Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of omega-3 fatty acid supplementation on inflammatory markers and advanced glycation end products in diabetic nephropaty patients

Protocol summary

Study aim
Objective: The aim of this study is to determine the effects of omega-3 fatty acid supplementation on inflammatory markers and advanced glycation end products in diabetic nephropathy patients.

Design
Randomized, double-blind, placebo-controlled clinical trial, phase 3, 60 patients

Settings and conduct
60 patients with diabetic nephropathy of eligible and referred to Akhavan Clinic, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients with diabetic nephropathy with FPG ≥ 126 mg/dl less than 15 years of their disease aged 45 to 85 years. Exclusion Criteria: The intake of omega-3 fatty acid supplements within the past 3 months, uncontrolled diabetes mellitus, current use of warfarin, malignancy, liver cirrhosis, smoking.

Intervention groups
Intervention group: Omega-3 fatty acid pearl, 1000 mg, daily, for 12 weeks orally. Control group: Placebo pearl, daily, for 12 weeks orally.

Main outcome variables
Outcomes: Inflammatory markers (primary outcomes) and advanced glycation end products (secondary outcomes) will be measured at baseline and End-of-trial.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT201504095623N41**
Registration date: **2015-04-10, 1394/01/21**
Registration timing: **prospective**

Last update: **2019-09-28, 1398/07/06**
Update count: **1**

Registration date
2015-04-10, 1394/01/21

Registrant information

Name
Zatollah Asemi

Name of organization / entity
Kashan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 36 1534 3570

Email address
asemi_z@kaums.ac.ir

Recruitment status
Recruitment complete

Funding source
Kashan University of Medical Sciences

Expected recruitment start date
2015-04-16, 1394/01/27

Expected recruitment end date
2015-04-22, 1394/02/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of omega-3 fatty acid supplementation on inflammatory markers and advanced glycation end products in diabetic nephropaty patients

Public title
Effects omega-3 fatty acid supplementation in the treatment of diabetes

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion Criteria: Patients with diabetic nephropathy with FPG ≥ 126 mg/dl less than 15 years of their disease aged 45 to 85 years.

Exclusion criteria:

The intake of omega-3 fatty acid supplements within the past 3 months Uncontrolled diabetes mellitus Current use of warfarin Malignancy Liver cirrhosis Smoking

Age

From **45 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

To decrease potential confounding effects, after balanced blocked randomisation, all participants will have allocated into two treatment groups to take either supplement or placebo. Randomization will be done by the use of Stat Trek software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Clinic in Kashan who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

8115187159

Approval date

2015-04-07, 1394/01/18

Ethics committee reference number

5979

Health conditions studied

1

Description of health condition studied

Diabetic Nephropathy

ICD-10 code

N08.3

ICD-10 code description

Glomerular disorders in diabetes mellitus (E10-E14 with common fourth character .2+)

Primary outcomes

1

Description

Tumor Necrosis Factor alpha (TNFα)

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa

2

Description

Receptor of Tumor Necrosis Factor alpha (TNFα)

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa

Secondary outcomes

1

Description

Receptor of Advanced Glycation End Products

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa

2

Description

Advanced Glycation End Products

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Fluorometeric method

Intervention groups

1

Description
Intervention group: Omega-3 fatty acid pearl, 1000 mg, daily, for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo pearl, daily, for 12 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akhavan outpatient Clinic
Full name of responsible person
Zatollah Asemi
Street address
Shahid Rajaee Avenue, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 5546 3378
Email
asemi_r@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 5546 3378
Email
asemi_r@yahoo.com

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
81151-87159
Phone
+98 31 5546 3378
Email
asemi_r@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
Nutrition PhD
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Ghotbe Ravandi Boulevard, Kashan
City

Kashan
Province
Isfehan
Postal code
81151-87159
Phone
+98 31 5546 3378
Fax
Email
asemi_r@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
81151-87159
Phone
+98 31 5546 3378
Fax
Email
asemi_r@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available