

# 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  $\geq 5\%$  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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1617763141

##### **Phone**

+98 921 218 5994

##### **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

##### **Province**

Tehran

##### **Postal code**

1617763141

**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**

Tehran

**Province**

Tehran

**Postal code**

1661645513

**Phone**

+98 21 2286 3637

**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**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1661645513

**Phone**

+98 21 2286 3637

**Email**

ghazaal.ghorbani.1@gmail.com

**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**

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**

Tehran

**Province**

Tehran

**Postal code**

1661645513

**Phone**

+98 21 2286 3637

**Email**

ghazaal.ghorbani.1@gmail.com

**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