

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Aug 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 clampease 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 7504

##### Email address

a\_hoseini@nm.mui.ac.ir

##### 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

##### City

Esfahan

##### Province

Isfahan

##### Postal code

8174673461

#### 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

##### **Street address**

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

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a-hoseini@nm.mui.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Isfahan University of Medical Sciences

##### **Full name of responsible person**

Dr. Mansour Siavash

##### **Street address**

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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

**Street address**Isfahan, Mushtaq 3rd St., after Shahrestan Bridge,  
next to Shahid Chamran Heart Training Center,  
Shahid Rahmani Alley, Isfahan Cardiovascular  
Research Institute**City**

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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**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

**Street address**Hezar Jerib St., Isfahan University of Medical Sciences  
and Health Services, School of Nursing and Midwifery**City**

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kianpour@mail.mui.ac.ir

**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**Responsible for the skills laboratory of the School of  
Nursing and Midwifery**Street address**Hezar Jerib St., Isfahan University of Medical Sciences,  
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**Person responsible for scientific inquiries****Contact**

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**Full name of responsible person**

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Master

**Other areas of specialty/work**

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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**

Syed Abas Hoseini

**Position**

Faculty member of Isfahan University of Medical Sciences

**Latest degree**

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**Other areas of specialty/work**

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