Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Omega-3 Supplementation on Inflammatory Clinical Markers and Body Composition in Hemodialysis Patients A randomized, triple-blind, placebo- controlled trial

Protocol summary

Study aim

Determining the effect of omega-3 supplementation on inflammatory and clinical indicators and body composition of chronic kidney failure patients undergoing hemodialysis

Design

Clinical trial with a control group, with parallel groups, triple blind, randomized, phase 3 on 120 patients. WinPepi 11.0 software was used for randomization.

Settings and conduct

This study will be conducted on dialysis patients of Rasht's Caspian Center's dialysis department and will be randomly assigned. A member of the research team not involved in the selection of samples will determine the sequence of random allocation using a computer program. Three capsules of omega-3 fatty acids supplement for 2 months to the intervention group patients and three placebo capsules containing MCT oil to the control group. The two groups are matched in terms of their dietary intake of omega-3 fatty acids. In order to prevent the abuse of supplements and follow up the process of drug consumption, the drugs will be given to the patients in the form of 21 packs on a weekly basis, and the method of taking the supplements will be followed up by the project colleagues on a weekly basis in person or by phone.

Participants/Inclusion and exclusion criteria

Written consent; Age above 20 years

Intervention groups

Omega-3 capsules contain 1000 mg of fish oil, 180 mg of EPA and 120 mg of DHA and auxiliary components of gelatin, glycerin, sodium methylparaben, sodium propylparaben, and the only difference is the absence of eicosapentaenoic acid and docosahexaenoic acid in placebo.

Main outcome variables

Average serum level of inflammatory indicators, body fat percentage, dialysis itch, anemia level, urea level, creatinine level, serum ferritin level, serum albumin level, muscle mass, serum PTH level, serum cholesterol and triglyceride and HDL LDL levels, hemodialysis quality based on calculation KT/V

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151226025699N6**
Registration date: **2022-12-24, 1401/10/03**
Registration timing: **retrospective**

Last update: **2022-12-24, 1401/10/03**
Update count: **0**

Registration date

2022-12-24, 1401/10/03

Registrant information

Name

Saeid Doaei

Name of organization / entity

National Nutrition and Food Technology Research Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 6643 6744

Email address

sdoaei@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-06, 1401/08/15

Expected recruitment end date
2022-12-06, 1401/09/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Omega-3 Supplementation on Inflammatory Clinical Markers and Body Composition in Hemodialysis Patients A randomized, triple-blind, placebo- controlled trial

Public title
Investigating the effect of omega-3 supplementation on inflammatory indices of dialysis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Written consent Age over 20 years
Exclusion criteria:
No tendency to participate in the study Having incomplete medical records Consumption of omega-3 fatty acids supplementation during the last 3-month before the study
Age
From **20 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Allocation of people to study groups (test and control) was done by random block method and using WinPepi11.0 software (http://www.brixtonhealth.com/pepi4windows.html). This software generates random groups. The output of the software is in the form of six blocks of numbers, in each block 3 people belong to the control group and 3 people belong to the intervention group, and the software itself randomly arranges the blocks. Finally, 16 blocks were used and the samples are entered into the study in order. The steps of using the mentioned software were as follows: ETCETERA, choose Random allocation (Randomization), then choose Balanced Randomization, and finally Successive blocks. A member of the research team not involved in the selection of samples will determine the sequence of random allocation using a computer program. Randomly sequenced opaque sealed envelopes will be used to conceal the allocation.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This research is done in a triple-blind way. In this way, the patient, the researcher, and the statistical analyst are not aware of the study arms. The patient is blinded by providing a placebo similar in shape and appearance to the drug in the intervention group. Project researchers do not know the groups of people when taking questionnaires and tests from the participants before and after the intervention. Someone outside the treatment team also does the evaluation of the results; In such a way that the evaluator researchers are not aware of the type of allocation.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Gilan University of Medical Sciences
Street address
Rasht, Namjo St., Shahid Siyadati St. in front of 17 Shahrivar Hospital, University Research and Technology Vice-Chancellor
City
Rasht
Province
Guilan
Postal code
3369741938
Approval date
2022-08-31, 1401/06/09
Ethics committee reference number
IR.GUMS.REC.1401.307

Health conditions studied

1

Description of health condition studied
Patients with chronic kidney failure undergoing hemodialysis
ICD-10 code
N18
ICD-10 code description
Chronic kidney disease (CKD)

Primary outcomes

1

Description
Body fat percentage
Timepoint
Before the intervention, after the intervention
Method of measurement
It is calculated with a bio-impedance analyzer (BIA)

2

Description
Dialysis itching
Timepoint
Before the intervention, after the intervention
Method of measurement
asking people and determining the intensity according to the Visual Analogue Scale

3

Description
Anemia rate based on KT/V calculation
Timepoint
Before the intervention, after the intervention
Method of measurement
It is calculated based on measuring the level of hemoglobin

4

Description
urea level
Timepoint
Before the intervention, after the intervention
Method of measurement
serum level per milliliter of blood recorded in the laboratory

5

Description
Creatinine level
Timepoint
Before the intervention, after the intervention
Method of measurement
serum level per milliliter of blood recorded in the laboratory

6

Description
Serum PTH level
Timepoint
Before the intervention, after the intervention
Method of measurement
serum level per milliliter of blood recorded in the laboratory

7

Description
muscle mass
Timepoint
Before the intervention, after the intervention
Method of measurement
It is calculated with a bio-impedance analyzer (BIA).

8

Description
Hemodialysis quality based on KT/V calculation
Timepoint
Before the intervention, after the intervention
Method of measurement
Dialysis quality is measured in this center or the KT/V index. (K= Clearance, T= Time on HD, V= Volume of distribution of Urea)

Secondary outcomes

1

Description
Cholesterol, triglyceride, and HDL and LDL serum levels
Timepoint
Before the intervention, after the intervention
Method of measurement
serum level per milliliter of blood recorded in the laboratory

2

Description
Serum ferritin level
Timepoint
Before the intervention, after the intervention
Method of measurement
serum level per milliliter of blood recorded in the laboratory

3

Description
Serum albumin level
Timepoint
Before the intervention, after the intervention
Method of measurement
serum level per milliliter of blood recorded in the laboratory

Intervention groups

1

Description
Intervention group: Omega-3 capsule contains 1000 mg of fish oil, 180 mg of EPA and 120 mg of DHA and auxiliary components of gelatin, glycerin, sodium methylparaben, sodium propylparaben. Three capsules of omega-3 fatty acids supplement by Zahrawi company are given orally daily for 2 months to patients in the

intervention group. The two groups are matched in terms of their dietary intake of omega-3 fatty acids. In order to prevent the abuse of supplements and follow up the process of drug consumption, the drugs will be given to the patients in the form of 21 packs on a weekly basis, and the method of taking the supplements will be followed up by the project colleagues on a weekly basis in person or by phone. Patients are contacted regularly (once a week) in order to prevent participants from withdrawing from the study, controlling drug use or non-use of other supplements, the occurrence of an incident affecting the study, as well as the absence of side effects or gastrointestinal symptoms in the participants. And if any of the above cases exist, the necessary actions and follow-ups will be carried out by the project researchers. Also, the research colleagues talked with the participants about the possible benefits of the study and encouraged them to continue the study. In addition to these cases, the supplements were delivered to the participants in eight 21 times at the Caspian center and they were asked to return the previously used envelopes. This allows researchers to measure adherence to treatment to some extent. After the completion of two months, in order to obtain post-test data and follow-up; The participants will be contacted again and will be invited and encouraged to complete the questionnaires and perform the tests.

Category

Treatment - Drugs

2

Description

Control group: Placebo is completely similar to the probiotic supplement in terms of shape, color, size and packaging, even fillers or auxiliary materials (gelatin, glycerin, sodium methylparaben, sodium propylparaben) and the only difference is the absence of eicosapentaenoic acid and docosahexaenoic acid. The acid is in the placebo. Three placebo capsules containing MCT oil (medium-chain triglyceride) of Zahrawi company, similar to the supplemental dose of the intervention group, are given during this period. The two groups are matched in terms of their dietary intake of omega-3 fatty acids. In order to prevent the abuse of supplements and follow up the process of drug consumption, the drugs will be given to the patients in the form of 21 packs on a weekly basis, and the method of taking the supplements will be followed up by the project colleagues on a weekly basis in person or by phone. Patients are contacted regularly (once a week) in order to prevent participants from withdrawing from the study, controlling drug use or non-use of other supplements, the occurrence of an incident affecting the study, as well as the absence of side effects or gastrointestinal symptoms in the participants. And if any of the above cases exist, the necessary actions and follow-ups will be carried out by the project researchers. Also, the research colleagues talked with the participants about the possible benefits of the study and encouraged them to continue the study. In addition to these cases, the supplements were delivered to the participants in eight 21 times at the Caspian center and they were asked to return the previously used envelopes. This allows researchers to measure adherence to treatment to some extent. After the completion of two months, in order to obtain post-test data and follow-up; The participants will be contacted again and will be invited and encouraged to complete the questionnaires and perform the tests.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Caspian Dialysis Center, Rasht

Full name of responsible person

Masoud Khosravi

Street address

Rasht . Staghat1 St. Next to Razi Hospital. Shahid Madani Alley

City

Rasht

Province

Guilan

Postal code

4144895655

Phone

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Email

drmasoud91@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Siavash Falahatkar

Street address

Rasht, Sardar Jangal St., Razi Medical Education and Research Center, Urology Research Center

City

Rasht

Province

Guilan

Postal code

9565541448

Phone

+98 13 3352 5259

Email

falahatkar_s@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht University of Medical Sciences

Proportion provided by this source

40

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

2

Sponsor

Name of organization / entity
Zahrawi Pharmaceutical Company

Full name of responsible person
Farhad Ghafourian

Street address
Tabriz, km 19 of Tabriz Road, Tehran, Serm Daro St

City
Tabriz

Province
East Azarbaijan

Postal code
8459143344

Phone
+98 41 3630 9401

Email
info@zahravipharma.com

Grant name

Grant code / Reference number

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

Title of funding source
Zahrawi Pharmaceutical Company

Proportion provided by this source
60

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
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Saeid Doaei

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
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Assistant Professor

Latest degree
Medical doctor

Other areas of specialty/work
Medical Education

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Rasht Rasht - Elkhebal Street (Haji Abad) - Corner of Towaf Alley - Baath Specialist and Subspecialty Clinic

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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009821
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Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
A part of the data, such as information related to the main outcome or the like, can be shared after de-identifying people with the coordination of the responsible author.
When the data will become available and for how long
-
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Correspondence with the corresponding author provides further information
From where data/document is obtainable
sdoaee@yahoo.com
What processes are involved for a request to access data/document
-
Comments