

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of Omega-3 polyunsaturated fatty acids (PUFAs) in serum CK-MB and Troponin I as markers of myocardial injury after PCI

Protocol summary

Summary

Importance and necessity of the project: Due to the fact that PCI is a critical treatment for cardiovascular patients, it has dangerous complications during and after that. By reducing the side effects of this vital treatment it will be safer and reliable. Objectives: The effect of Omega 3 in the prevention of myocardial injury induced by coronary interventional procedures. The effect of Omega3 in reducing the level of CK-MB and Troponin I after PCI. The design and method of the project: Among those who are supposed to be for elective PCI were randomly assigned to 2 groups of 50 persons chosen 100 people we share quite similar. In Group A, 12 hours before PCI approximately 3 grams of omega-3 can be combined with routine medications before PCI include Aspirin and Plavix. In Group B 12 hours before PCI ' placebo with routine medication before PCI given to do and compare the CK-MB and Troponin I levels in the two groups against each measure and against the values before PCI. participants: there are 100 patients who divided to 2 groups of 50 persons in range of 36-68 years. Inclusion criteria: patients who require elective PCI; patients with angiographic indications for PCI; patients with personal satisfaction conscious to taking part in the study. Exclusion criteria: patients who require emergency PCI; renal insufficiency; treatment with anticoagulant drugs; myocarditis or myopericarditis; myopathies; infection and chemotherapy. interventions: our intervention is medical(3 grams of omega-3) before coronary intervention (PCI) The main outcome variables: The main outcome variables, are CK-MB and Troponin I, those we are expecting to decrease in their rise in omega 3 group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072329035N1**

Registration date: **2016-09-08, 1395/06/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-08, 1395/06/18

Registrant information

Name

Hamoon Shahalinia

Name of organization / entity

Ardabil University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Ardabil University of Medical Sciences(Vice President of Research)

Expected recruitment start date

2016-09-07, 1395/06/17

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Omega-3 polyunsaturated fatty acids (PUFAs) in serum CK-MB and Troponin I as markers of myocardial injury after PCI

Public title

The effect of omega-3 in the prevention of cardiac complications after PCI

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients who require elective PCI; patients with angiographic indications for PCI; patients with personal satisfaction conscious to taking part in the study . Exclusion criteria: patients who require emergency PCI; renal insufficiency; treatment with anticoagulant drugs; myocarditis or myopericarditis; myopathies; infection and chemotherapy.

Age

From **36 years** old to **68 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ardabil University of Medical Sciences

Street address

Ardabil University of Medical Sciences, Daneshgah street

City

Ardabil

Postal code

Approval date

2015-08-24, 1394/06/02

Ethics committee reference number

IR.ARUMS.REC.1394.23

Health conditions studied

1

Description of health condition studied

Chronic ischaemic heart disease

ICD-10 code

I25

ICD-10 code description

Atherosclerotic heart disease

Primary outcomes

1

Description

Troponin I

Timepoint

Before PCI and 24 hours after PCI

Method of measurement

Blood test

2

Description

CK-MB

Timepoint

Before PCI and 24 hours after PCI

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups

1

Description

placebo/ 12 hours before PCI/stat

Category

Placebo

2

Description

omega-3/ 3gr/ 12hours before PCI/ stat

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeyni hospital

Full name of responsible person

Street address

City

Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr. Shahram Habibzadeh

Street address

Ardabil University of Medical Sciences, Daneshgah St.

City

Ardabil

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Dr. Leili Avesta

Position

Assistant Professor of cardiology / Echocardiography
Fellow

Other areas of specialty/work

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Position

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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