

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 $\geq 5\%$ in the last 3 months or 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 $\geq 5\%$ 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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Postal code

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

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Tehran

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Resident

Latest degree

Medical doctor

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

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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