

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effects of omega-3 fatty acid supplementation on metabolic profiles, hs-CRP and biomarkers of oxidative stress in diabetic nephropathy patients

Protocol summary

Study aim

The aim of this study is to determine the effects of omega-3 fatty acid supplementation on metabolic profiles, inflammatory factor and biomarkers of oxidative stress in diabetic nephropathy patients.

Design

Randomized, double-blind, placebo-controlled clinical trial, phase 2, 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

Patients with diabetic nephropathy with a proteinuria level >0.3 g/24 h, with or without elevation of serum creatinine levels and aged 45 to 85 years will be included in this study. Exclusion criteria: the intake of omega-3 fatty acid supplements within 3 months, patients with uncontrolled diabetes, the current use of warfarin, malignancy and/or liver cirrhosis.

Intervention groups

Patients will be assigned to receive either omega-3 fatty acid (intervention group: n=30) or placebo (control group: n=30).

Main outcome variables

Metabolic profiles, inflammatory factor and biomarkers of oxidative stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201502255623N36**

Registration date: **2015-03-10, 1393/12/19**

Registration timing: **prospective**

Last update: **2019-09-16, 1398/06/25**

Update count: **1**

Registration date

2015-03-10, 1393/12/19

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2015-03-11, 1393/12/20

Expected recruitment end date

2015-03-15, 1393/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of omega-3 fatty acid supplementation on metabolic profiles, hs-CRP and biomarkers of oxidative stress in diabetic nephropathy patients

Public title

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

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with diabetic nephropathy aged 45 to 85 years. Proteinuria level >0.3 g/24 h, with or without elevation of serum creatinine levels

Exclusion criteria:

The intake of omega-3 fatty acid supplements within 3 months Patients with uncontrolled diabetes The current use of warfarin Malignancy and/or liver cirrhosis.

Age

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

Gender

Both

Phase

2

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, all participants will have stratified randomization according to BMI and age. Then, participants in each block will be randomly allocated into two treatment groups to take either omega-3 fatty acid supplement or placebo. Randomization will be done by the use of Stat Trek software.

<https://stattrek.com/statistics/random-number-generator.aspx>

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 Akhavan 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

Bolvare Ghotbe Ravandi, Kashan

City

Kashan

Province

Isfahan

Postal code

8715981151

Approval date

2015-02-28, 1393/12/09

Ethics committee reference number

93211

Health conditions studied

1

Description of health condition studied

Diabetic nephropathy

ICD-10 code

E10

ICD-10 code description

Insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Insulin resistance

Timepoint

Baseline and End-of-trial

Method of measurement

Calculation using HOMA formula

2

Description

Insulin

Timepoint

Baseline and End-of-trial

Method of measurement

ELISA kit

Secondary outcomes

1

Description

High-sensitivity C-reactive protein

Timepoint

Baseline and End-of-trial

Method of measurement

ELISA test

2

Description

Malondialdehyde

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

3

Description

Glutathione

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

4

Description

Total antioxidant capacity

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

5

Description

Nitric oxide

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

6

Description

Triglycerides

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic kit

7

Description

Total cholesterol

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic kit

8

Description

HDL

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic kit

9

Description

Fasting blood sugar

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic kit

10

Description

LDL

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic kit

11

Description

Blood Urea Nitrogen

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

12

Description

Serum Creatinine

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

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 Clinic

Full name of responsible person

Alireza Soleimani

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Nutritionist

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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