

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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		groups is aware of the status of the individuals and who is in the intervention group and who is in the control group.	
Public title	Assessment the Effect of omega 3 supplementation on Improving Metabolic Syndrome indices	Placebo	Used
Purpose	Treatment	Assignment	Parallel
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	Other design features	
Age	No age limit	Secondary Ids	empty
Gender	Both	Ethics committees	
Phase	3	1	
Groups that have been masked	- Participant - Care provider - Investigator - Outcome assessor	Ethics committee	
Sample size	Target sample size: 90	Name of ethics committee	Ethics committee of Urmia University of Medical Sciences
Randomization (investigator's opinion)	Randomized	Street address	Department of Nutrition, Faculty of Medicine, Urmia University of Medical Sciences, Sero Highway, Urmia, Iran
Randomization description	Participants will be divided into two groups according to the stratified block randomization method.	City	Urmia
Blinding (investigator's opinion)	Double blinded	Province	West Azarbaijan
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	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

City

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Province

West Azarbaijan

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5714783734

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Email

behzadrahimi57@yahoo.com

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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Urmia

Province

West Azarbaijan

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Fax

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Email

asma_wzm@yahoo.com

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

Street address

Kosar Dormitory, Urmia University of Medical Sciences, Nazlou, Serow Road

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Person responsible for scientific inquiries

Contact

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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

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

Oroumia University of Medical Sciences

Full name of responsible person

Asma Zamanian

Position

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Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address