Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Farzaneh Foroughinia
Name of organization / entity
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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

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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
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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

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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