

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Effect of omega 3 on cardiac necrosis biomarkers, Tnl and CK-MB, and 30-days major adverse cardiac effects (MACE) after percutaneous coronary intervention (PCI) in chronic kidney disease patients (CKD)

Protocol summary

Summary

The aim of this study is to investigate the efficacy of omega 3 fatty acids in decreasing cardiac necrosis biomarkers, Tnl and CK-MB, and major adverse cardiac effects after percutaneous coronary intervention in patients with chronic kidney disease. 80 patients with chronic kidney disease, who are candidate of elective percutaneous coronary intervention, will be included. Patients with these exclusion criteria will be excluded: performing Coronary Artery Bypass Graft during last 3 months, treatment with glycoprotein IIb/IIIa inhibitors during percutaneous coronary intervention, treatment with bivalirudine during percutaneous coronary intervention, sensitivity or tolerance to ASA or Clopidogrel, sever active bleeding. The intervention group will receive 3 gr single dose of omega 3 plus standard regimen before percutaneous coronary intervention (ASA, clopidogrel and heparin) whereas the control group just will receive standard regimen. Tnl and CK-MB will be assessed before and 24 hrs after percutaneous coronary intervention as a primary outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015040920441N2**

Registration date: **2015-04-12, 1394/01/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-04-12, 1394/01/23

Registrant information

Name

Farzaneh Foroughinia

Name of organization / entity

Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences, International branch

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of omega 3 on cardiac necrosis biomarkers, Tnl and CK-MB, and 30-days major adverse cardiac effects (MACE) after percutaneous coronary intervention (PCI) in chronic kidney disease patients (CKD)

Public title

Effect of omega 3 on cardiac necrosis biomarkers, Tnl and CK-MB

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Informed consent form; NSTEMI-ACS candidate for elective PCI; treatment with ASA at least 5 days before PCI; CKD patients (GFR < 60 ml/min)
Exclusion criteria: CABG during last 3 months; treatment with glycoprotein IIb/IIIa inhibitors during PCI; treatment with bivalirudine during PCI; sensitivity or tolerance to ASA or Clopidogrel; unsatisfactory PCI; severe active bleeding; severe adverse effects to drugs

Age

From **18 years** old to **80 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)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shiraz University of Medical Sciences, Deputy for research

Street address

Deputy for research, Central building of Shiraz University of Medical Sciences, Zand avenue

City

Shiraz

Postal code**Approval date**

2016-01-04, 1394/10/14

Ethics committee reference number

CT-2015-231

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

heart disease

ICD-10 code

I70

ICD-10 code description

Atherosclerosis

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

Creatine kinase-MB

Timepoint

24 hours after PCI

Method of measurement

ELISA

2**Description**

troponin I

Timepoint

24 hours after PCI

Method of measurement

ELISA

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

Major Adverse Cardiac Effect (MACE)

Timepoint

30 days after PCI

Method of measurement

Following patients by phone

Intervention groups**1****Description**

Standard treatment before PCI (clopidogrel+heparin+ASA) plus 3gr single dose of omega 3 soft gel at least 12 hours before PCI

Category

N/A

2**Description**

Standard drug treatment before PCI (clopidogrel+heparin+ASA)

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Namazi hospital

Full name of responsible person

Maryam Forouzmehr

Street address

City

Shiraz

2

Recruitment center

Name of recruitment center

Kowsar heart center

Full name of responsible person

Maryam Forouzmehr

Street address

City

Shiraz

3

Recruitment center

Name of recruitment center

Alzahra heart center

Full name of responsible person

Maryam Forouzmehr

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences, International branch

Full name of responsible person

Dr Farzaneh Foroughinia

Street address

Faculty of pharmacy, Shiraz University of Medical Sciences, Rokn Abad street

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences, International branch

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

Shiraz University of Medical Sciences

Full name of responsible person

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specialist/assistant professor

Other areas of specialty/work

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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