

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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

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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

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6135715794

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<https://vchresearch.ajums.ac.ir>

Grant name

Evaluation of effect of vitamin D deficiency 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

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Email

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Shahla Ahmadi Halili
Position
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Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
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Postal code
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Phone
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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