

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The Effect of Oral Nutritional protein Supplement on Nutritional Status and protein energy wasting of Hemodialysis Patients : a randomized double-blind, placebo-controlled trial

Protocol summary

Study aim

Investigating the effect of protein nutrition supplements on the improvement of protein energy loss and nutritional status of hemodialysis patients referred to Imam Hossein Hospital in 1402

Design

In this clinical trial, 52 patients undergoing hemodialysis were randomly assigned into two groups receiving vm protein supplement and placebo. In the intervention group, according to the prescription and under the supervision of a nutritionist and nephrologist, vm protein powder is used for six months.

Settings and conduct

Patients with chronic kidney disease under routine hemodialysis diagnosed with protein-energy wasting referred to Imam Hossein hospital in Tehran in 1402

Participants/Inclusion and exclusion criteria

Inclusion criteria: including the age range of 20 to 70 years, albumin less than 4 gr/dl, at least 6 months under treatment with Hemodialysis, performing hemodialysis at least twice a week, malnourished patients who are undergoing hemodialysis and have a score of 1 or higher according to the MUST questionnaire. Exclusion criteria Severe heart and respiratory failure, chronic inflammatory disease with known origin, chronic liver disease, nephrotic syndrome, cancer, dementia, neurological disease, hepatitis B, hepatitis C, HIV, active and acute infection in the last 4 weeks, recent surgery in the last three months or during follow-up, malignancy Accompanying and hospitalization in the last 3 months that may affect the nutritional or functional status was not using parenteral nutrition and oral supplements.

Intervention groups

Consumption of VM-protein in the amount of 24 grams orally manufactured by Iran Daru Company for six months on a daily basis (within 6 months from the beginning of the study)

Main outcome variables

Improving the state of energy protein loss

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230622058559N1**

Registration date: **2023-08-15, 1402/05/24**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-15, 1402/05/24**

Update count: **0**

Registration date

2023-08-15, 1402/05/24

Registrant information

Name

fataneh babrisha

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8841 5905

Email address

farnaz.saberian@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-06, 1402/05/15

Expected recruitment end date

2024-01-05, 1402/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of Oral Nutritional protein Supplement on Nutritional Status and protein energy wasting of Hemodialysis Patients : a randomized double-blind, placebo-controlled trial

Public title
The Effect of Oral Nutritional protein Supplement on Nutritional Status and protein energy wasting of Hemodialysis Patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 20-70 years albumin<4gr/dl the patient under hemodialysis from 6 months ago (at least 2 times in a week) malnutrition based on must score>1
Exclusion criteria:
 lack of informed consent for participating history of chronic diseases such as liver diseases, malignancies, severe cardiopulmonary diseases history of any surgery within past 3 months history of hospitalization due to malignancies within past 3 months history of allergy due to oral nutritional supplements

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Data analyser
- Data and Safety Monitoring Board

Sample size
 Target sample size: **52**
 More than 1 sample in each individual
 Number of samples in each individual: **1**
 Interpretation of bioimpedance before and after intervention

Randomization (investigator's opinion)
Randomized

Randomization description
All eligible people will be randomly assigned to one of the two groups to receive medicine or placebo with a ratio of 1:1. The randomization method will be permuted block randomization, and the blocks will be based on the sample size in sizes 2, 4, 6, 8, 10 or more using the "Ralloc" package in STATA software. Patients will be included in each group based on the determined sample size and based on the list of randomized individuals (along with a specific research code for each individual).

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double-blind. The medicine and placebo

needed for the people participating in the study will be sent to the treatment center from the manufacturing company in a completely covered and indistinguishable form for use by patients. The people participating in the study and the clinical evaluators of the patients (specialist doctors) will not be aware of the drug or placebo.

Placebo
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
 439 Heydari St., Unit 13, South Majidiyeh
City
 tehran
Province
 Tehran
Postal code
 1636618173

Approval date
2023-06-03, 1402/03/13

Ethics committee reference number
IR.SBMU.MSP.REC.1402.097

Health conditions studied

1

Description of health condition studied
Chronic kidney failure stage 5

ICD-10 code
N18.5

ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Bio-impedance device analysis

Timepoint
At the beginning of the study (before the start of the intervention) and 6 months after the start of VM protein

Method of measurement
Bio-impedance device

Secondary outcomes

1

Description

MUST score

Timepoint

before the start of the intervention and six months after the start of vm protein

Method of measurement

Malnutrition Universal Screening Tool (MUST)

Intervention groups

1

Description

Consumption of VM-protein powder in the amount of 24 grams orally manufactured by Iran Daru Company for 6 months on a daily basis (within 6 months from the start of the study)

Category

Treatment - Drugs

2

Description

Control group: Taking 24 grams of placebo powder orally manufactured by Iran Daru Company for 6 months on a daily basis (within 6 months of the start of the study)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Fataneh Babrishal

Street address

Shahid Madani Street, Imam Hossein Hospital

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7343 0000

Email

farnaz.saberian@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

madani

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7343 0000

Email

farnaz.saberian@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

0

Proportion provided by this source

1

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Farnaz Saberian

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Shahid Madani Street, Imam Hossein Hospital

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7343 0000

Email

farnaz.saberian@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Farnaz Saberian

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Phone

+98 21 7343 0000

Email

farnaz.saberian@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fataneh Babrishal

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

No. 439, Majidieh St., Heydari St

City

Tehran

Province

Tehran

Postal code

1636618173

Phone

+98 21 8841 5905

Email

fatanehbabrishal@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Statistical analyzes are performed on the delivered data

From where data/document is obtainable

Dialysis Department of Imam Hossein Hospital

What processes are involved for a request to access data/document

After a period of 6 months

Comments