Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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 Asprin 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 devided 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

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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.
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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

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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