

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Omega-3 in the prevention of contrast-induced nephropathy after percutaneous coronary intervention

Protocol summary

Summary

Based on the antioxidant effect of omega-3 polyunsaturated fatty acids and the potential role of free radicals in the pathogenesis of contrast-induced nephropathy (CIN), in this study, we aimed to assess the effect of omega-3 in the prevention of CIN in patients undergoing percutaneous coronary intervention (PCI). Eighty patients candidate of elective PCI will be randomly assigned into two groups. Inclusion criteria are eGFR higher than 60 ml/min/1.73 m², the ages of 18 to 80 years, and patients undergoing elective PCI. The patients treated with N-acetyl cysteine or receiving vitamin C before PCI will be excluded from the study. The intervention group will receive 2500 mg single dose of omega-3 plus standard preventive therapy of CIN (hydration) 12 hrs before PCI whereas the control group will just receive standard regimen. Only analysts are blinded in this study. Serum cystatin C and creatinine will be assessed before and 24 hrs after PCI as a primary outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041920441N4**

Registration date: **2016-05-31, 1395/03/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-31, 1395/03/11

Registrant information

Name

Farzaneh Froughinia

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

2016-03-10, 1394/12/20

Expected recruitment end date

2017-03-10, 1395/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Omega-3 in the prevention of contrast-induced nephropathy after percutaneous coronary intervention

Public title

The role of omega-3 polyunsaturated fatty acids in the prevention of contrast-induced nephropathy (CIN) in post percutaneous coronary intervention (PCI) patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria included GFR more than 60 ml/min/1.73 m²; the ages of 18 to 80 years; patients undergoing elective PCI. Exclusion criteria: Pretreatment with N-acetyl cysteine or intravenous vitamin C; sensitivity or tolerance to ASA or Clopidogrel or omega-3; 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

Single

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

Shiraz University of Medical Sciences, Zand avenue, Shiraz, Iran

City

Shiraz

Postal code**Approval date**

2016-03-06, 1394/12/16

Ethics committee reference number

IR.SUMS.REC.1394.208

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

Renal disease

ICD-10 code

N14.1

ICD-10 code description

Contrast-induced nephropathy

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

Cystatin C

Timepoint

Baseline and 24 hours after PCI

Method of measurement

Kit

2**Description**

Serum creatinine

Timepoint

Baseline and 24 hours after PCI

Method of measurement

Kit

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

Contrast-induced nephropathy occurrence

Timepoint

24 hrs after PCI

Method of measurement

Based on cystatin C

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

Intervention: administration of omega-3, 12hr before percutaneous coronary intervention plus standard contrast-induced nephropathy preventive therapy (hydration)

Category

Prevention

2**Description**

Control: just standard contrast-induced nephropathy preventive therapy (hydration)

Category

Prevention

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

Alzahra heart center

Full name of responsible person

Farzaneh Foroughinia

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Alzahra heart center, Sibooeye avenue, Shiraz, Fars, Iran

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2

Recruitment center

Name of recruitment center

Kowsar hospital

Full name of responsible person

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Kowsar hospital, Ghasrodasht gharbi avenue, Shiraz,
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City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences, international
branch

Full name of responsible person

Ali Poostforoosh Fard

Street address

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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

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Full name of responsible person

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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