

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

AgeFrom **20 years** old**Gender**

Both

Phase

3

Groups that have been masked

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

Sample sizeTarget 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

+98 13 3352 8801

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

Street address

National Nutrition and Food Technology Research Institute, Farahzadi St.

City

Tehran

Province

Tehran

Postal code

4532166542

Phone

+98 21 6643 6744

Fax

+98 13 3333 3413

Email

sdoaei@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Haider Ali Baloo

Position

Assistant Professor

Latest degree

Medical doctor

Other areas of specialty/work

Medical Education

Street address

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

City

Rasht

Province

Guilan

Postal code

4735166734

Phone

+98 13 3326 1446

Fax

+98 13 3326 1446

Email

Balou@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Saeid Doaei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Shahid Beheshti University of Medical Sciences, Tehran, IRAN.

City

Tehran

Province

Tehran

Postal code

009821

Phone

+98 21 6643 6744

Email

sdoaei@sbmu.ac.ir

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

sdoae@yaho.com

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

-

Comments