

# 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 m<sup>2</sup>, 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3635 9357

##### Email address

froughinia@sums.ac.ir

##### 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 m<sup>2</sup>; 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

**Street address**

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

**City**

Shiraz

**2**

**Recruitment center**

**Name of recruitment center**

Kowsar hospital

**Full name of responsible person**

Farzaneh Foroughinia

**Street address**

Kowsar hospital, Ghasrodasht gharbi avenue, Shiraz,  
Fars, Iran

**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

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Shiraz University of Medical Sciences, Zand avenue

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**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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**Position**

Assistant professor

**Other areas of specialty/work**

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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*