

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Effect of Omega-3 supplementation on endothelial function & quality of life in hemodialysis patients

#### Protocol summary

##### Summary

End stage renal disease (ESRD) is a condition that endothelial dysfunction plays an important role in atherosclerosis and quality of life. 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 endothelial function markers and subsequently quality of life of hemodialysis patients. In this study, 60 patients arrived if they are 18 years old, at least, on hemodialysis for 3 months and dosent using omega-3 in past 3 months. If patient have chronic diarrhea, malignancy, coagulation disorders or need to anticoagulant drugs exclude from study. Group 1 (30 patients) using omega 3 capsuls, 1000mg, manufactured by Zahravi Pharmaceutical, 3 times a day for 6 months. Group 2 (30 patients) using placebo capsules, manufactured by Zahravi pharmaceutical, 3 times a day for 6 months. Serum level of ICAM and VCAM are measured and quality of life questioner is fulfilled at beginning and end of the study. the relationship between these variables will evaluate.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201309242417N13**

Registration date: **2013-10-29, 1392/08/07**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-10-29, 1392/08/07

##### 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

2013-10-23, 1392/08/01

##### Expected recruitment end date

2014-04-21, 1393/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Omega-3 supplementation on endothelial function & quality of life in hemodialysis patients

##### Public title

Effect of Omega-3 supplementation on endothelial function & quality of life in hemodialysis patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1)at least 18 years old. 2)hemodialysis for at least 3 months. 3)consent for cooperation 4) without usage of omega-3 during past 3 months  
Exclusion criteria: 1)history of steatorrhea. 2)

malignancy. 3) abnormal coagulation profile. 4) need for anticoagulation therapy.

#### 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: **60**

#### 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 jerib street

###### City

Isfahan

###### Postal code

##### Approval date

2013-09-14, 1392/06/23

##### Ethics committee reference number

292161

### 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 ICAM level

##### Timepoint

at beginning and after 6 months

##### Method of measurement

ELISA kit, µg/mL

#### 2

##### Description

serum VCAM level

##### Timepoint

at beginning and after 6 months

##### Method of measurement

ELISA kit, µg/mL

#### 3

##### Description

quality of life of hemodialysis patients

##### Timepoint

at beginning and after 6 months

##### Method of measurement

questionnaire

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

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

##### Category

Treatment - Drugs

#### 2

##### Description

Cap placebo for 6 months manufactured by Zahravi company

##### Category

Placebo

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Alzahra Hospital, Hemodialysis centre

###### Full name of responsible person

Dr Firouzeh Moeinzadeh

###### Street address

###### City

Isfahan

## 2

### **Recruitment center**

**Name of recruitment center**

Nour Hospital, Hemodialysis centre

**Full name of responsible person**

Dr Shahrzad Shahidi

**Street address**

**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**

**Street address**

Sofe street, Alzahra hospital

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### **Person responsible for scientific inquiries**

#### **Contact**

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### **Person responsible for updating data**

#### **Contact**

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felloship of nephrology

**Other areas of specialty/work**

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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*