

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effect of Supplementation of ω 3 and its combination with Vitamin E on gene expressions of adiponectin and its receptors in men's PBMC with Coronary Artery Disease(CAD).

Protocol summary

Summary

In this study refer to the heart hospital TEHRAN, 60 men contracted the disease and vascular heart disease, with shortness of breath more than 50% in at least one of the veins has been proved **کرونی** with angiography in three months and according to recent arrival with the criteria will be selected and then at random to three groups receiving the Supplement ω 3 and the group receiving the combined supplement ω 3 and vitamin E and placebo group . Of these patients 10 cc venous blood sample is taken and then weight of each patient with patient consent in clothes and without shoes, so around the waist with the use of the feet which entails measurements is also remembered 24 hour food in patients beginning and end study complete. patients will receive for 8 weeks 4 day hot Omega 3 and vitamin e gel capsule to form soft (softgel). blood cells were taken from patients in the beginning and end study and will separate and were measured gene expression of PPAR γ and adiponectin and its receptors in PBMC in patients. Also Serum criteria before and after eight weeks of intervention AND THEN comparison in the groups will be done with the use of software of Nutritionist 4.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013080514273N1**
Registration date: **2013-08-13, 1392/05/22**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-08-13, 1392/05/22

Registrant information

Name

Mahmoud Jalali

Name of organization / entity

Faculty of Nutrition. Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 4911

Email address

jalalikh87@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences, School of Nutrition
Tehran Heart Hospital

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2013-07-23, 1392/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Supplementation of ω 3 and its combination with Vitamin E on gene expressions of adiponectin and its receptors in men's PBMC with Coronary Artery Disease(CAD).

Public title

The effect of Supplementation of ω 3 and its combination with Vitamin E in Coronary Artery Disease(CAD).

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: □ BMI less than 30 □ aged 65-45 years
□ More than 50% of patients with at least one coronary artery stenosis confirmed by angiography in three months □ Lack of PPAR γ agonist drugs such Tyazvlydyn Dion (TZDs), and fiber and taking angiotensin receptor type 1 blockers and inhibitors of non-ACE, □ willingness to cooperate
Criteria excluded: □ kidney disease, liver disease, diabetes, cancer, thyroid disorders, according to the patient's medical history □ smoking (at least 5 threads in the last 6 months) □ omega-3 supplements or fish oil and vitamin E for three months □ Allergy and sensitivity to fish oil □ Lack of cooperation is likely to continue. Mbar excluded Any drastic changes in diet (the doctor, the patient himself)

Age

From **45 years** old to **65 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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 Ethics Committee

Street address

Keshavarz Blvd, corner of Ghods St.

City

tehran

Postal code

Approval date

2013-07-31, 1392/05/09

Ethics committee reference number

86686

Health conditions studied

1

Description of health condition studied

coronary artery Disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

Primary outcomes

1

Description

gene expression of adiponectin in PBMC

Timepoint

Baseline, After8 weeks

Method of measurement

Realtime PCR

2

Description

gene expression of adiponectin receptors , R1 and R2 in PBMC

Timepoint

Baseline , after 8 weeks

Method of measurement

Realtime PCR

3

Description

gene expression of PPAR gamma in PBMC

Timepoint

Baseline , after 8 weeks

Method of measurement

Realtime PCR

4

Description

serum A-FABP

Timepoint

Baseline , after 8 weeks

Method of measurement

ELISA

5

Description

serum hs-CRP

Timepoint

Baseline , after 8 weeks

Method of measurement

ELISA

6

Description

serum adiponectin

Timepoint

Baseline , after 8 weeks

Method of measurement

ELISA

7**Description**

adiponectin / A-FABP

Timepoint

Baseline , after 8 weeks

Method of measurement

Calculate

8**Description**

Systolic Blood pressure

Timepoint

Baseline , after 8 weeks

Method of measurement

Mercury Sphygmomanometer

9**Description**

Diastolic Blood pressure

Timepoint

Baseline , after 8 weeks

Method of measurement

Mercury Sphygmomanometer

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

serum cratinine

Timepoint

baseline, after 8 weeks

Method of measurement

ELISA

2**Description**

waist circumference

Timepoint

baseline, after 8 weeks

Method of measurement

meter

3**Description**

hip circumference

Timepoint

baseline, after 8 weeks

Method of measurement

meter

4**Description**

serum fasting glucose

Timepoint

baseline, after 8 weeks

Method of measurement

Autoanalyser

5**Description**

serum triglyceride

Timepoint

baseline, after 8 weeks

Method of measurement

Autoanalyser

6**Description**

serum total cholesterol

Timepoint

baseline, after 8 weeks

Method of measurement

Autoanalyser

7**Description**

Low density lipoprotein

Timepoint

baseline, after 8 weeks

Method of measurement

Autoanalyser

8**Description**

high Density Lipoprotein

Timepoint

baseline, after 8 weeks

Method of measurement

Autoanalyser

9**Description**

Body Composition

Timepoint

baseline, after 8 weeks

Method of measurement

BIA

10**Description**

height

Timepoint

Baseline

Method of measurement

meter

11

Description

weight

Timepoint

baseline, after 8 weeks

Method of measurement

Weighing scales

12

Description

Body mass index(BMI)

Timepoint

baseline, after 8 weeks

Method of measurement

calculate

13

Description

24 hours recall

Timepoint

baseline, after 8 weeks

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: receiving omega 3 capsule (two 2 gr capsule two times daily, total 4 gr) for 8 weeks

Category

Treatment - Drugs

2

Description

Intervention group: receiving omega 3 capsule (two 2 gr capsule two times daily, total 4 gr) and 1 capsule vitamin E(400 IU)for 8 weeks

Category

Treatment - Drugs

3

Description

control group: receiving placebo capsule contain: omega 3 placebo capsule (two 2 gr capsule two times daily, total 4 gr) and 1 placebo of vitamin E(400 IU)for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Heart Hospital

Full name of responsible person

Atena Ramezani

Street address

tehran -kargar St

City

tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

tehran university of medical sciences

Full name of responsible person

Dr. Akbar Fotoohi

Street address

Vice-chancellor for Research, 6th floor, Tehran University of Medical Sciences, Central building, Keshavarz blvd.

City

tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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 Cellular And Molecular Nutrition, Tehran University of Medical Sciences

Full name of responsible person

Atena Ramezani

Position

ph.D student of Nutrition

Other areas of specialty/work

Street address

Nutrition Department, Health Faculty, Tehran University of Medical Sciences, Poorsina street

City

tehran

Postal code

Phone

+218 8954911

Fax

Email

ramezaniatena@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of cellular and molecular Nutrition, Tehran University of Medical Sciences

Full name of responsible person

Dr. Mahmoud Jalali

Position

Professor of Biochemistry/PhD

Other areas of specialty/work

Street address

Nutrition and Biochemistry Department, Health Faculty, Tehran University of Medical Sciences, Poorsina Street

City

tehran

Postal code

00982188974463

Phone

+98 21 8895 4911

Fax

Email

jalalimahmoud@hotmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Atena Ramezani

Position

ph.D student of Nutrition

Other areas of specialty/work

Street address

Nutrition and biochemistry Department, 4th floor, Health Faculty, Poorsina street

City

Tehran

Postal code

Phone

+98 21 8895 4911

Fax

+98 21 8897 4462

Email

ramezani_a@razi.tums.ac.ir

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