

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effect of omega-3 fatty acids on Glycemic control in type 2 diabetic patients

Protocol summary

Study aim

Determining the effect of omega-3 on blood sugar control in type 2 diabetic patients

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized on the number of 188 patients with type 2 diabetes in Farhikhtegan Hospital using simple randomization.

Settings and conduct

In this trial, after obtaining the code of ethics, 188 patients with type 2 diabetes of Farhikhtegan Hospital were enrolled in the study after filling out the questionnaire. For double-blindness of the drugs used by the supervisor, they were divided into A/B groups. 3 capsules of 1000 mg of omega-3 were given for 12 weeks, and the control group took 3 placebo pills daily for 12 weeks.

Participants/Inclusion and exclusion criteria

Age 30 to 40 years, declaration of satisfaction by the patient, suffering from type 2 diabetes, under the care of Farhikhtegan Hospital, body mass index less than 30

Intervention groups

The treatment group was given 3000 mg of omega-3 fatty acid to investigate the effect of omega-3 on the blood sugar of type 2 diabetic patients, and the control group was given a placebo for 12 weeks to compare with the results of the intervention group.

Main outcome variables

The meaningless effect of omega-3 on fasting blood sugar; The meaningless effect of omega-3 on hemoglobin A1c; Significant effect of omega-3 on triglycerides.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210928052621N1**

Registration date: **2023-09-04, 1402/06/13**

Registration timing: **prospective**

Last update: **2023-09-04, 1402/06/13**

Update count: **0**

Registration date

2023-09-04, 1402/06/13

Registrant information

Name

Alireza Panahian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3368 4906

Email address

ar_pannahian@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-11, 1402/06/20

Expected recruitment end date

2023-12-11, 1402/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of omega-3 fatty acids on Glycemic control in type 2 diabetic patients

Public title

The effect of omega-3 on Diabet

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Suffering from type 2 diabetes Consent to participate in the intervention Age between 40 and 70 years Under the care of Farhikhtegan Hospital bmi less than 30

Exclusion criteria:

Age
From **40 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **188**

Randomization (investigator's opinion)
Randomized

Randomization description
Due to the double-blindness of this study, the drugs used for the patients were divided by the head of the department in A/B form at the beginning of the study so that the researcher and the participants did not know the type of drug received. For randomization, each patient was first given a number from 1 to 188, then using online random numbers from 1 to 188, 94 numbers were randomly generated. Patients with these numbers were in the treatment group and patients with The remaining numbers were placed in the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The doctor is unaware of the study groups, the patient is unaware of the study groups, the researcher is unaware of the study groups, the data analyst is unaware of the study groups .The division of patients into drug and placebo groups is done by a nurse outside of the above groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran Azad University of Medical Sciences

Street address

Headquarters Building of Islamic Azad University of

Medical Sciences , Corner of Gol Yakh St , Ayene Blvd , Amir Pabarja St , Doctor Shariati St.

City

tehran

Province

Tehran

Postal code

1949635881

Approval date

2022-10-17, 1401/07/25

Ethics committee reference number

IR.IAU.TMU.REC.1401.323

Health conditions studied

1

Description of health condition studied

diabet type 2

ICD-10 code

Z71.3

ICD-10 code description

Dietary counseling and surveillance

Primary outcomes

1

Description

FBS

Timepoint

At the beginning of the study (before the start of the intervention) and 12 weeks after receiving the Omega 3 drug

Method of measurement

Blood Test

2

Description

HbA1C

Timepoint

At the beginning of the study (before the start of the intervention) and 12 weeks after receiving the Omega 3 drug

Method of measurement

Blood Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, 3000 mg of omega-3 fatty acid (3 capsules of 1000 mg in the morning, noon, and night from Dana Pharmaceutical Company under the brand name Omega Rex) was given for 12 weeks.

Category

Treatment - Drugs

2**Description**

Control group: The placebo control group (containing 300 mg of polyunsaturated fatty acid, 100 mg of unsaturated fatty acid and 600 mg of linoleic acid) was given 3 times a day for 12 weeks.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

farhikhtegan hospital

Full name of responsible person

Alireza Panahian

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Farhikhtegan Hospita , Daneshgah Square , At the end of Sattari Highway

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

Islamic Azad University

Full name of responsible person

معاون تحقیقات و فناوری

Street address

Tehran Azad University of Medical Sciences , Danesh Dead End, Atardi Moghadam St., Khagani St., Doctor Shariati St.

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Int.affairs@tms.iau.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor****organization/entity?**

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

10

Public or private sector

Private

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**

Islamic Azad University

Full name of responsible person

Alireza Panahian

Position

دانشجو

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Medical Student

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

A Level or less

Other areas of specialty/work

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City

Tehran

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The intervention was conducted on a small number of samples, and to draw conclusions, a large sample size and more facilities are needed, which were not possible in this trial.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available