at least twice a week. Vitamin D is less than 30 ng / dl. First, the concentration of hemoglobin, calcium, phosphorus, parathyroid hormone, C-reactive protein, iron, Total iron-binding capacity, ferritin and vitamin D levels are checked. Then, treated with Tehran darou vitamin D, we give 50,000 oral units once a week for three months. Will be taken

Category
Treatment - Drugs

2

Description
Control group: 30 patients who have undergone hemodialysis for 6 months, and for the treatment of anemia in these six months, treated with Aprex ampoule 4000 units three times a week subcutaneously with 100 mg Venofer ampoule of Saha Kish company at least twice a week and despite complete iron storage is still anemic And vitamin D levels are less than 30 ng / dl. First, the concentration of hemoglobin, calcium, phosphorus, parathyroid hormone, C-reactive protein and iron, total iron-binding capacity, ferritin and vitamin D levels are checked . Then we are treated with placebo from Tehran Daroo Company once a week for three months And vitamin D and other tests will be measured three months later

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
shohadaye gomnam Medical and Educational Center
Full name of responsible person
Sara Salarian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sara Salarian
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The whole potential data after being unidentifiable is published

When the data will become available and for how long
From 1400

To whom data/document is available
Medical Society

Under which criteria data/document could be used
Contributing to studies

From where data/document is obtainable
sarasalarian@sbmu.ac.ir

What processes are involved for a request to access data/document
two months

Comments