

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of omega-3 fatty acid supplementation on oxidative stress in continuous ambulatory peritoneal dialysis patients

Protocol summary

Summary

End stage renal disease (ESRD) is a condition that inflammation and oxidative stress plays an important role in damaging to tissues, especially in vascular system. The effect of omega-3 fatty acids is well documented in some inflammatory diseases via eicosapentanoic acid (EPA) and docosahexanoic acid (DHA) components of fish oil. The aim of this study was to investigate the effects of dietary omega-3 fatty acid supplementation on levels of lipid peroxidation and oxidative stress in ESRD patients. In this study, 90 patients arrived if they are on chronic ambulatory peritoneal dialysis for 3 months, clinically stable without serious disease and in stage 1 hypertension. If patient have chronic diarrhea, malignancy, thrombocytopenia (less than 100000/mm³, coagulation disorders, need to anticoagulant drugs or psychosomatic disorders exclude from study. Group 1 (45 patients) using omega 3 capsuls, 1000mg, manufactured by Zahravi Pharmaceutical, 3 times a day for 6 weeks. Group 2 (45 patients) using placebo capsules, manufactured by Zahravi pharmaceutical, 3 times a day for 6 weeks. Serum level of reduced glutathione and superoxid dismutase are measured at beginning and end of the study so iron, ferritin, lipid profile. Erythropoietin requirement is measured at beginning and end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212142417N10**

Registration date: **2012-12-27, 1391/10/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-12-27, 1391/10/07

Registrant information

Name

Firouzeh Moeinzadeh

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1625 5555

Email address

moinzade@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

Expected recruitment start date

2012-04-28, 1391/02/09

Expected recruitment end date

2012-06-21, 1391/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of omega-3 fatty acid supplementation on oxidative stress in continuous ambulatory peritoneal dialysis patients

Public title

The effect of omega-3 fatty acid supplementation on oxidative stress in continuous ambulatory peritoneal dialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: 1)Clinically stable patients without serious disease. 2)continuous ambulatory peritoneal dialysis (CAPD) for at least 3 months. 3)hypertension stage 1(according to JNC VII) or under treatment. Exclusion criteria: 1)history of steatorrhea. 2) malignancy. 3) thrombocytopenia (PLT<100000/mm3). 4) abnormal coagulation profile. 5)need for anticoagulation therapy. 6)psychosomatic disorders.

Age
 From **18 years** old to **99 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **90**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Double blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice Chancellor for Research, Isfahan University of Medical Sciences

Street address

Hezar Jarib Street

City

Isfahan

Postal code

Approval date

2012-04-23, 1391/02/04

Ethics committee reference number

290370

Health conditions studied

1

Description of health condition studied

End Stage Renal Disease

ICD-10 code

N18.0

ICD-10 code description

End Stage Renal Disease

Primary outcomes

1

Description

Reduced glutathation

Timepoint

Begining of the study, after 6 weeks

Method of measurement

ELISA kit, U/mL

2

Description

Srum superoxide dismutase

Timepoint

Begining of the study, after 6 weeks

Method of measurement

ELISA kit, U/mL

Secondary outcomes

1

Description

Serum Iron

Timepoint

Begining of the study, after 6 weeks

Method of measurement

ELISA kit, mg/dL

2

Description

Serum ferritin

Timepoint

Begining of the study, after 6 weeks

Method of measurement

ELISA kit, mg/dL

3

Description

Low density lipoprotein(LDL)

Timepoint

Begining of the study, after 6 weeks

Method of measurement

mg/dL

4

Description

High density lipoprotein (HDL)

Timepoint

Begining of the study, after 6 weeks

Method of measurement

mg/dL

5

Description

Triglyceride

Timepoint

Beginning of the study, after 6 weeks

Method of measurement

mg/dL

6

Description

Cholesterol

Timepoint

Beginning of the study, after 6 weeks

Method of measurement

mg/dL

Intervention groups

1

Description

Cap Omega-3 1000mg 3capsule per day for 6 weeks
manufactured by Zahravi company

Category

Treatment - Drugs

2

Description

Cap placebo for 6 weeks manufactured by Zahravi
company

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital, Peritoneal dialysis centre

Full name of responsible person

Shirin Karimi

Street address

Sofe Street

City

Isfahan

2

Recruitment center

Name of recruitment center

Nour Hospital, Peritoneal Dialysis centre

Full name of responsible person

Dr Fsoon Emami Naini

Street address

Ostandari Street

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Isfahan University of
Medical Sciences

Full name of responsible person

Dr. Peyman Adibi

Street address

Hezar Jarib Street

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Isfahan University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Firouzeh Moeinzadeh

Position

Fellowship of Nephrology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

Person responsible for updating data**Contact****Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Firouzeh Moeinzadeh

Position

Fellowship of Nephrology

Other areas of specialty/work