

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of effectiveness of drug-coated balloon angioplasty versus plain balloon angioplasty in chronic lower extremity ischemia patients

Protocol summary

Study aim

Comparison of effectiveness of drug coated balloon angioplasty versus plain balloon angioplasty in chronic lower extremity ischemia patients in Ahvaz Golestan Hospital

Design

Clinical trial with control group, parallel group randomized trial with random number table. Phase 4 of randomized clinical trial and probably the number of patients is 60 .

Settings and conduct

All eligible patients based on inclusion criteria will be recruited. Their ankle brachial index will be measured and CT angiography will be done. After matching, they will be divided in to two groups of control and intervention. In control group plain balloon angioplasty and in intervention group drug coated balloon angioplasty will be performed. Patients will be followed for Rutherford class and ankle brachial index changes for 6 months.

Participants/Inclusion and exclusion criteria

patients in Rutherford class 3 to 6, length of arterial lesion less than 15 centimeters(TASC A,B), single new arterial lesion. Serum creatinine less than 1.5 milligram per deciliter. No history of hemorrhagic stroke in past 3 months.

Intervention groups

Intervention : drug coated balloon angioplasty in chronic lower extremity ischemia patients Control : plain balloon angioplasty in chronic lower extremity ischemia patients

Main outcome variables

Ankle brachial index; Rutherford classification

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180520039745N1**

Registration date: **2019-05-27, 1398/03/06**

Registration timing: **prospective**

Last update: **2019-05-27, 1398/03/06**

Update count: **0**

Registration date

2019-05-27, 1398/03/06

Registrant information

Name

Ahmad Sadegh pour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3001

Email address

sadeghpour.ahmad@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of drug-coated balloon angioplasty versus plain balloon angioplasty in chronic lower extremity ischemia patients

Public title

drug-coated and plain balloon angioplasty in chronic

lower extremity ischemia patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
lower limb chronic ischemia (Rutherford class 3-6)
Arterial lesion TASC A, B
Exclusion criteria:
previous surgery on femoral artery severe arterial lesion
calcification sudden symptom onset acute or subacute
arterial occlusion or thrombus

Age
From **18 years** old

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
After matching according to Rutherford and TASC classification, randomization is done with random number table.

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

Ethic committee of Ahvaz University of Medical Science

Street address

Golestan Ave, Golestan Hospital

City

Ahvaz

Province

Khouzestan

Postal code

6135733118

Approval date

2019-02-18, 1397/11/29

Ethics committee reference number

IR.AJUMS.REC.1397.849

Health conditions studied

1

Description of health condition studied

lower limb chronic ischemia

ICD-10 code

I70.2

ICD-10 code description

Atherosclerosis of native arteries of the extremities

Primary outcomes

1

Description

ankle brachial index change

Timepoint

measurement of ankle brachial index before, 10 days, 2 months and 6 months after intervention

Method of measurement

ankle brachial index device

2

Description

Change of Rutherford class

Timepoint

Evaluation of Rutherford class before, 10 days, 2 months and 6 months after intervention

Method of measurement

Rutherford classification scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: drug coated balloon angioplasty. According to inclusion criteria and after randomizing , patients in intervention group will undergo drug coated balloon angioplasty. Drug coated balloon is containing 2 micro gram per milliliter of Paclitoxcel with american brand of BARD.

Category

Treatment - Surgery

2

Description

Control group: plain balloon angioplasty. According to inclusion criteria and after randomizing , patients in control group will undergo plain balloon angioplasty.Plain balloons are american brand of BARD.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Golestan Hospital
Full name of responsible person
Iraj Nazari
Street address
Golestan Ave, Golestan Hospital
City
Ahvaz
Province
Khouzestan
Postal code
6135733118
Phone
+98 61 3374 3001
Email
golestanhospital@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badvi
Street address
Golestan Ave, Ahvaz University of Medical Science
City
Ahvaz
Province
Khouzestan
Postal code
6135733118
Phone
+98 61 3336 2414
Email
itc@ajums.ac.ir
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Ahmad Sadeghpour
Position
Fellowship
Latest degree
Subspecialist
Other areas of specialty/work
Vascular Surgery
Street address
Golestan Ave, Golestan Hospital
City
Ahvaz
Province
Khouzestan
Postal code
6135733118
Phone
+98 61 3374 3001
Email
dr.ahmadsadeghpour@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Ahmad Sadegh pour
Position
fellowship
Latest degree
Subspecialist
Other areas of specialty/work
Vascular surgery
Street address
Golestan Hospital, Golestan Ave.
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Khouzestan
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6135733118
Phone
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Fax
Email
dr.ahmadsadeghpour@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
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Golestan Hospital, Golestan Ave.

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Fax

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dr.ahmadsadeghpour@gmail.com

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

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

Title and more details about the data/document

Data of main consequence is participate.

When the data will become available and for how long

Initiate of accessibility 6 months after printing of results.

To whom data/document is available

Data will be accessible only for academic and scientific researchers.

Under which criteria data/document could be used

Using of data for meta analysis is permissible.

From where data/document is obtainable

Ahmad Sadegh pour Tel number: 989128092249 E.mail: dr.ahmadsadeghpour@gmail.com

What processes are involved for a request to access data/document

After sending application to scientific responsible via call or E.mail, data files will be sent within a week.

Comments