

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Effects of omega-3 fatty acid supplementation on inflammatory markers and advanced glycation end products in diabetic nephropathy 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 \geq 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 nephropathy 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 \geq 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

Isfahan

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 (TNF α)

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 (TNF α)

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

Fluorometric 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

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Shahid Rajaei Avenue, Kashan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

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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

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Nutrition PhD

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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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