

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effect of Omega-3 supplementation on the inflammatory factors in hemodialysis patients

Protocol summary

Summary

End stage renal disease (ESRD) is a condition that endothelial dysfunction plays an important role in atherosclerosis. The aim of this study was to investigate the effects of dietary omega-3 fatty acid supplementation on levels of inflammatory markers. We entered 60 patients in the study if they are more than 18 years old, hemodialysis for 3 months and without using omega-3 in 3 months ago. If a patient has chronic diarrhea, malignancy, coagulation disorders or anticoagulation drugs use, excluded 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 Q-CRP and TNF- α are measured at beginning and 6 months after the study. The relationship between these variables will evaluate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201602012417N18**

Registration date: **2016-09-16, 1395/06/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-16, 1395/06/26

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 the inflammatory factors in hemodialysis patients

Public title

Omega-3 and inflammation in hemodialysis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: at least 18 years old; hemodialysis for at least 3 months; consent for cooperation; without usage of omega-3 during past 3 months Exclusion criteria: history of steatorrhea; malignancy; abnormal coagulation profile; need for anticoagulation therapy.

Age

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

Gender

Both

Phase

3

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

Ethics committee of Vice Chancellor for Research,
Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences , Hezar Jarib
Ave

City

Isfahan

Postal code

Approval date

2014-01-16, 1392/10/26

Ethics committee reference number

293185

Health conditions studied

1

Description of health condition studied

End Stage Renal Disease

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Serum Q-CRP level

Timepoint

At beginning and after 6 months

Method of measurement

ELISA kit, mg/dL

2

Description

Serum TNF-a level

Timepoint

At beginning and after 6 months

Method of measurement

ELISA kit, mg/dL

Secondary outcomes

empty

Intervention groups

1

Description

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

Category

Treatment - Drugs

2

Description

Control group: Cap placebo for 6 months manufactured
by Zahravi company

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Nour Hospital, Hemodialysis centre

Full name of responsible person

Dr. Yaser Salehi

Street address

Ostandari street, Nour Hospital

City

Isfahan

2

Recruitment center

Name of recruitment center

Alzahra Hospital, Hemodialysis center

Full name of responsible person

Dr. Yaser Salehi

Street address

Sofe street, Alzahra Hospital

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, Isfahan University of Medical Sciences

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. Yaser Salehi

Position

Internal medicine resident

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Isfahan University of Medical Sciences

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Isfahan University of Medical Sciences

Full name of responsible person

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Position

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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