Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of protein nutritional supplements on erythropoietin resistance in individuals with protein-energy wasting syndrome undergoing hemodialysis at Imam Hussein Hospital: A randomized clinical trial

Protocol summary

Study aim

To determine the effect of improving nutritional status on the response of hemodialysis patients to erythropoietin therapy, we conducted a study to determine whether correction of malnutrition could reduce the need for high doses of erythropoietin-stimulating agents (ESAs), improve anemia, and improve patients' quality of life.

Design

All eligible subjects will be randomly assigned to one of two groups, either supplement or control, in a 1:1 ratio. The randomization method will be permuted block randomization. Sample size = 50

Settings and conduct

In the intervention group, 25 patients will use vm protein powder for three months as prescribed and under the supervision of a nutritionist and nephrologist. 25 patients in the control group will continue their routine diet. For both groups before and after the intervention, erythropoietin resistance index, serum erythropoietin levels, ferritin, hemoglobin, CRP, nutritional status and prevalence of PEW will be measured based on MUST scales and body composition analysis with the InBody S10 device.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with chronic kidney disease undergoing chronic hemodialysis for at least 6 months. Diagnosis of PEW according to international criteria weight loss ≥ 5% in the last 3 monthsor BMI<23 Reduced muscle mass based on BIA measurement Reduced serum albumin or reduced serum TIBC level Reduced energy and protein intake Written consent to participate in the study

Intervention groups

In the intervention group, 25 patients used VM protein powder for three months as prescribed and under the supervision of a nutritionist and nephrologist. In the control group, 25 patients will enter the study without any changes in their diet and lifestyle.

Main outcome variables

serum erythropoietin, erythropoietin resistance index, erythropoietin dose, hemoglobin levels, Esr,Crp

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210301050546N1**
Registration date: **2025-08-02, 1404/05/11**
Registration timing: **prospective**

Last update: **2025-08-02, 1404/05/11**
Update count: **0**

Registration date

2025-08-02, 1404/05/11

Registrant information

Name

Ghazale Ghorbani Garakani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2286 3637

Email address

ghazaal.ghorbani.1@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-06, 1404/05/15

Expected recruitment end date
2025-11-06, 1404/08/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of protein nutritional supplements on erythropoietin resistance in individuals with protein-energy wasting syndrome undergoing hemodialysis at Imam Hussein Hospital: A randomized clinical trial

Public title
Investigating the effect of protein nutritional supplements on erythropoietin resistance in individuals with protein-energy wasting syndrome undergoing hemodialysis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with chronic kidney disease (CKD) who are undergoing chronic hemodialysis for at least 6 months. Diagnosis of protein-energy wasting syndrome based on international criteria Weight loss ≥ 5% in the last 3 months or body mass index less than 23 Decreased muscle mass based on BIA measurement or SGA index Decreased serum albumin (<3.8 g/dL) or decreased serum TIBC level (<200 mg/dL) Reduced energy and protein intake (<25 kcal/kg/day and <1.0 g/kg/day) Receiving erythropoietin treatment for at least the last 3 months Written consent to participate in the study
Exclusion criteria:
Acute inflammatory diseases or active infections Malignant diseases (active cancer) or receiving chemotherapy Anemia due to non-renal causes (MDS hemoglobinopathy) Taking steroids or immunosuppressant drugs
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
All eligible subjects will be randomly assigned to one of two groups, either the supplement or the control, in a 1:1 ratio. The randomization method will be permuted block randomization, with blocks based on sample size in 7 blocks of sizes 4, 6, 8, and 10 using the “Ralloc” package in STATA software. Participants will be assigned to each group based on the sample size determined and the list of randomized individuals (along with a specific research code for each individual).
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 Shahid Beheshti University of Medical Sciences
Street address
No. 6. Seyed Khandan, Abuzar Ghaffari South, 6th Alley, , Unit 1
City
Tehran
Province
Tehran
Postal code
1661645513
Approval date
2025-07-12, 1404/04/21
Ethics committee reference number
IR.SBMU.MSP.REC.1404.173

Health conditions studied

1

Description of health condition studied
Patients with protein energy wasting syndrome undergoing hemodialysis
ICD-10 code
N18.9
ICD-10 code description
Chronic kidney disease, unspecified

Primary outcomes

1

Description
Serum erythropoietin changes
Timepoint
At the beginning of the study and three months after consuming the protein powder
Method of measurement
Blood sample and laboratory examination

2

Description
Erythropoietin resistance index
Timepoint
At the beginning of the study and three months after consuming the protein powder
Method of measurement
Blood sample and laboratory examination

3

Description
Serum hemoglobin level
Timepoint
At the beginning of the study and three months after consuming the protein powder
Method of measurement
Blood sample and laboratory examination

4

Description
Changes in serum albumin and TIBC levels
Timepoint
At the beginning of the study and three months after consuming the protein powder
Method of measurement
Blood sample and laboratory examination

5

Description
Changes in serum ferritin levels
Timepoint
At the beginning of the study and three months after consuming the protein powder
Method of measurement
Blood sample and laboratory examination

6

Description
CRP and ESR changes
Timepoint
At the beginning of the study and three months after consuming the protein powder
Method of measurement
Blood sample and laboratory examination

7

Description
Changes in body analysis indicators
Timepoint
At the beginning of the study and three months after consuming the protein powder
Method of measurement
InBody S10 device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 25 patients, as prescribed and under the supervision of a nutritionist and nephrologist, use VM protein powder for three months. VM-protein 24 grams orally, manufactured by Iran Darou Company, daily for three months.
Category
Treatment - Other

2

Description
Control group: Adherence to the standard treatment protocol for hemodialysis patients without making any changes to their lifestyle
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hussein (AS) Educational and Research Center
Full name of responsible person
Ghazaleh Ghorbani Garakani
Street address
Tehran - Shahid Madani Street - Imam Hussein (AS) Educational, Research and Treatment Center
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1617763141
Phone
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Email
info@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Farnaz Sabrian
Street address
Haran - Shahid Madani Street - Imam Hussein (AS) Educational, Research and Treatment Center
City
Tehran
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Tehran
Postal code

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Phone

+98 921 218 5994

Email

farnaz.saberain@sbmu.ac.ir

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

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ghazale Ghorbani Garakani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

No. 6. Seyed Khandan, Abuzar Ghaffari South, 6th Alley, , Unit 1

City

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Email

ghazaal.ghorbani.1@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ghazale Ghorbani Garakani

Position

Resident

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ghazale Ghorbani Garakani

Position

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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