

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison between Cheatham-Platinum Stent and Self-Expandable Uncovered Nitinol Stent in patients with Coarctation of Aorta - A Randomized Controlled Trial

Protocol summary

Study aim

Comparison of two methods of stenting with Patients with Nitinol Uncovered Self-expandable Stent versus Cheatham Platinum Stent in patient with native coarctation of aorta

Design

Two parallel groups randomized trial with blinded outcome assessment

Settings and conduct

The trial will be held in a hospital setting (Rajaie Cardiovascular Medical and Research center) on patients with native coarctation of aorta . Patients will be randomized via central web based method into two interventional groups with two different stenting methods. Treating physician and patients will not be blinded. Stenting outcome after the procedure and 6 months later will be evaluated via echocardiography. Coarctoplasty complications will be evaluated via aortic CT-angiography after one year.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with native coarctation of aorta who were referred to Rajaie cardiovascular medical and research center for coarctoplasty Exclusion Criteria : Patients with Non-circular aortic arch, patients with preductal coarctation of aorta, patients with hypoplastic Aortic Arch, patients with right aberrant subclavian artery, patients with stenosis more than 20 mm in length, patients with an aneurysm along with coarctation, patients with common femoral and external iliac artery less than 7 mm in diameters

Intervention groups

In this study there are two interventional groups: First group: Patients with coarctation of aorta who underwent coarctoplasty with Nitinol Uncovered Self-expandable Stent, and the second group: patients with coarctation of aorta who underwent coarctoplasty with Cheatham Platinum Stent.

Main outcome variables

Stent migration, aortic perforation, success rate, access site complication, recoarctation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181022041406N3**

Registration date: **2019-04-20, 1398/01/31**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-20, 1398/01/31**

Update count: **0**

Registration date

2019-04-20, 1398/01/31

Registrant information

Name

Parham Sadeghipour

Name of organization / entity

Rajaie Cardiovascular Medical and Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 2392 2092

Email address

psadeghipour@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2019-05-21, 1398/02/31

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison between Cheatham-Platinum Stent and Self-Expandable Uncovered Nitinol Stent in patients with Coarctation of Aorta - A Randomized Controlled Trial

Public title
Stenting in Coarctation of Aorta (CoA)

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 All patients with native Coarctation of aorta referred to rajaie cardiovascular medical and research center for stenting
Exclusion criteria:
 Patients with noncircular aortic arch Patients with preductal coarctation Patients with hypoplastic aortic arch Patients with right aberrant subclavian artery Patients with stenosis more than 20 mm in length Patients having aneurysm along with coarctation Patients with common femoral artery and external iliac artery less than 7 mm in diameter

Age
From **16 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be performed via permuted block randomization method. Allocation will be generated via a web based system and consequently concealment will be central using computer software. Unit of randomization will be individual patients and no stratification will be applied.

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

Rajaie Cardiovascular Medical and Research Center
Ethic committee

Street address

Vali-Asr ave, Hashemi Rafsanjani Exp

City

Tehran

Province

Tehran

Postal code

1995614331

Approval date

2016-10-01, 1395/07/10

Ethics committee reference number

9540

Health conditions studied

1

Description of health condition studied

Coarctation of aorta

ICD-10 code

Q25.1

ICD-10 code description

Coarctation of aorta

Primary outcomes

1

Description

Stent migration

Timepoint

During the procedure

Method of measurement

Fluoroscopy

2

Description

Aortic perforation

Timepoint

During the procedure

Method of measurement

Angiography

3

Description

Procedural success rate

Timepoint

Just after the procedure

Method of measurement

Catheterization

4

Description

Access site complication

Timepoint

Just after the procedure

Method of measurement

CT angiography

5

Description

Recoarctation

Timepoint

6 and 12 months after the intervention

Method of measurement

Catheterization

Secondary outcomes

1

Description

mortality

Timepoint

During hospitalization

Method of measurement

Questionnaire

2

Description

Aneurysm formation

Timepoint

12 months after intervention

Method of measurement

CT angiography

Intervention groups

1

Description

Intervention group: Coarctoplasty with Self-Expandable
Uncovered Nitinol stent

Category

Treatment - Devices

2

Description

Intervention group: Coarctoplasty with Cheatham-
Platinum Stent

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaie cardiovascular medical and research center

Full name of responsible person

Parham Sadeghipour

Street address

Vali-Asr ave, Hashemi Rafsanjani Exp

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Email

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Rajaie cardiovascular medical and research center

Full name of responsible person

Feridoun Nouhi

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fnoohi@rhc.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Rajaie cardiovascular medical and research center

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**

Rajaie cardiovascular medical and research center

Full name of responsible person

Parham Sadeghipour

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Rajaie cardiovascular medical and research center

Full name of responsible person

Parham Sadeghipour

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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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