

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial of the effect of omega-3 supplementation compared with the placebo on metabolic profiles in patients with diabetic foot

Protocol summary

Study aim

The aim of this study is to determine the effects of omega-3 supplementation on metabolic profiles in patients with diabetic foot.

Design

Randomized controlled clinical trial, Parallel, double-blind, 60 patients, phase 2

Settings and conduct

Sixty patients with diabetic foot of eligible and referred to Infectious Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Patients with diabetic foot and aged 40 to 85 years will be included in this study. Exclusion criteria is as follows: grade 3 DFU with abscess formation and osteomyelitis, subjects with significant arterial disease, major deformities e.g. Charcot's neuroarthropathy, pregnant and breastfed patients, taking antioxidant and/or anti-inflammatory supplements such as vitamin E, vitamin C and omega-3 fatty acids and change in consuming medications throughout the study.

Intervention groups

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

Main outcome variables

Fasting plasma glucose, lipid profiles, inflammatory factors, oxidative stress, and mean ulcer area

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201604025623N72**

Registration date: **2016-04-15, 1395/01/27**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-22, 1398/06/31**

Update count: **2**

Registration date

2016-04-15, 1395/01/27

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

2016-03-10, 1394/12/20

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of omega-3 supplementation compared with the placebo on metabolic profiles in patients with diabetic foot

Public title

Effect of supplementation in treatment of patients with diabetic foot

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with diabetic foot; Aged 40 to 85 years

Exclusion criteria:
Grade 3 DFU with abscess formation and osteomyelitis
Subjects with significant arterial disease Major deformities e.g. Charcot's neuroarthropathy Pregnant and breastfed patients Taking antioxidant and/or anti-inflammatory supplements such as vitamin E, vitamin C and omega-3 fatty acids Change in consuming medications throughout the study

Age
From **40 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
At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to take either omega-3 supplements (n = 30) or placebo (n = 30). Randomization will be done by the use of computer-generated random numbers.

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 infectious clinic affiliated to Kashan University of Medical Sciences, 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

Ethics committee of Kashan University of Medical

Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Approval date

2016-03-09, 1394/12/19

Ethics committee reference number

IR.Kaums.REC.1394.173

Health conditions studied

1

Description of health condition studied

Diabetic foot

ICD-10 code

E11 and E1

ICD-10 code description

Non-insulin-dependent diabetes mellitus and with peripheral circulatory complications

Primary outcomes

1

Description

Insulin resistance

Timepoint

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

Method of measurement

Calculation using HOMA formula

2

Description

Healing of diabetic foot ulcer

Timepoint

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

Method of measurement

Decrease of the wound size relative to original size: ulcer length (cm), ulcer width (cm), Ulcer depth (cm)

Secondary outcomes

1

Description

Triglycerides

Timepoint

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

Method of measurement

Enzymatic kit

2

Description

HDL-cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

3

Description

Total cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

4

Description

Total antioxidant

Timepoint

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

Method of measurement

Spectrophotometry

5

Description

Glutathione

Timepoint

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

Method of measurement

Spectrophotometry

6

Description

hs-CRP

Timepoint

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

Method of measurement

Elisa kit

7

Description

Nitric oxide

Timepoint

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

Method of measurement

Spectrophotometry

8

Description

LDL-cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

9

Description

Malondialdehyde

Timepoint

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

Method of measurement

Spectrophotometry

10

Description

HbA1c

Timepoint

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

Method of measurement

Biochemical kit

11

Description

Fasting plasma glucose

Timepoint

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

Method of measurement

Enzymatic kit

12

Description

Insulin

Timepoint

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

Method of measurement

Elisa kit

Intervention groups

1

Description

Intervention group: Omega-3 fatty acid capsule, 2000 mg omega-3 fatty acid, daily for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo, daily, for 12 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infectious clinic affiliated to Kashan University of Medical Sciences

Full name of responsible person

Zahra Soleimani

Street address

Shahid Rajaee Avenue, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Phone

+98 31 5554 0026

Email

soleimani.zahra@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

81151-87159

Phone

+98 31 5557 8010

Fax**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

Isfahan

Postal code

81151-87159

Phone

+98 31 5562 0608

Email

asemi_z@kaums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

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

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

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