Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the relationship between stenting in stenosed carotid artery in patients candidate for CABG and clinical outcomes in patients in comparison with Patients candidate for CABG without stenting.

Protocol summary

Study aim

Evaluation of the relationship between stenting in stenosed carotid artery in patients candidate for CABG and clinical outcomes in patients in comparison with Patients candidate for CABG without stenting.

Design

Case Group Patients: All patients who are candidates for CABG and are eligible for inclusion will undergo stenting and then undergo CABG 6 weeks late. Patients in the control group: Selected patients who had CABG without carotid artery stenting and had carotid artery stenosis on their ultrasound. Patients were matched for age, sex, underlying disease and coronary artery disease.Due to ethical considerations and the type of intervention, there was no possibility of blinded and random allocation.

Settings and conduct

All patients who are candidates for vascular grafts and who meet the inclusion criteria are screened by Doppler ultrasound for at least 3 days before carotid artery stenting.6 weeks after stenting, vascular grafts are performed. Finally, they will be monitored for 6 months to evaluate for myocardial infarction, stroke, transient ischemia, and death.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate for CABG Carotid stenosis more than 60% with a previous history of stroke or TIA Carotid stenosis more than 85% in asymptomatic individuals Exclusion criteria: Severe stricture The previous severe disabling stroke Inability to use anticoagulants such as drug sensitivity or gastric ulcer

Intervention groups

Intervention group 1 includes people who are candidates for CABG and have carotid artery stenosis of 60% or more and have a previous history of stroke or TIA and receive stenting intervention. Intervention group 2 includes people who are candidates for CABG with carotid artery stenosis of 85% or more and receive stenting intervention.

Main outcome variables

transient ischemic attack Stroke myocardial infarction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190305042937N2**
Registration date: **2019-12-03, 1398/09/12**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-03, 1398/09/12**
Update count: **0**

Registration date

2019-12-03, 1398/09/12

Registrant information

Name

soroush sharifimoghadam

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the relationship between stenting in stenosed carotid artery in patients candidate for CABG and clinical outcomes in patients in comparison with Patients candidate for CABG without stenting.

Public title
Evaluation of the relationship between stenting in stenosed carotid artery in patients candidate for CABG and clinical outcomes in patients in comparison with Patients candidate for CABG without stenting.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Candidate for CABG practice Carotid stenosis more than 60% with a previous history of stroke or TIA Carotid stenosis more than 85% in asymptomatic individuals
Exclusion criteria:
Severe stricture The previous severe debilitating stroke Inability to use anticoagulants such as drug sensitivity or gastric ulcer
Age
From **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **117**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not 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 Qom University of Medical Sciences
Street address
Vice chancellor for research, Qom University of Medical Sciences - Safashahr St - Qom
City
Qom
Province
Ghoum
Postal code
3713649373
Approval date
2019-09-03, 1398/06/12
Ethics committee reference number
IR.MUQ.REC.1398.086

Health conditions studied

1

Description of health condition studied
Carotid artery stenosis
ICD-10 code
170
ICD-10 code description
Atherosclerosis

Primary outcomes

1

Description
TIA, cerebral stroke or heart attack
Timepoint
Up to 6 months after CABG at 3 month intervals
Method of measurement
Outcome assessment based on hospital admission records and phone calls at 3 months intervals

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: At least 3 days before carotid artery stenting, patients will receive antiplatelet therapy with aspirin 80 mg and clopidogrel 75 mg. The stenting procedure in the angiography unit will be performed by a neurointervention specialist. Self-expanding stents will be used in this study and balloons will be assisted if needed. After the operation, one-way brain angiography and one carotid artery are performed to confirm that it is successful. Clopidogrel 75 mg will be continued for all patients and discontinued one week prior to CABG. In those with bilateral carotid artery stenosis, or at a 3-week interval, the same procedure will be performed. Six weeks after stenting, CABG is performed
Category
Treatment - Surgery

2

Description
Control group: These patients undergo CABG without stenting for the carotid artery.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
Ghoum University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Ehsan Sharifipur
Position
Assistant Professor Qom University of Medical Sciences
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The unnamed person information file will be released.

When the data will become available and for how long
After publishing the article

To whom data/document is available
Vice chancellor for research, Qom University of Medical Sciences

Under which criteria data/document could be used
To assist in further studies and with the permission of the Research Assistant

From where data/document is obtainable
Vice chancellor for research, Qom University of Medical Sciences

What processes are involved for a request to access data/document
Qom University of Medical Sciences Vice Chancellor for Research

Comments