Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of omega-3 supplementation on renal biomarkers in patients with diabetic nephropathy

Protocol summary

Study aim
Effect of omega-3 supplementation on renal biomarkers in patients with diabetic nephropathy

Design
Two-arm parallel group, placebo-controlled double blind clinical trial

Settings and conduct
In this double-blind randomized clinical trial, 60 patients with type 2 and 1 diabetic nephropathy who referred to the Rasoul-akram clinic were selected by convenience sampling method and randomly assigned into control and intervention groups. A questionnaire containing demographic information of patients at the time of enrollment is completed. Both groups are matched in terms of receiving conventional treatment and HbA1C level. Patients in the intervention group receive conventional treatments and omega-3 capsules and in the control group receive conventional and placebo treatments. Random blood and urine samples of patients are collected to measure the urinary creatinine-to-albumin ratio, and the ratio, protein-to-creatinine ratio, GFR, and serum levels of creatinine, albumin, urea.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with type 1 and type 2 diabetic nephropathy and glomerular purification rate more than 60 ml / min and over 21 years of age
Exclusion criteria: Uncontrolled hypertension, hyperlipidemia, urinary tract infection and heart failure, dose adjustment of drugs, warfarin use, allergy or omega-3 intolerance

Intervention groups
Patients in the intervention group would receive conventional treatments and omega-3 capsules (1000 mg daily for 12 weeks) and the placebo group receive conventional treatment and placebo (continued for 12 weeks).

Main outcome variables
Creatinine and blood urea; urinary creatinine and albumin; blood pressure ; glomerular filtration rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220301054158N1**
Registration date: **2023-03-09, 1401/12/18**
Registration timing: **retrospective**

Last update: **2023-03-09, 1401/12/18**
Update count: **0**

Registration date
2023-03-09, 1401/12/18

Registrant information

Name
Fatemeh Ghasemi Korani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 913 004 5793

Email address
fatemehghasemi2015@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-05, 1401/02/15

Expected recruitment end date
2022-09-06, 1401/06/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of omega-3 supplementation on renal biomarkers in patients with diabetic nephropathy

Public title
The effect of omega-3 supplementation on renal biomarkers in patients with diabetic nephropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with type 1 and type 2 diabetic nephropathy Fasting blood sugar more than 126 mg/ dl and/ or taking glucose-lowering drugs or insulin Proteinuria is more than 300 mg per day Glomerular filtration rate more than 60 ml per minute Minimum 21 years of age
Exclusion criteria:
Uncontrolled hypertension Hyperlipidemia Urinary tract infection Heart failure Changing the dose of medication Taking warfarin Allergies or omega-3 intolerance
Age
From **21 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling of patients will be available as two groups are blocked by random allocation method and two groups of 30 people are formed with the help of software
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants and physicians are unaware that omega-3s are a drug or a placebo
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahrekord University of Medical Sciences
Street address
Building No. 2, University Headquarters Campus, Kashani Blvd.,
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Approval date
2021-08-24, 1400/06/02
Ethics committee reference number
IR.SKUMS.REC.1400.112

Health conditions studied

1

Description of health condition studied
Diabetic nephropathy
ICD-10 code
E08.21
ICD-10 code description
Diabetes mellitus due to underlying condition with diabetic nephropathy;

Primary outcomes

1

Description
Blood creatinine level
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
High-performance liquid chromatography

2

Description
Blood urea level
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
Enzyme assay

3

Description
Urine creatinine
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
High-performance liquid chromatography

4

Description
Urine Albumin
Timepoint
Before the intervention and 12 weeks after the

intervention

Method of measurement

BCG (Bromocresol Green) Albumin Assay Kit

5

Description

Blood pressure

Timepoint

Before the intervention and 12 weeks after the intervention

Method of measurement

Manometer

6

Description

Glomerular filtration rate

Timepoint

Before the intervention and 12 weeks after the intervention

Method of measurement

Using the CKD-EPI formula

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Conventional treatment and omega-3

Category

Treatment - Drugs

2

Description

Control group: Conventional treatment and placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat-Rasoul Clinic

Full name of responsible person

Fatemeh Ghasemi

Street address

Hazrat Rasool Clinic, Molavi St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

دکتر اسفندیار حیدریان

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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

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Fatemeh Ghasemi Korani

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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1st floor, 72nd alley, West Sa'di Ave

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Parisa Javadian

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Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

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Person responsible for updating data

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Position
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A Level or less

Other areas of specialty/work
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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