

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Role of Omega-3 in the prevention of contrast-induced nephropathy

Protocol summary

Summary

Based on antioxidant effect of omega-3 polyunsaturated fatty acids and the role of free radicals in the pathogenesis of CIN, as well as a higher risk of CIN in patients with chronic kidney disease (CKD), this study is aimed to assess the effect of omega-3 in the prevention of CIN in CKD patients undergoing PCI. Inclusion criteria included chronic kidney disease with GFR 15- 60 ml/min/1.73 m², the ages of 18 to 80 years, and patients undergoing elective PCI. The patients who treated with N-acetyl cysteine or receiving vitamin C before PCI were excluded. Eighty patients with CKD who are candidate for elective PCI will be randomly assigned into two groups. The intervention group will receive 2.5 g single dose of omega-3 plus standard CIN preventive therapy (hydration) 12 hrs before PCI whereas the control group will just receive standard regimen. Cystatin C and creatinine will be assessed before and 24 hrs after PCI as a primary outcome. Only analysts are blinded in this study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016031320441N3**

Registration date: **2016-04-29, 1395/02/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-04-29, 1395/02/10

Registrant information

Name

Farzaneh Foroughinia

Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences, International branch

Expected recruitment start date

2015-09-30, 1394/07/08

Expected recruitment end date

2016-12-30, 1395/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Role of Omega-3 in the prevention of contrast-induced nephropathy

Public title

The role of Omega-3 polyunsaturated fatty acids in the prevention of contrast-induced nephropathy (CIN) after percutaneous coronary intervention (PCI) in chronic kidney disease (CKD) patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria included chronic kidney disease with GFR 15- 60 ml/min/1.73 m², the ages of 18 to 80 years, and patients undergoing elective PCI. Exclusion criteria: Pretreatment with N-acetyl cystein or intravenous vitamin C; sensitivity or tolerance to ASA or Clopidogrel or omega-3; sever 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**

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand avenue, Shiraz University of Medical Sciences

City

Shiraz

Postal code**Approval date**

2016-03-06, 1394/12/16

Ethics committee reference number

IR.SUMS.REC.1394.207

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

renal disease

ICD-10 code

N14.1

ICD-10 code description

Nephropathy induced by other drugs, medicaments and biological substances

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

cystatin C

Timepoint

24 hours after PCI

Method of measurement

kit

2**Description**

serum creatinine

Timepoint

24 hours after PCI

Method of measurement

kit

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

CIN occurrence

Timepoint

24 hrs after PCI

Method of measurement

based on cystatin C

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

Intervention: omega-3 12hrs before PCI plus standard CIN preventive therapy (hydration)

Category

Prevention

2**Description**

Control: just standard CIN preventive therapy (hydration)

Category

Prevention

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

Kowsar Heart Center

Full name of responsible person**Street address****City**

Shiraz

2**Recruitment center****Name of recruitment center**

Alzahra Heart Center

Full name of responsible person**Street address****City**

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences, International branch

Full name of responsible person

Ali Poostforoosh Fard

Street address

Shiraz University of Medical Sciences building, Zand avenue

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, 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**

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Full name of responsible person

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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