

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 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

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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

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

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Position

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Other areas of specialty/work

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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