Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Effect of Omega-3 therapy on the serum level of Homocysteine in peritoneal dialysis patients

Protocol summary

Study aim
The aim of this study is to investigate several parameters related to oxidative stress and systemic inflammation, especially homocysteine in peritoneal dialysis patients receiving omega-3 fatty acids.

Design
A concealed, randomized, blinded, sham-controlled clinical trial with a parallel-group design of 100 patients, block randomization was used for randomization.

Settings and conduct
Individuals who meet the inclusion criteria will be randomly assigned to the intervention and control groups. Demographic and clinical characteristics of patients will be recorded. Patients in the omega-3 soft capsule intervention group will receive one gram with each meal for 8 weeks. Participants in the control group will receive a placebo. Serum lipid profile, serum albumin level, ESR level, hs-CRP level and serum homocysteine level were measured in all patients before the start of the study and after 8 weeks at the end of the study. Finally, using statistical tests, the average of the measured tests will be compared between the two groups. Researchers and patients are blinded

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 18 years and older, ESRD patients undergoing peritoneal dialysis, informed consent to participate in this study Exclusion criteria: history of malignancy, patients with a history of known allergies to products containing omega-3, coagulation disorders and use of anticoagulants, use of any antioxidant or anti-inflammatory drugs, severe systemic diseases or infectious diseases

Intervention groups
For the intervention group omega-3 capsules (120 mg DHA plus 180 mg EPA) at a dose of 3000 mg per day, ie 1000 mg with each meal per day for 8 weeks will be prescribed and the control group will receive a placebo.

Main outcome variables
Homocysteine levels and inflammatory and oxidative markers

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160713028901N2**
Registration date: **2020-09-07, 1399/06/17**
Registration timing: **prospective**

Last update: **2020-09-07, 1399/06/17**
Update count: **0**

Registration date
2020-09-07, 1399/06/17

Registrant information

Name
Shirinsadat Badri

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-22, 1399/07/01

Expected recruitment end date
2021-06-22, 1400/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effect of Omega-3 therapy on the serum level of Homocysteine in peritoneal dialysis patients

Public title
The effect of omega-3 on the serum level of homocysteine in peritoneal dialysis patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
At least 18 years old ESRD patients undergoing peritoneal dialysis Informed consent to participate in this study

Exclusion criteria:

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

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

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the basis of randomization of samples will be based on the Blocked randomization method. Information such as the number of treatment groups (the two main intervention groups, for example, A and placebo, for example, B), the size of the blocks (a multiple of the number of groups that will be selected in this study to reduce the complexity of size 4 work) and the total number of patients (Enter the sample size of 100 people) into the Internet software for this calculation (for example, available at https://www.sealedenvelope.com/simple-randomiser/v1/lists) and according to the codes with the final analysis is obtained, a code is assigned to each patient who enters the study, and the type of group that should take medication or placebo will be determined. Blocking is usually used to balance the number of samples assigned to each of the groups studied. In this method, equal blocking will be used. In this way, the samples are randomized as much as possible in both groups. At the end of the sampling, the code of each patient is opened and matched with the software output, and as far as possible, the data collector and intervener try to be informed of the drug code information only after analyzing the data.

Blinding (investigator's opinion)
Double blinded

Blinding description
Due to the nature of soft gelatin, preparation of placebo related to omega-3 capsules cannot be done in Isfahan School of Pharmacy and will be done in coordination with Zahravi Company in that factory. According to the company's pharmaceutical experts, edible vegetable oils that do not contain linoleic acid are used to make placebo. Also, the main omega-3 product containing each capsule (EPA equivalent of 180 mg and equivalent of 120 mg) is prepared from the same factory so that the drug and placebo are in the same package and the blinding method can be performed well. Then a small number of placebo and supplement products for a patient, provided they complete the entire course with a dose of three times a day and a special code, are provided to the student. The information in this special code on drug packages is only available to the main executor of the project who is not involved in the sampling, and the rest of the project partners do not know if the relevant code is for the drug or placebo. Thus, sampling will be done by the blind method.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Isfahan university of medical sciences

Street address
Hezar-Jerib street

City
Isfahan

Province
Isfehan

Postal code

Approval date
2020-09-04, 1399/06/14

Ethics committee reference number
IR.MUI.MED.REC.1399.458

Health conditions studied

1

Description of health condition studied
Peritoneal dialysis

ICD-10 code
Z49.2

ICD-10 code description
Other dialysis

Primary outcomes

1

Description
Homocysteine levels and inflammatory and oxidative factors
Timepoint
Before the start and at the end of week 8
Method of measurement
Homocysteine measurement kit; Other parameters will be measured according to the laboratory standard

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Omega-3 capsules (120 mg DHA plus 180 mg EPA) at a dose of 3000 mg per day, ie 1000 mg with each meal per day for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: Placebo, with each meal for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra University Hospital
Full name of responsible person
Shirinsadat Badri
Street address
Soffe Blvd
City
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Postal code
8174675731
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2

Recruitment center
Name of recruitment center
Isfahan Noor Hospital
Full name of responsible person
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Intersection of Hasht Behesht Street and Governor Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
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

Person responsible for general inquiries

Contact
Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person
Shirinsadat Badri

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Confidentiality of information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not 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
No - There is not a plan to make this available