

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparative study of the consequences of performing angiography and angioplasty of the lower limb in one stage by simultaneous ipsilateral double puncture technique and in two-stage delayed technique in patients with chronic lower limb ischemia

Protocol summary

Study aim

Comparison of the consequences of performing angiography and angioplasty of the lower limb in one stage by simultaneous ipsilateral double puncture technique and in two-stage delayed technique in patients with chronic lower limb ischemia

Design

A randomized controlled trial with random allocation of 71 patients in each group, and followed for 1 month.

Settings and conduct

This study will be conducted on patients in Razi and Golsar hospitals. Patients will be divided into two equal groups of 71 people. The subjects will be divided into two blocks by random allocation method. For intervention group, an angiography and angioplasty will be performed simultaneously with two puncture in the femoral artery on the lesion side. In control group, these two diagnostic methods will be performed with a delay of at least 2 weeks. After angiography and angioplasty, patients will be admitted for 24 hours in both of these procedures, and then will be followed one week and one month later. The results and complications will be documented.

Participants/Inclusion and exclusion criteria

Inclusion criteria: chronic limb ischemia symptoms with pain during rest; unhealing wounds or gangrene.
Exclusion criteria: overweight; pregnancy; previous hypersensitivity to the contrast agent; renal failure, coagulopathy.

Intervention groups

In intervention group, an angiography and angioplasty will be performed simultaneously with two puncture in the femoral artery on the lesion side. In control group, these two diagnostic methods will be performed with a delay of at least 2 weeks.

Main outcome variables

Angiographic and angioplastic complications such as;

pseudo aneurysm ; retro peritoneal hematoma;
embolism; embolism requiring surgery; vessel
rupture; perforation ; thrombosis; re-occlusion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161026030508N3**

Registration date: **2018-06-24, 1397/04/03**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-24, 1397/04/03**

Update count: **0**

Registration date

2018-06-24, 1397/04/03

Registrant information

Name

Hosein Hemmati

Name of organization / entity

Vascular surgery and dialysis research center, Guilan
University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 13 3354 2460

Email address

hemmati@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-21, 1397/03/31

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the consequences of performing angiography and angioplasty of the lower limb in one stage by simultaneous Ipsilateral double puncture technique and in two-stage delayed technique in patients with chronic lower limb ischemia

Public title

Comparative study of the consequences of performing angiography and angioplasty of the lower limb in one stage by simultaneous Ipsilateral double puncture technique and in two-stage delayed technique in patients with chronic lower limb ischemia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Presence of ILC symptoms presence of pain during rest
Gangrene Unhealing wound

Exclusion criteria:

Overweight Pregnancy Previous sensitivity to contrast agent Renal failure Coagulopathy Noting have indication of angioplasty after angiography

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **142****Randomization (investigator's opinion)**

Randomized

Randomization description

The subjects will be divided into two blocks by random allocation method. In this study, patients will be divided into two equal groups of 71 people in each group.

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 Guilan University of Medical Sciences

Street address

Razi Hospital, Sardar jangal street

City

Rasht

Province

Guilan

Postal code

4144895655

Approval date

2018-05-19, 1397/02/29

Ethics committee reference number

IR.GUMS.REC.1397.048

Health conditions studied**1****Description of health condition studied**

Chronic Limb Ischemia

ICD-10 code

I73.9

ICD-10 code description

Peripheral vascular disease, unspecified

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

Complications of angiography and angioplasty

Timepoint

One week and one month after each method

Method of measurement

Researcher made questionnaire

2**Description**

Consequences of angiography and angioplasty

Timepoint

One week and one month after each method

Method of measurement

Researcher made questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: performing angiography and

angioplasty simultaneously with two puncture in the femoral artery at the lesion side

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital in Rasht City

Full name of responsible person

Hossein Hemmati

Street address

Razi Hospital, Sardarjanganal Street

City

Rasht

Province

Guilan

Postal code

4144895655

Phone

+98 13 3354 2460

Email

RDC@gums.ac.ir

2

Recruitment center

Name of recruitment center

Golsar Hospital in Rasht City

Full name of responsible person

Hossein Hemmati

Street address

Golsar Street, Golsar Hospital

City

Rasht

Province

Guilan

Postal code

001333113911

Email

RDC@gums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Shadman Nemati

Street address

17 Shahrivar St., Dept. of Research and Technology

City

Rasht

Province

Guilan

Postal code

4144666949

Phone

+98 13 3333 5820

Email

research@gums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Hossein Hemmati

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Razi Hospital, Sardar Jangal Street

City

Rasht

Province

Guilan

Postal code

4144895655

Phone

+98 13 3354 2460

Email

RDC@gums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Hossein Hemmati

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Vascular surgery

Street address

Sardar Jangal Street, Razi Hospital

City

Rasht

Province

Guilan

Postal code

4144895655

Phone

+98 13 3354 2460

Email

RDC@gums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Zakiyeh Jafaryparvar

Position

master science

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Sardar Jangal Street, Razi Hospital

City

Rasht

Province

Guilan

Postal code

4144895655

Phone

+98 13 3354 2460

Email

jafaryparvar_zakiyeh@yahoo.com

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

Not applicable