Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of vascular complication incidence in patients with Internal Carotid Artery(ICA) stenosis treated with Carotid Artery Stenting (CAS) without Embolic protection device (EPD) in comparison to CAS with EPD

Protocol summary

Study aim

To determine complications of carotid artery stenting without the use of embolic protective device compared to usage of embolic protective device in patients with carotid artery stenosis

Design

A single-blinded parallel randomized Clinical trial with control group is performed on 60 patients using block randomization (10 blocks of 6)

Settings and conduct

In this study, patients with carotid artery stenosis who are candidates for carotid artery stenting, will be treated in two groups: in the first group carotid artery stenting is done using embolic protective device and in the second group without embolic protective device. For all patients, brain magnetic resonance imaging (MRI) including diffusion-weighted imaging before and early (24 hours) after the procedure is performed. then, patients are examined 24 hours and 2 years after the procedure regarding probable complications. The single blind method is used, so that the evaluation team who assess the results of the intervention (including the physician who examines the patients before and after the treatment to evaluate the results of the intervention and the radiologist who reviews patients MRI) are blinded to the type of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients over 18 years old, Carotid artery stenosis more than 70% in asymptomatic patients, Carotid artery stenosis more than 50% in symptomatic patients. Exclusion criteria: Ideal candidates for carotid Endarterectomy, Renal failure, history of allergy to radiocontrast agents.

Intervention groups

Intervention group: The group treated with carotid artery stenting using embolic protection device (Type: EZ, Manufacturer: Boston Scientific). Control group: The group treated with carotid artery stenting without using embolic protection device

Main outcome variables

Neurological complications including stroke symptoms; restenosis of carotid artery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140712018457N7**
Registration date: **2022-11-14, 1401/08/23**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-14, 1401/08/23**
Update count: **0**

Registration date

2022-11-14, 1401/08/23

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-07, 1401/07/15

Expected recruitment end date
2024-10-06, 1403/07/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of vascular complication incidence in patients with Internal Carotid Artery(ICA) stenosis treated with Carotid Artery Stenting (CAS) without Embolic protection device (EPD) in comparison to CAS with EPD

Public title
Comparison of vascular complications in carotid artery stenting with and without the use of embolic protection device
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients over 18 years old Internal carotid artery stenosis more than 70% in asymptomatic patients Internal carotid artery stenosis more than 50% in symptomatic patients
Exclusion criteria:
Proper candidate for Endarterectomy Renal failure History of allergy to radio contrast agents.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, we will use the restricted randomization method of the block randomization type. Blocking is usually used in order to balance the number of samples allocated to each of the study groups. This feature allows researchers to assign the same number of samples to each of the examined groups in circumstances where intermediate analyses are required during taking samples. The size of all the blocks is equal and will be 6 in this two-group experiment (including 3 participants in the intervention group and 3 participants in the control group). Additionally, random allocation software is used to generate random sequences using the block approach in addition to simple randomization. To conceal the random allocation, we utilize allocation concealment, which refers to the method of performing a random sequence on the research participants in such a way that the allocated group is unknown prior to the allocation of the individual. Using opaque letter envelopes sealed with a random sequence, each random sequence formed is recorded on a card, and the cards are placed inside the letter envelopes in the order they are inserted. To preserve a random sequence, the exterior surface of the envelopes is numbered in the same order. The letter envelope lids are then sealed with adhesive and set within a box. At the time of participant registration, one of the envelopes will be opened, revealing the individual's assigned group depending on the sequence in which the eligible participants entered the study.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this single-blinded study, the evaluation team who assess outcomes (Including the physician who examines the patients before and after the treatment to evaluate the intervention results and the radiologist who reviews MRI results) are blinded to the type of the treatment. In fact, the outcome evaluation team is not part of the treatment team and only evaluates the procedure outcome.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Imam Khomeini Hospital Complex Medical Ethics Committee
Street address
Imam Khomeini Hospital Complex, Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1419733141
Approval date
2022-08-30, 1401/06/08
Ethics committee reference number
IR.TUMS.IKHC.REC.1401.120

Health conditions studied

1

Description of health condition studied
Carotid Stenosis
ICD-10 code
I65.2
ICD-10 code description
Occlusion and stenosis of carotid artery

Primary outcomes

1

Description
Brain stroke
Timepoint
Twenty-four hours after treatment (early complication), 6 months and 2 years after treatment
Method of measurement
Physical examination and history taking, Magnetic Resonance Imaging (MRI)

2

Description
Myocardial Infarction
Timepoint
Twenty-four hours after treatment (early complication), 6 months and 2 years after treatment
Method of measurement
Physical examination and history taking, Electrocardiography

3

Description
New lesions in MR imaging (Diffusion-weighted imaging)
Timepoint
Twenty-four hours after treatment
Method of measurement
MR Imaging

4

Description
Carotid artery restenosis
Timepoint
6 months and 2years after treatment.
Method of measurement
Carotid artery ultrasonography

5

Description
Mortality
Timepoint
Follow-up of patients 24 hours after treatment, 6 months and 2 years after treatment
Method of measurement
Physical examination and history taking, telephone follow-up

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Carotid artery stenting with an protective device in patient with carotid artery stenosis (A device used to reduce the risk of embolic complications during carotid artery stenting procedure. Type of device: EZ, Company Name: Boston Scientific)
Category
Treatment - Devices

2

Description
Control group: Carotid artery stenting without a protective device in patient with carotid artery stenosis.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Tehran 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

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Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available