Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessment the Effect of omega 3 supplementation on Improving Metabolic Syndrome indices in Patients with Ischemic heart disease

Protocol summary

Study aim
The effect of omega-3 fatty acid supplementation on improvement of metabolic syndrome indices in patients with ischemic heart disease

Design
A clinical trial with control group, with parallel groups and in each group 45 patients, double blind, randomized by block randomization method.

Settings and conduct
The project will focus on improving metabolic syndrome indices at the Seyed al-Shohada Medical Center in Urmia. Physical activity will be extracted through the International Physical Activity Questionnaire. Blood samples are taken for biochemical examinations after 10 to 12 hours fasting. In this research study, researcher, clinical Caregiver and participants are blinded. Blinding of Omega-3 supplements and placebo supplements is done using coding. Code is also considered for each individual, only the statistical expert is aware of each person's code and group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Interested in attending study and having metabolic syndrome indicators Exclusion criteria include: mental, emotional, cognitive impairments, specific dietary restrictions, autoimmune disease, alcohol consumption, pregnancy, lactation, infectious diseases, chronic kidney disease, liver disease, drug abuse, physical activity change, allergy to fish and omega supplement -3, Consume more than one serving of fish per week

Intervention groups
The intervention group was 45 and the control group was 45, the duration of the intervention was 12 weeks. The intervention group received omega-3 tablets daily at a dose of 1000 mg and the control group received placebo omega-3 supplements.

Main outcome variables
Waist circumference, HDL, LDL, TG, FBS, total cholesterol, weight, BMI

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190819044563N1**
Registration date: **2019-11-10, 1398/08/19**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-10, 1398/08/19**
Update count: **0**

Registration date
2019-11-10, 1398/08/19

Registrant information

Name
Asma Zamanian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4409 2875

Email address
asma_wzm@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2020-01-20, 1398/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Assessment the Effect of omega 3 supplementation on Improving Metabolic Syndrome indices in Patients with Ischemic heart disease

Public title
Assessment the Effect of omega 3 supplementation on Improving Metabolic Syndrome indices
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Interested in attending the study who have completed and signed the informed consent form. Metabolic syndrome according to existing criteria, including: There are 3 of the following: Waist circumference ≥ 80 cm for women and Waist circumference ≥ 94 cm for men, fasting blood glucose ≥ 100 mg / dl , Systolic blood pressure ≥ 130 and diastolic blood pressure above ≥ 85 , mm Hg, HDL less than 50 mg / dL for women and less than 40 mg / dL for men and triglycerides; 150 mg / dL and drug administration for triglycerides Blood glyceride, cholesterol and LDL (including statins, etc.). With ischemic heart disease.
Exclusion criteria:
Mental, emotional, cognitive, or any disorders that may prevent a person from participating in this study. People who have certain dietary restrictions and follow a specific diet. autoimmune diseases (corticosteroids), cancer alcohol consumption Pregnancy Breastfeeding Infectious Diseases Chronic Kidney Disease Liver disease Food intolerance and sensitivity to fish Drug abuse Anticoagulants such as warfarin Changes in the level of physical activity during the study People taking Omega-3 supplements Consume more than one serving of fish per week Omega-3 sensitivity cases
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be divided into two groups according to the stratified block randomization method.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants are unaware of either the intervention group or the control group. Also, the clinical researcher and outcome assessor do not know which individuals are in the intervention and control groups. Only the statistical expert who randomly divided the subjects into two groups is aware of the status of the individuals and who is in the intervention group and who is in the control group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Urmia University of Medical Sciences
Street address
Department of Nutrition, Faculty of Medicine, Urmia University of Medical Sciences, Sero Highway, Urmia, Iran
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2019-08-19, 1398/05/28
Ethics committee reference number
IR.UMSU.REC.1398.190

Health conditions studied

1

Description of health condition studied
Metabolic syndrome
ICD-10 code
E88.81
ICD-10 code description
Metabolic syndrome

Primary outcomes

1

Description
triglyceride
Timepoint
Blood triglyceride levels at baseline (before intervention) and at the end of the study at week 12
Method of measurement
Serum triglyceride concentration measurement by enzymatic method with BT1500

2

Description
High-density lipoprotein
Timepoint
Blood High-density lipoprotein levels at baseline (before intervention) and at the end of the study at week 12
Method of measurement
Serum high-density lipoprotein concentration measurement by enzymatic method with BT1500

3

Description
Low-density lipoprotein
Timepoint
Blood Low-density lipoprotein levels at baseline (before intervention) and at the end of the study at week 12
Method of measurement
Serum low-density lipoprotein concentration measurement by enzymatic method with BT1500

4

Description
Fasting blood sugar
Timepoint
Blood Fasting blood sugar levels at baseline (before intervention) and at the end of the study at week 12
Method of measurement
Serum fasting blood sugar concentration measurement by enzymatic method with BT1500

5

Description
Total cholesterol
Timepoint
Blood Total cholesterol levels at baseline (before intervention) and at the end of the study at week 12
Method of measurement
Serum total cholesterol concentration measurement by enzymatic method with BT1500

6

Description
Waist circumference
Timepoint
Waist measurement at baseline (before intervention) and at weeks 4, 8 and end of study at week 12
Method of measurement
Using meters and in centimeters

Secondary outcomes

1

Description
Weight
Timepoint
Weight measurement at baseline (before intervention) and at 4, 8 and 12 weeks
Method of measurement
The weight of a person with minimal clothing and no shoes is measured to the nearest 100 grams

2

Description
Body Mass Index
Timepoint
Body Mass Index measurement at baseline (before intervention) and at 4, 8 and 12 weeks
Method of measurement
Using the values of height and weight and by the formula of weight divided by the square of height in meters

3

Description
Physical activity
Timepoint
Physical activity measurement at baseline (before intervention) and at 4, 8 and 12 weeks
Method of measurement
Measurement of physical activity at three levels of light, moderate and vigorous using the International Physical Activity Questionnaire

4

Description
Systolic blood pressure
Timepoint
Systolic blood pressure measurement at baseline (before intervention) and at 4, 8 and 12 weeks
Method of measurement
Using a calibrated digital barometer

5

Description
Diastolic blood pressure
Timepoint
Diastolic blood pressure measurement at baseline (before intervention) and at 4, 8 and 12 weeks
Method of measurement
Using a calibrated digital barometer

6

Description
Feed Frequency Questionnaire
Timepoint
Feed Frequency Questionnaire at the beginning of the study (before the intervention) and at the end of the 12 week study
Method of measurement
Using a food frequency questionnaire

7

Description
Height
Timepoint

Measurement of individuals height at baseline (before intervention)

Method of measurement

Using the height gauge

Intervention groups

1

Description

Intervention group: Intervention group given daily omega-3 supplement in the form of 1000 mg gel made by Zahravi Pharmaceutical Company of Tabriz

Category

Treatment - Drugs

2

Description

Control group: Omega-3 supplemented placebo control group given by Tabriz Zahravi Pharmaceutical Company

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyed al-Shohada Heart Training Center in Urmia

Full name of responsible person

Behzad Rahimi darabad

Street address

Opposite Samadzadeh Street, West Azarbaijan, Urmia, Shahrivar Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

Street address

Vice Chancellor for Research and Technology, Urmia University, University Headquarters, Resalat Boulevard, Emergency Stage

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Asma Zamanian

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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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