

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

The effect of omega-3 supplementation with lifestyle modification on anthropometric indices and VO2max in overweight women

Protocol summary

Summary

The present study is a double blind randomized controlled trial. The purpose of this study is to evaluate the effect of omega 3 supplement along with lifestyle modification including exercise and healthy nutrition on anthropometric indices and VO2max. Fifty overweight women with age between 20 to 45 years and sedentary lifestyle who referred to obesity clinic of Imam Khomeini Hospital will be recruited to the study. Fifty subjects will be divided randomly into two groups. Both groups receive healthy nutrition education and exercise program including 150 minutes aerobic exercise per week with moderate intensity on lactate threshold. In addition, intervention group receive one omega 3 capsule (1250 mg) daily and control group receive placebo capsule for 8 weeks. In the beginning of the study, weight, abdominal circumference, percentage body fat and maximal oxygen consumption with exercise test on treadmill are assessed. The assessments will be repeated at the 4th and 8th weeks of the study again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201504267903N4**

Registration date: **2015-05-08, 1394/02/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-08, 1394/02/18

Registrant information

Name

Zahra Alizadeh

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2282

Email address

z_alizadeh@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-05-05, 1394/02/15

Expected recruitment end date

2015-07-06, 1394/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of omega-3 supplementation with lifestyle modification on anthropometric indices and VO2max in overweight women

Public title

Weight loss and omega 3

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: female sex; age between 20-45 years; no history of disease or musculoskeletal problems; no history of using drugs or supplements; no history of significant weight reduction over the past 6 months; sedentary lifestyle. Exclusion criteria: pregnancy; musculoskeletal pain with exercise.

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

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**

Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Ghods St.,
Keshavarz Blvd.

City

Tehran

Postal code**Approval date**

2015-04-18, 1394/01/29

Ethics committee reference number

93-04-30-27247-145306

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

Obesity

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

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

Weight loss

Timepoint

Beginning of the study, Day 28, Day 56

Method of measurement

Seca Medical Scale according to kilogram

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

Increasing VO2 max

Timepoint

Beginning of the study, Day 56

Method of measurement

Exercise test on treadmill according to VO2 max/liter

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

Intervention group: Prescription one capsule of omega 3
(1250 mg) per day, healthy nutrition and moderate
intensity aerobic exercise within 8 weeks

Category

Treatment - Drugs

2**Description**

Control group: Prescription healthy nutrition and
moderate intensity aerobic exercise within 8 weeks

Category

Lifestyle

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

Imam Khomeini Hospital

Full name of responsible person**Street address****City**

Tehran

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

Deputy of Chancellor for Research of Tehran
University of Medical Sciences

Full name of responsible person

Hajar Moammaee

Street address

Tehran University of Medical Sciences, Ghods St.,
Keshavarz Blvd.

City

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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

Deputy of Chancellor for Research of 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

Zahra Alizadeh

Position

Assistant Professor of Sports Medicine

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