Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

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
2015-03-11, 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 nephropaty 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

Isfehan

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
Street address
Shahid Rajaee Avenue, Kashan
City
Kashan
Province
Isfehan
Postal code
8715981151
Phone
+98 31 5554 0026

Email
soleimani_a@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Gholam Ali Hamidi
Street address
Bolvare Ghotbe Ravandi, Kashan
City
Kashan
Province
Isfehan
Postal code
81151-87159
Phone
+98 31 5554 2999
Email
research@kaums.ac.ir
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
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
81151-87159
Phone
+98 31 5562 0608
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
Bolvare Ghotbe Ravandi, Kashan
City
Kashan
Province
Isfehan
Postal code
81151-87159
Phone
+98 31 5546 3378
Fax
Email
asemi_z@kaums.ac.ir
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
Nutritionist
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_z@kaums.ac.ir

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