Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of vitamin D deficiency treatment on hemoglobin levels in hemodialysis patients

Protocol summary

Study aim
To study the effect of treatment with Vitamin D3 on Hemoglobin Levels in patients with ESRD undergoing hemodialysis and treatment with Erythropoietin

Design
Phase II randomized clinical trial, unblinded, 2 groups of 30 patients each for a total of 60 patients, followed for 12 weeks.

Settings and conduct
Vitamin D deficient patients undergoing Hemodialysis weekly and treated with erythropoietin, Referred to Sina and Imam Khomeini Hospitals in 2020 are divided between two groups. no blinding takes place.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients Undergoing Hemodialysis at least once weekly due to ESRD, Treatment with erythropoietin, Serum 25-hydroxy vitamin D content less than 30 nanograms/milliliter Exclusion Criteria: Serum 25-hydroxy vitamin D content more than 30 nanograms/milliliter

Intervention groups
2 Intervention groups, One Undergoing treatment with 50000 IU Pearl Vitamin D3 once weekly, the other group Undergoes treatment with Calcium-Vitamin D3 500 mg Oral tablets three times a day, each for 12 weeks.

Main outcome variables
Serum Hemoglobin Levels

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190107042264N4**
Registration date: **2020-12-16, 1399/09/26**
Registration timing: **retrospective**

Last update: **2020-12-16, 1399/09/26**
Update count: **0**

Registration date
2020-12-16, 1399/09/26

Registrant information

Name
Ehsan Hedayatinejad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3334 3368

Email address
hedayatee.e@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-21, 1399/04/01

Expected recruitment end date
2020-08-19, 1399/05/29

Actual recruitment start date
2020-06-21, 1399/04/01

Actual recruitment end date
2020-08-22, 1399/06/01

Trial completion date
2020-11-30, 1399/09/10

Scientific title
Evaluation of the effect of vitamin D deficiency treatment on hemoglobin levels in hemodialysis patients

Public title
Vitamin D Treatment in Hemodialysis patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients Undergoing Hemodialysis at least once weekly due to ESRD Treatment with erythropoietin Serum 25-

hydroxy vitamin D content less than 30 nanograms/milliliter

Exclusion criteria:

Serum 25-hydroxy vitamin D content more than 30 nanograms/milliliter

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **55**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a Sequence Generator (freely available at www.random.org), A set of numbers from 1 to 60 was requested in two columns, the results were two columns of 30 Integers from one to 60, without repetition, which were used for division.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Faculty of Medicine, Ahvaz Jundishapur University of Medical Sciences, Esfand Street, Golestan, Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

1579461357

Approval date

2020-06-20, 1399/03/31

Ethics committee reference number

IR.AJUMS.REC.1399.288

Health conditions studied

1

Description of health condition studied

Anemia in patients with End Stage Kidney Disease (ESRD)

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Serum Hemoglobin level

Timepoint

before intervention, 3 months after intervention

Method of measurement

Complete Blood Count

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: This group Undergoes treatment with 50000 IU Pearl Vitamin D3 once weekly for 12 weeks.

Category

Treatment - Drugs

2

Description

Intervention group 2: This group Undergoes treatment with Calcium-Vitamin D3 500 mg Oral tablets three times a day for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Teaching Hospital

Full name of responsible person

Shahla Ahmadi Halili

Street address

Imam Khomeini Hospital - Shahid Ahvazian Street - Azadegan Street

City

Ahvaz

Province

Khouzestan

Postal code

6193673111
Phone
+98 61 3222 2114
Email
ahmadihalili-sh@ajums.ac.ir
Web page address
https://himam.ajums.ac.ir/

2

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Shahla Ahmadi Halili
Street address
Sina Hospital, Imam Ali Square, Ayatollah Behbehani Highway, Karun
City
Karun
Province
Khouzestan
Postal code
1711161991
Phone
+98 61 1555 0591
Email
ahmadihalili-sh@ajums.ac.ir
Web page address
https://hsina.ajums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehdi Ahmadi Moghadam
Street address
Vice Chancellory of Research and Technology, Central Library, Daneshjou Square, Ahvaz Jundishpaur University of Medical Sciences, Esfand Street, Golestan
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8383
Email
ahmadi-m@ajums.ac.ir
Web page address
https://vchresearch.ajums.ac.ir
Grant name
Evaluation of effect of vitamin D defieiency treatment on level of HB in Hemodialysis patients
Grant code / Reference number
CRD-9902
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Shahla Ahmadi Halili
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Imam Khomeini Hospital - Shahid Ahvazian Street - Azadegan Street
City
Ahvaz
Province
Khouzestan
Postal code
6193673111
Phone
+98 61 3222 2114
Email
ahmadihalili-sh@ajums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Shahla Ahmadi Halili
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Imam Khomeini Hospital - Shahid Ahvazian Street - Azadegan Street
City

Ahvaz
Province
Khouzestan
Postal code
6193673111
Phone
+98 61 3222 2114
Email
ahmadihalili-sh@ajums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Shahla Ahmadi Halili
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Imam Khomeini Hospital - Shahid Ahvazian Street - Azadegan Street
City
Ahvaz
Province
Khouzestan
Postal code
6193673111
Phone
+98 61 3222 2114
Email
ahmadihalili-sh@ajums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available