

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

The effect of omega-3 fatty acid supplements on serum nitric oxide in cardiovascular men patients referred to the heart center of Tehran

Protocol summary

Summary

The present study aimed to determine the effect of omega-3 fatty acids supplementation on serum nitric oxide levels in men with coronary artery disease. Design and Implementation: In this Clinical Trial Double Blind study, 42 patients are selected from Tehran Heart center. Consent form, general questionnaire, 24-hour recall of food and international physical activity questionnaire were completed. Patient's blood pressure, anthropometric measurements, height, weight and fat mass of patients are measured. Then, in order to perform the test, 10cc blood sample is taken. At the end, we give patients with omega-3 supplementation at a dose of 4 g / day or placebo (oral paraffin) at a dose of 4 g / day for two months. After 2 months, patient's physical activity, questionnaire were asked and weight, and blood pressure of the patient were measured. Inclusion criteria for this study include heart disease, any other diseases, and do not use vitamin supplements or diets at least 4-6 weeks before the intervention. Exclusion criteria are an allergic reaction to Omega-3. In this randomized double blind study, 42 cardiac patients were selected based on inclusion and exclusion criteria. Patients were randomly assigned into two groups, including group 1- receiving omega-3 supplements and group 2-receiving placebo. The omega 3 treated group received 4 capsules of 1 g (4 g) of omega-3 daily and placebo group received 4 capsules of 1 g of oral paraffin for 3 months. Two capsules are taken along with lunch and two capsules are taken with dinner. Primary outcome variable: Determination of mean serum NO level before and after intervention in the omega-3 fatty acid supplement group compared to placebo group

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081335665N1**

Registration date: **2017-11-06, 1396/08/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-06, 1396/08/15

Registrant information

Name

Mahnaz Zarei

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4293 3057

Email address

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Recruitment status

Recruitment complete

Funding source

Grant 6 papers in one year. Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2013-10-12, 1392/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of omega-3 fatty acid supplements on serum nitric oxide in cardiovascular men patients referred to the heart center of Tehran

Public title

Effect of omega-3 fatty acid supplementation on serum nitric oxide levels

Purpose

Prevention

Inclusion/Exclusion criteria

Cardiac patients, Lack of other diseases, Avoid dietary supplements, vitamins at least 4-6 weeks before and throughout the intervention, No diet, supplements or special activity. Exclusion criteria: A reaction to Omega compounds

Age

No age limit

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 42

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committe Of Tehran University Of MedicalSciences

Street address

Pour Sina Street

City

Tehran

Postal code**Approval date**

2017-07-24, 1396/05/02

Ethics committee reference number

IR.TUMS.VCR.REC.1396.2578

Health conditions studied**1****Description of health condition studied**

Atherosclerotic Heart Disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

Primary outcomes**1****Description**

Determination of mean serum NO level before and after intervention in the omega-3 fatty acid supplement group compared to placebo group

Timepoint

2Month

Method of measurement

Elisa

Secondary outcomes**1****Description**

Body Mass Index (BMI)

Timepoint

Before and after 2 months of intervention

Method of measurement

Weight ratio to squared height

2**Description**

weight

Timepoint

Before and after 2 months of intervention

Method of measurement

seca scale in kilograms

3**Description**

Waist

Timepoint

Before and after 2 months of intervention

Method of measurement

Band meters in cm

Intervention groups**1****Description**

First group intervention: receptor of omega-3 fatty acids, 4 g oral cups, twice a day with lunch, for 2 months

Category

Treatment - Drugs

2**Description**

Placebo (oral paraffin) at a dose of 4 g per day for two months

Category

Treatment - Drugs

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

Tehran Heart Center

Full name of responsible person

Dr Ebrahim Nematipour

Street address

North Karegar street, Tehran Heart Center

City

Tehran

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

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Ms Javadi

Street address

Sixth Floor, Setad Department, Ghods Street

City

Tehran

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

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mahnaz Zarei

Position

Msc

Other areas of specialty/work**Street address**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty*

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty