

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of omega-3 supplementation on inflammatory parameters in patients on chronic ambulatory peritoneal dialysis

#### Protocol summary

##### Summary

End stage renal disease (ESRD) is a condition that inflammation 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 inflammatory parameters in ESRD patients. In this study, 40 patients with 18 years old, at least, arrived if they are on chronic ambulatory peritoneal dialysis for 3 months. If patient have chronic diarrhea, malignancy, thrombocytopenia(less than 100000/mm<sup>3</sup>, coagulation disorders, need to anticoagulant drugs exclude from study. Group 1 (20 patients) using omega 3 capsules, 1000mg, manufactured by Zahravi Pharmaceutical, 3 times a day for 2 months. Group 2 (20 patients) using placebo capsules, manufactured by Zahravi pharmaceutical, 3 times a day for 2 months. Serum level of Interlukin-6 and C-reactive protein(CRP) are measured at beginning and end of the study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201303052417N11**

Registration date: **2013-06-12, 1392/03/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-06-12, 1392/03/22

##### 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

2012-11-02, 1391/08/12

##### Expected recruitment end date

2013-01-01, 1391/10/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of omega-3 supplementation on inflammatory parameters in patients on chronic ambulatory peritoneal dialysis

##### Public title

Effect of omega-3 supplementation on inflammatory parameters in patients on chronic ambulatory peritoneal dialysis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion criteria: 1- age more than 18 years old. 2- peritoneal dialysis for 3 months at least. Exclusion criteria: 1- history of malignancy. 2- steatorrhea. 3-

thrombocytopenia (platelet less than 100000/mm<sup>3</sup>). 4- coagulopathy. 5- anticoagulation therapy.

#### Age

From **18 years** old to **90 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **40**

#### 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

2012-10-31, 1391/08/10

#### Ethics committee reference number

391350

## 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

Serum Interlukin-6 level

#### Timepoint

Beginning of the study, after 2 months

#### Method of measurement

ELISA Kit pg/mL

### 2

#### Description

Serum CRP level

#### Timepoint

Beginning of the study, after 2 months

#### Method of measurement

ELISA Kit, mg/L

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Cap Omega-3 1000mg 3capsule per day for 2 months manufactured by Zahravi company

#### Category

Treatment - Drugs

### 2

#### Description

Cap placebo for 2 months 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

## 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  
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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**  
University of Medical Sciences  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*