

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effect of omega 3 in the prevention of major adverse cardiovascular events

Protocol summary

Summary

Regarding the antiplatelet effect of omega-3 polyunsaturated fatty acids and the potential role of platelet inhibitor drugs in the prevention of cardiovascular events after vascular stenting interventions, in this study, we aimed to assess the effect of omega-3 in the prevention of 30-days major adverse cardiovascular events following Carotid Stenting. Sixty patients candidate of carotid stenting with the ages of 18 to 80 years will be randomly assigned into two groups. The patients with unsatisfactory carotid artery stenting; treatment with glycoprotein IIb/IIIa antagonists or bivalirudin; active bleeding; sensitivity or tolerance to aspirin or clopidogrel or omega-3; and history of percutaneous intervention or coronary artery bypass grafting surgery within 30 days of carotid stenting will be excluded from the study. The intervention group will receive 3g single dose of omega-3, 12 hrs before intervention plus standard treatment before carotid stenting (clopidogrel+ASA) whereas the control group will just receive the standard regimen. Occurrence of major adverse cardiovascular events (stroke, myocardial infarction, revascularization, death) will be assessed during 30-days after intervention as a primary outcome. Only analysts are blinded in this study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011120441N6**
Registration date: **2017-01-24, 1395/11/05**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-24, 1395/11/05

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

Expected recruitment start date

2016-01-14, 1394/10/24

Expected recruitment end date

2017-11-14, 1396/08/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of omega 3 in the prevention of major adverse cardiovascular events

Public title

Effect of omega 3 in the prevention of 30-days major adverse cardiovascular events following Carotid Stenting

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: □Patients undergoing carotid stenting (more than 50% stenosis of the internal carotid artery in symptomatic patients, or □70% stenosis in asymptomatic patients); The ages of 18 to 80 years Exclusion criteria:

Unsatisfactory carotid artery stenting; Intraluminal thrombus over the stenosis; pretreatment with glycoprotein IIb/IIIa antagonists or bivalirudin; Active bleeding; Sensitivity or tolerance to aspirin or Clopidogrel or omega-3; Sever adverse effects to drugs; Percutaneous intervention or surgery less than 30 days

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: **60**

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

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

Street address

Shiraz University of Medical Sciences, Deputy for research

City

Shiraz

Postal code

Approval date

2016-04-10, 1395/01/22

Ethics committee reference number

IR.SUMS.REC.1395.6

Health conditions studied

1

Description of health condition studied

Cerebrovascular diseases

ICD-10 code

I65.2

ICD-10 code description

Occlusion and stenosis of carotid artery

Primary outcomes

1

Description

Major adverse cardiovascular events (MACE)

Timepoint

30 days after carotid stenting

Method of measurement

Following patients by phone

Secondary outcomes

1

Description

stroke

Timepoint

24-hrs following carotid stenting

Method of measurement

MRI

Intervention groups

1

Description

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

Category

Prevention

2

Description

Standard treatment (clopidogrel+ASA) before carotid stenting

Category

Prevention

Recruitment centers

1

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

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences, Vice Chancellor of Research

Full name of responsible person

Ali Poostforoosh Fard

Street address

Vice Chancellor of Research, Shiraz University of Medical Sciences, Zand avenue, Shiraz, Fars, Iran

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, Vice Chancellor of Research

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

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Position

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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