Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Endovascular stenting with covered cp stent compared with bare cp stent for adult patients with coarctation: the initial and intermediate-term follow up results

Protocol summary

Summary

Target of this study is comparing six months follow up between covered and bare cp stent in adult patients with coarctation . Thirty above 12 years of age patients with COA, will go under the stenting procedure by two interventionists. All the information will be recorded before and after the procedure. The patients will go under echocardiography after the stenting and the success of procedure is defined as a 20 mmHg decrease in gradient immediately after stenting and increase of aortic lumen. The patients will be flowed up in 1st, 3d and 6th months of stenting by clinical examinations and echocardiography to evaluate the location of stent and incidence of pseudoaneurysm. Also the patients will go under angiographic follow up 6 months after stenting with a multi-slice CT angiography, 64 (MSCT).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012045311N1**
Registration date: **2011-12-03, 1390/09/12**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-12-03, 1390/09/12

Registrant information

Name

Bahram Sohrabi

Name of organization / entity

Tabriz University of Medical Sciences and Health Services

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences and Health Services

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2012-01-21, 1390/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Endovascular stenting with covered cp stent compared with bare cp stent for adult patients with coarctation: the initial and intermediate-term follow up results

Public title

Comparison of short-term and intermediate-term outcomes between covered and bare cp stent in adult patients with coarctation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The patients above 12 years of age with accurate documented information diagnosed with post ductal COA and average gradient above 20 mmHg with or without hypertension candidates of stenting.
Exclusion criteria: Patients with segmental coarctation; aortic arch hypoplasia; ductal coarctation blades.

Age
From **12 years** old to **100 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
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
Tabriz University of Medical Sciences and Health Services
Street address
Golgasht St
City
Tabriz
Postal code
Approval date
2011-02-20, 1389/12/01
Ethics committee reference number
9626/4/5

Health conditions studied

1

Description of health condition studied
Aortic Coarectation
ICD-10 code
Q25.1
ICD-10 code description
Coarctation of aorta

Primary outcomes

1

Description
Recoarectation
Timepoint
3 months
Method of measurement
Echocardiography and Angiographic followup

Secondary outcomes

1

Description
Hypertension during follow-up
Timepoint
3 months
Method of measurement
physical exam

Intervention groups

1

Description
stenting of aortic coarection with bare stent
Category
Treatment - Surgery

2

Description
stenting of aortic coarection with coverd stent
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Madani Hospital
Full name of responsible person
Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences and Health Services
Full name of responsible person
Dr. Babak Kazemi
Street address
Madani hospital
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences and Health Services
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
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Full name of responsible person
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Person responsible for updating data

Contact

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