Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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Iran (Islamic Republic of)
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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
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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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Postal code
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Phone
+98 21 2200 6660
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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
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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