

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 2077

##### Email address

sohrabib@tbzmed.ac.ir

##### 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 Coarctation

**ICD-10 code**

Q25.1

**ICD-10 code description**

Coarctation of aorta

**Primary outcomes****1****Description**

Recoarctation

**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 coarctation with bare stent

**Category**

Treatment - Surgery

**2****Description**

stenting of aortic coarctation with covered 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**

Tabriz University of Medical Sciences and Health Services

**Full name of responsible person**

Dr. Mohammadreza Baghaie

**Position**

Assistant, heart superspecialty

**Other areas of specialty/work****Street address**

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Tabriz University of Medical Sciences and Health Services

**Full name of responsible person**

Dr. Bahram Sohrabi

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Interventional Cardiology Fellowship

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sohrabib@tbzmed.ac.ir

**Web page address****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*