

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Effect of omega-3 on blood pressure and serum lipids in continuous ambulatory peritoneal dialysis patients

#### Protocol summary

##### Summary

End stage renal disease (ESRD) is a condition that metabolic disorders play an critical role in body physiology. 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 profile and blood pressure 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/mm<sup>3</sup>, 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 total cholestrol, triglycerid, high- density lipoprotein and systolic and diastolic blood pressure are measured at begining and end of the study

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201501112417N16**  
Registration date: **2015-01-17, 1393/10/27**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-01-17, 1393/10/27

#### 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

Effect of omega-3 on blood pressure and serum lipids in continuous ambulatory peritoneal dialysis patients

#### Public title

Effect of omega-3 on blood pressure and serum lipids in continuous ambulatory peritoneal dialysis patients

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

inclusion criteria: Clinically stable patients without serious disease; continuous ambulatory peritoneal dialysis (CAPD) for at least 3 months; hypertension stage

1(according to JNC VII) or under treatment. Exclusion criteria: history of steatorrhea; malignancy; thrombocytopenia (PLT<100000/mm<sup>3</sup>); abnormal coagulation profile; need for anticoagulation therapy; 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 Ave.

**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**

Triglyceride

**Timepoint**

Beginning of the study, after 6 weeks

**Method of measurement**

mg/dL

**2****Description**

Cholesterol

**Timepoint**

Beginning of the study, after 6 weeks

**Method of measurement**

mg/dL

**3****Description**

High density lipoprotein (HDL)

**Timepoint**

Beginning of the study, after 6 weeks

**Method of measurement**

mg/dL

**4****Description**

Systolic blood pressure

**Timepoint**

Beginning of the study, after 6 weeks

**Method of measurement**

mmHg

**5****Description**

Diastolic blood pressure

**Timepoint**

Beginning of the study, after 6 weeks

**Method of measurement**

mmHg

**Secondary outcomes**

empty

**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

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**2**

**Recruitment center**

**Name of recruitment center**

Nour Hospital, Peritoneal Dialysis centre

**Full name of responsible person**

Dr Fsoon Emami Naini

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**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

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**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**

Nephrologist

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**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*