

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Impact of Cilostazol on results of Balloon Angioplasty for Infrapopliteal Artery Disease in Patients with Lower Limb Ischemia admitted to Ahwaz Golestan hospital vascular surgery ward

Protocol summary

Registration timing: **retrospective**

Study aim

Impact of Cilostazol on improvement of ischemic symptoms after infrapopliteal angioplasty in patients with lower extremity ischemia

Last update: **2019-06-11, 1398/03/21**

Update count: **0**

Registration date

2019-06-11, 1398/03/21

Design

Two arm parallel group randomized clinical trial

Registrant information

Name

Navid Salimi

Name of organization / entity

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Iran (Islamic Republic of)

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Settings and conduct

All patients with lower extremity ischemia and indication of infrapopliteal angioplasty that admitted to Ahwaz Golestan hospital vascular surgery ward randomized in two case and control groups and after successful angioplasty case group will treat with Cilostazol plus Plavix and control group will treat with Plavix and after 3 months results will be assessed.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria are patients with lower extremity ischemic symptoms and age greater than 40 years old and exclusion criteria are previous lower extremity endovascular therapy, previous lower extremity bypass surgery and patients with congestive heart failure.

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

2018-03-21, 1397/01/01

Actual recruitment end date

2019-01-21, 1397/11/01

Trial completion date

2019-01-21, 1397/11/01

Intervention groups

After successful infrapopliteal angioplasty one group of patients will treat with cilostazol plus Plavix and another group will treat with Plavix .

Main outcome variables

Relief of ischemic symptoms (based on Rutherford classification); Ischemic ulcer healing; need for limb amputation; need for repeat endovascular therapy; need for open surgery

Scientific title

Impact of Cilostazol on results of Balloon Angioplasty for Infrapopliteal Artery Disease in Patients with Lower Limb Ischemia admitted to Ahwaz Golestan hospital vascular surgery ward

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190418043306N1**

Registration date: **2019-06-11, 1398/03/21**

Public title

Impact of cilostazol on infrapopliteal angioplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Lower Limb Ischemia age over 40 years

Exclusion criteria:

Patients with congestive heart failure Patients with previous lower extremity endovascular therapy Patients with previous lower extremity bypass surgery

Age

From **40 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will divide into two groups by block randomization. Each block will be four in size and randomization is individualized by a person that is unaware of patient's group sequences.

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

Ethics committee of Ahvaz Jundishapur university of medical sciences

Street address

Ahvaz Jundishapur university of medical sciences, Golestan st., Ahvaz, Iran

City

Ahvaz

Province

Khuzestan

Postal code

1579461357

Approval date

2019-04-13, 1398/01/24

Ethics committee reference number

IR.AJUMS.REC.1398.025

Health conditions studied

1

Description of health condition studied

Peripheral arterial disease

ICD-10 code

I73.9

ICD-10 code description

Peripheral vascular disease, unspecified

Primary outcomes

1

Description

Relief of lower extremity ischemic symptoms based on Rutherford classification

Timepoint

Documentation of lower extremity ischemic symptoms based on Rutherford classification in the beginning of trial and after 3 months of medicine consumption

Method of measurement

Measurement of severity of symptoms based on Rutherford classification

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After successful infrapopliteal angioplasty patients of this group will treat with 200 mg of cilostazol every 12 hours and 75 mg of Plavix daily for 3 months.

Category

Treatment - Drugs

2

Description

Control group: After successful infrapopliteal angioplasty patients of this group will treat 75 mg of Plavix daily for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Iraj Nazari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Ahvaz University of Medical Sciences Vice chancellor
of research
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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
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

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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