

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Assessment of serum levels of adiponectin and asymmetric dimethylarginine in patients with persistent and permanent atrial fibrillation following supplementation with fish oil

Protocol summary

Summary

The present research is a randomized clinical trial for Determinant of the effects of fish oil supplementation on the adiponectin and ADMA serum levels in patients with chronic atrial fibrillation. The samples of the study will constitute 80 patients with chronic atrial fibrillation including men and women above 50 years with BMI higher than 25 kg/m² coming to the Shahid Rajaei Heart Center. Exclusion criteria included the following: 1) suffering from hyperthyroidism, 2) disorders of heart valves, and 3) people who started taking in fish oil supplement within the three months to the intervention. Patients will be randomly divided into two groups. At the first meeting the purpose of study will be described and asked them to fill the consent form. Group 1 will receive 2000 mg fish oil capsules for eight weeks and group 2 will receive 2000mg placebo capsules (same shape, colour, size) two times after meal (each time 1capsule including 1000mg). The intake of nutrients will assess through 24-hour questionnaire filled in by the patients before and after treatment. Height, weight and waist circumference, will measure before and after the treatment. Furthermore, fasting blood will be collected and stored at -80 (c) refrigerator before and after the intervention. The serum levels of adiponectin, Asymmetric dimethylarginine, total cholesterol, low density lipoprotein, high density lipoprotein, very low density lipoprotein, triglyceride and fasting blood sugar will measure before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012110411362N1**

Registration date: **2012-12-03, 1391/09/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-12-03, 1391/09/13

Registrant information

Name

Elnaz Khorrami

Name of organization / entity

Public Health Department of Tehran University

Country

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences School of Public Health and Institute of Public Health Researches

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2012-08-22, 1391/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of serum levels of adiponectin and asymmetric dimethylarginine in patients with persistent and permanent atrial fibrillation following supplementation with fish oil

Public title

Effect of fish oil supplement on chronic atrial fibrillation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: postmenopausal women; men; above 50 years old; BMI higher than 25 kg/m²; patients without hyperthyroidism; patients without heart valve disorders; patients did not underwent coronary artery bypass surgery in the last three months; patients without heart failure of class IV; patients without history of alcohol abuse; not started taking in fish oil supplement within the three months before intervention; patients without allergy to fish oil
Exclusion criteria: patients who stops taking supplement or placebo; patients who lose interest in participating in the study; patient who undergo coronary bypass

Age

From **50 years** old to **81 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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

Poursina st, 16 Azar st, Keshavarz blv

City

Tehran

Postal code**Approval date**

2012-06-20, 1391/03/31

Ethics committee reference number

130/382

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

Atrial fibrillation

ICD-10 code

I48

ICD-10 code description

Atrial fibrillation and flutter

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

adiponectin

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

µg/ml, elisa kit

2**Description**

Asymmetric dimethylarginine (ADMA)

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

mol/Lµ, elisa kit

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

HDL

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

mg/dl, enzymatic

2**Description**

LDL

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

mg/dl, enzymatic

3**Description**

total cholesterol

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

mg/dl, enzymatic

4

Description

VLDL

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

mg/dl, Friedewald-Formel

5

Description

triglyceride

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

mg/dl, enzymatic

6

Description

fasting blood sugar

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

mg/dl, enzymatic

7

Description

weight

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

Seca scale, kg

8

Description

body mass index (BMI)

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

calculation, kg/cm²

9

Description

waist circumference

Timepoint

waist Circumference

Method of measurement

meter tape, cm

Intervention groups

1

Description

intervention group: fish oil supplement, 2000mg for 8 weeks after a meal

Category

Prevention

2

Description

control group: olive oil placebo, 2000mg for 8 weeks after a meal

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Heart Center

Full name of responsible person

Elnaz Khorrami

Street address

beside Melat park, Valiasr st

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

School of Public Health, Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammad Javad Hosseinzadeh

Street address

Ghods st, Poursina st, School of Public Health, Tehran University of Medical Sciences

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

School of Public Health, 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

Department of Nutrition and Biochemistry

Full name of responsible person

Elnaz Khorrami

Position

Master of Nutritional Science

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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