Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 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 babrishal
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 8841 5905
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Afshin Zarghi
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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
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Person responsible for updating data

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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