Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

The effect of Supplemetation of ω3 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 man contracted the disease and vascular heart disease, with shortness of breath more than 50% in at least one of the veins has been proved کرونری 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 cellswere 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 a 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 Supplemetation of ω3 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 Supplemetation of ω3 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 PPARγ 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 cirumfrence
Timepoint
baseline, after 8 weeks
Method of measurement
meter

3

Description
hip cirumfrence
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
Depatment 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
Depatment 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