Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 2026

A Comparison of Complications and Outcome of Aortoiliac and Aortofemoral Bypass in the Treatment of Patients with Aortoiliac occlusive Disease

Protocol summary

Summary

The purpose of this study is to compare the complications and outcome of aortic reconstruction in patients with aortoiliac occlusive disease with one of the aortoiliac or aortofemoral bypass surgery methods. 118 patients with lower limb ischemia symptoms in whom aortoilliac occlusion was confirmed before surgery and were candidate for open aortoillac reconstructive surgery were included in the study. Patients who suffered femoral or external iliac obstruction in addition to aortolliac occlusion were excluded. One of the surgical procedures –aortofemoral or aortoiliac- is randomly selected for patient. Post-operation follow ups are carried out after 3, 6 and 12 months and surgical complications, graft behavior and the necessity for re-operation is evaluated. Finally, the collected data is statistically analyzed

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106196832N1**
Registration date: **2012-04-08, 1391/01/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-04-08, 1391/01/20

Registrant information

Name

Hosein Taheri

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1853 5211

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Mashhad University of Medical Sciences

Expected recruitment start date

2011-08-06, 1390/05/15

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison of Complications and Outcome of Aortoiliac and Aortofemoral Bypass in the Treatment of Patients with Aortoiliac occlusive Disease

Public title

A Comparison of Aortoiliac and Aortofemoral Bypass in the Treatment of Aortoiliac Occlusive Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with lower limb ischemia who have aortoiliac stenosis or obstruction disease and are candidate for aortiiliac reconstruction. Exclusion criteria: Patients who suffer from external iliac or femoral artery obstruction in addition to aortoiliac stenosis. Patients who couldn’t continue or wish to discontinue their

participation in the study due to any reason.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **118**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Vice Chancellor for Research of Mashhad University of Medical Sciences

Street address
Ghoreshi Building, Daneshgah Street, Mashhad, Iran

City
Mashhad

Postal code

Approval date
2011-08-06, 1390/05/15

Ethics committee reference number
89436

Health conditions studied

1

Description of health condition studied
Aortoiliac occlusive disease

ICD-10 code
174.0

ICD-10 code description
Embolism and thrombosis of abdominal aorta

Primary outcomes

1

Description
Ankle Brachial Index

Timepoint
3, 6, 12 months

Method of measurement
doppler sonography, Sphygmomanometer

2

Description
toe pressure

Timepoint
3, 6, 12 months

Method of measurement
digital toe pressure

Secondary outcomes

1

Description
Surgical Complication

Timepoint
3,6,12 months

Method of measurement
Clinical Evaluation

Intervention groups

1

Description
Aortic Reconstraction by Aortofemoral Bypass

Category
Treatment - Surgery

2

Description
Aortic Reconstraction by Aortoiliac Bypass

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person

Street address

City
Mashhad

2

Recruitment center

Name of recruitment center
Razavi Hospital

Full name of responsible person

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Mashhad University of Medical Sciences
Full name of responsible person
Dr Jalil Tavakoli Afshar
Street address
Ghoreshi Building, Daneshgah Street
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research of Mashhad University of Medical Sciences
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
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Person responsible for updating data

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Web page address

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