

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of the efficacy and safety of autologous blood injection with c-clamp vascular closure device in treatment of iatrogenic pseudoaneurysm after femoral artery puncture

Protocol summary

Study aim

Comparison of the efficacy and safety of autologous blood injection with c-clamp vascular closure device in treatment of iatrogenic pseudoaneurysm after femoral artery puncture

Design

Clinical trial with control group with parallel groups, phase 2 on 105 patients

Settings and conduct

This study is performed in Chamran Hospital in Isfahan. Patients will be cared for in two ways. The success rate of the treatment method in closing pseudoaneurysm and the complications of treatment in both groups of patients will be evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with pseudoaneurysm of femoral artery following angiography, pseudoaneurysm size greater than 2 cm, patients' consent to enter the study. Exclusion criteria: Active infection of groin area, hematoma larger than 2 cm on ultrasound, skin necrosis, symptoms of lower limb ischemia

Intervention groups

Intervention group 1: Patients in this group, after diagnosis of femoral artery pseudoaneurysm, under mechanical compression by C-clamp, the pressure of which is marked under the ultrasound guide, and then the amount of pressure applied to the site of the sheath is applied. That homeostasis is established while the distal pulse of the lower limb is palpable. The rate of improvement and treatment complications in patients are evaluated. Intervention group 2: Patients in this group, after diagnosis of pseudoaneurysm of the femoral artery, 10 to 20 cc of the patient's blood is injected by the same sonographer according to the sonographer's estimate of the sac volume after clot formation under the ultrasound guide in sterile conditions in the pseudoaneurysm sac. The rate of improvement and

treatment complications in patients are evaluated.

Main outcome variables

Success rate of treatment in closing pseudoaneurysm and treatment complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210614051574N7**

Registration date: **2022-01-07, 1400/10/17**

Registration timing: **prospective**

Last update: **2022-01-07, 1400/10/17**

Update count: **0**

Registration date

2022-01-07, 1400/10/17

Registrant information

Name

Ghasem Mohammadsharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3729 4005

Email address

mohammadsharifi.ghasem@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-03, 1400/11/14

Expected recruitment end date

2022-03-05, 1400/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy and safety of autologous blood injection with c-clamp vascular closure device in treatment of iatrogenic pseudoaneurysm after femoral artery puncture

Public title

Autologous blood transfusion with mechanical compression in the treatment of iatrogenic pseudoaneurysm of the femoral artery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with pseudoaneurysm of the femoral artery following angiography Pseudoaneurysm size larger than 2 cm Patient consent to enter the study

Exclusion criteria:

Active infection of the groin area Hematoma larger than 2 cm on ultrasound Skin necrosis Symptoms of lower limb ischemia

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Not 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

Ethics committee of Esfahan University of Medical Sciences

Street address

Esfahan University of Medical Sciences, Hezar Jarib Ave., Esfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-02-06, 1399/11/18

Ethics committee reference number

IR.MUI.MED.REC.1399.1026

Health conditions studied

1

Description of health condition studied

Iatrogenic pseudoaneurysm of the femoral artery

ICD-10 code

S75.0

ICD-10 code description

Injury of femoral artery

Primary outcomes

1

Description

Success of the treatment method in closing pseudoaneurysm

Timepoint

24 hours and one week after interventions

Method of measurement

By ultrasound

2

Description

Complications of treatment

Timepoint

24 hours and one week after interventions

Method of measurement

Examination of patients

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Patients in this group, after diagnosis of femoral artery pseudoaneurysm, under mechanical compression by C-clamp, the pressure of which is marked under the ultrasound guide, and then the amount of pressure applied to the site of the sheath is applied. That homeostasis is established while the distal pulse of the lower limb is palpable. The rate of improvement and treatment complications in patients

are evaluated.

Category

Treatment - Devices

2**Description**

Intervention group 2: Patients in this group, after diagnosis of pseudoaneurysm of the femoral artery, 10 to 20 cc of the patient's blood is injected by the same sonographer according to the sonographer's estimate of the sac volume after clot formation under the ultrasound guide in sterile conditions in the pseudoaneurysm sac. The rate of improvement and treatment complications in patients are evaluated.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Chamran hospital

Full name of responsible person

Mohammad Hadi Mansouri

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No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad Hadi Mansouri

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Mohammad Hadi Mansouri

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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Position
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Other areas of specialty/work
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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after people have requested.

When the data will become available and for how long

Six months after publishing the results.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

Website of the Research Committee of Isfahan University of Medical Sciences

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

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments