

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Comparative of vascular complications related to arterial sheet extraction using clamp ease and hand pressure in patients undergoing angiography.

Protocol summary

Study aim

General purpose: Comparative study of vascular complications related to arterial sheet extraction using clamp ease and hand pressure in patients undergoing angiography admitted to the Post Angiography ward of Shahid Chamran Hospital in Isfahan in 1400.

Design

Experimental study and clinical trial. No blinding. Random sample allocation and 94 samples and file number with even and patient file numbers were used for randomization.

Settings and conduct

This study was conducted for the first time in Iran and before that in the United Kingdom as a systematic review and based on previous studies, the manual method had more complications. In this study, blinding was not performed.

Participants/Inclusion and exclusion criteria

Having the consent to participate in the study Normal international ratio (less than 1.8) Has not had a surgical incision on the femoral artery in the past week. (35) Use the minimum dose of heparin (less than 5000) units during angiography (36) In other centers, it has not received anticoagulants (reteplase, streptokinase, altplase) (7). Absence of previous hematoma and ecchymosis during the angiographic procedure in Cat Lab or during recent hospitalization No osteoporosis Undergo angiography through the femoral artery. The process of implantation of arterial sheet and angiography of the patient should be performed by a specific doctor. Lack of history of femoral and pelvic surgeries, including femoral head replacement and pelvic bone fractures

Intervention groups

Removal of arterial sheet after angiography is done in two general ways: sheet removal with the help of hand (usual method and control group) and method of using clamp ease tool (intervention group) in many cardiovascular centers. Vascular complications after sheet removal It is examined in these two groups.

Main outcome variables

Hemorrhage; hematoma; ecchymosis; Homeostasis time

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20211121053121N2**

Registration date: **2021-12-04, 1400/09/13**

Registration timing: **prospective**

Last update: **2021-12-04, 1400/09/13**

Update count: **0**

Registration date

2021-12-04, 1400/09/13

Registrant information

Name

Seyed Abbas Hoseini

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-06, 1400/09/15

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparative of vascular complications related to arterial sheet extraction using clamp ease and hand pressure in patients undergoing angiography.

Public title
Comparative study of vascular complications related to arterial sheet extraction using clamp ease device and hand pressure in patients undergoing angiography.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Informed consent to participate in the study International normal ratio less than 1.8 had not a surgical incision on the femoral artery in the past week. (35) Use the minimum dose of heparin (less than 5000) units during angiography (36) The patient has not received anticoagulants in other centers (rateplase, streptokinase, altplase) (7). Absence of previous hematoma and ecchymosis during the angiographic procedure in Cat Lab or during recent hospitalization (35) The patient should not have osteoporosis (37) The patient underwent angiography through the femoral artery. The process of implantation of arterial sheet and angiography of the patient should be performed by a specific doctor. Lack of history of femoral and pelvic surgeries, including femoral head replacement and pelvic bone fractures (38)
Exclusion criteria:
Does not exist

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **94**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, initial sampling is easy and sample allocation between the two groups is done randomly so that patients with Odd file number (patients with the last digit of individual file number) in the group of arterial sheet exit by hand and patients with Even file number (patients with the last digit of the even number) are in the group of using the clamp ease device.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

This study is an experimental study with two groups (manual method group and clampase method group) randomly and prospectively during which two groups of patients a doctor is randomly selected and divided into groups with hand pressure and the group using clampase device.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib St., Isfahan University of Medical Sciences, School of Nursing, Management and Rehabilitation

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Approval date

2021-10-30, 1400/08/08

Ethics committee reference number

IR.MUI.NUREMA.REC.1400.177

Health conditions studied

1

Description of health condition studied

This study is performed in the field of vascular injuries after the invasive action of arterial sheet removal

ICD-10 code

I51.6

ICD-10 code description

cardiovascular disease NOS

Primary outcomes

1

Description

The primary variables hemorrhage

Timepoint

The initial outcome of bleeding is assessed immediately after the sheet is removed; 15 minutes later; 30 minutes later; 45 minutes later; 1 hour later; 2 hours later; 4 hours later; 8 hours later; 12 hours later; 24 hours later. In total, it is examined in 10 steps.

Method of measurement

Measurement of bleeding volume is checked with a DM3 digital scale with an error level of 0.01 mg.

2

Description

Primary outcome of hematoma

Timepoint

The initial outcome of hematoma is assessed immediately after the sheet is removed; 15 minutes later; 30 minutes later; 45 minutes later; 1 hour later; 2 hours later; 4 hours later; 8 hours later; 12 hours later; 24 hours later. In total, it is examined in 10 steps.

Method of measurement

Hematoma outcome is measured by calculating the area of the hardened area by hand with using a standard transparent ruler.

3

Description

Primary outcome of vascular ecchymosis

Timepoint

The initial outcome of ecchymosis is assessed immediately after the sheet is removed; 15 minutes later; 30 minutes later; 45 minutes later; 1 hour later; 2 hours later; 4 hours later; 8 hours later; 12 hours later; 24 hours later. In total, it is examined in 10 steps.

Method of measurement

The outcome of ecchymosis is measured by calculating the area of skin discoloration to bruising without stiffness when touched by hand using a standard transparent ruler.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group consists of 47 patients of a specific physician who refer to the angiography department on an outpatient basis for angiography. In this group, which are randomly selected and available, one of the types of Vascular closing devices (VCDs) available in Iran, which was made in California, USA in 2005 and widely distributed around the world, including Shahid Chamran Hospital in Isfahan. Used to exit the sheet. This device, which includes a flat plate to be placed under the patient, a height-adjustable base that can be changed depending on the patient's thigh size, and a transparent sterile plate that is changed from patient to patient to reduce the risk of disease transmission. In both Method, after the necessary training, we proceed to remove the arterial sheet. After removing the sheet, the clamp device is fixed on the patient's artery. After 20 minutes, if there is no bleeding, the device returns completely and the patient is examined for bleeding. Hematoma and ecchymosis are evaluated for 24 hours. Another method is to remove the arterial sheet: The manual method is to remove the sheet, which is the usual method of removing the sheet, which is similar to the previous method. To ensure the

absence of bleeding, the hand pressure is removed and the patient is examined for hematoma bleeding and ecchymosis for 24 hours.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Dr. Chamran Heart Specialized Hospital

Full name of responsible person

Syed Abas Hoseini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

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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

Isfahan University of Medical Sciences

Proportion provided by this source

50

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

2**Sponsor****Name of organization / entity**

Shahid Dr. Chamran Cardiovascular Research Institute, Isfahan

Full name of responsible person

Dr. Alireza Khosravi

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Yes

Title of funding source

Shahid Dr. Chamran Cardiovascular Research Institute, Isfahan

Proportion provided by this source

10

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

3**Sponsor****Name of organization / entity**

Vice Chancellor for Research, Isfahan School of Nursing and Midwifery

Full name of responsible person

Dr. Maryam Kianpour

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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

Vice Chancellor for Research, Isfahan School of Nursing and Midwifery

Proportion provided by this source

40

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**

Isfahan University of Medical Sciences

Full name of responsible person

Syed Abas Hosseini

Position

Faculty member of Isfahan University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

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Person responsible for scientific 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

No - There is not 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

No - There is not a plan to make this available

Title and more details about the data/document

I have not decided yet, but if you agree, I have no problem with publishing the data

When the data will become available and for how long

I have not decided yet, but if you agree, I have no problem with publishing the data

To whom data/document is available

I have not decided yet, but if you agree, I have no problem with publishing the data

Under which criteria data/document could be used

I have not decided yet, but if you agree, I have no problem with publishing the data

From where data/document is obtainable

I have not decided yet, but if you agree, I have no problem with publishing the data

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

I have not decided yet, but if you agree, I have no problem with publishing the data

Comments

I have not decided yet, but if you agree, I have no problem with publishing the data

Person responsible for updating data**Contact****Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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