

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### A clinical trial to comparison the effectiveness of common ultrasound-guided with the recently invented device in treatment of the angiography-induced pseudoaneurysm

#### Protocol summary

##### Study aim

The effectiveness of common ultrasound-guided with the recently invented device in treatment of the angiography-induced pseudoaneurysm

##### Design

In this pragmatic double-blind, controlled clinical trial, 22 patients with pseudoaneurysm caused by angiography were assigned into parallel groups using the table of random numbers in a community-based setting.

##### Settings and conduct

Patients with pseudoaneurysm caused by angiography in Ghaem Hospital, Mashhad, Iran, were chosen. In this double-blind study, the clinical care and data collector were blind to group assignment and the type of treatment.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with pseudoaneurysm caused by angiography base on color Doppler ultrasound diagnostic criteria. Exclusion criteria: Complete aneurysm block; complete thrombosis of the pseudoaneurysm; abscess, surface tissue infection, or open wound in the area; history of angiography.

##### Intervention groups

The control group will ultrasound-guided compression by hand. The intervention group will receive ultrasound-guided compression by the invented device.

##### Main outcome variables

Evaluation and comparison of length, width and neck of pseudoaneurysm and pain levels before and 6 hours after the intervention in the intervention and control groups.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190701044059N1**

Registration date: **2019-07-14, 1398/04/23**

Registration timing: **prospective**

Last update: **2019-07-14, 1398/04/23**

Update count: **0**

##### Registration date

2019-07-14, 1398/04/23

##### Registrant information

###### Name

Zahra Kermani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3606 5215

###### Email address

kermaniz@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-07-23, 1398/05/01

##### Expected recruitment end date

2020-07-22, 1399/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A clinical trial to comparison the effectiveness of common ultrasound-guided with the recently invented device in treatment of the angiography-induced

pseudoaneurysm

## Public title

Effect of recently invented device in treatment of the angiography-induced pseudoaneurysm

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with pseudoaneurysm caused by angiography base on color Doppler ultrasound diagnostic criteria

### Exclusion criteria:

Complete aneurysm block Complete thrombosis of the pseudoaneurysm Abscess, surface tissue infection, or open wound in the area History of angiography

## Age

No age limit

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Care provider
- Outcome assessor

## Sample size

Target sample size: 22

## Randomization (investigator's opinion)

Randomized

## Randomization description

Totally 22 patients with pseudoaneurysm caused by angiography in Ghaem Hospital, Mashhad, Iran, were chosen. The participants were allocated into groups of intervention and control using the table of random numbers based on computer programs.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Patients with pseudoaneurysm caused by angiography in Ghaem Hospital, Mashhad, Iran, were chosen. In this double-blind study, the clinical care and data collector were blind to group assignment and the type of treatment.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

##### Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9195965919

#### Approval date

2019-01-14, 1397/10/24

#### Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.587

## Health conditions studied

### 1

#### Description of health condition studied

The angiography-induced pseudoaneurysm

#### ICD-10 code

I72.4

#### ICD-10 code description

Aneurysm and dissection of artery of lower extremity

## Primary outcomes

### 1

#### Description

Length, width and neck of pseudoaneurysm

#### Timepoint

Before and 6 hours after the intervention

#### Method of measurement

Ultrasound

## Secondary outcomes

### 1

#### Description

Pain levels

#### Timepoint

Before and 6 hours after the intervention

#### Method of measurement

Visual Analogue Scale

## Intervention groups

### 1

#### Description

Intervention group: The intervention group will receive ultrasound-guided compression by the invented device.

#### Category

Treatment - Devices

### 2

#### Description

Control group: The control group will ultrasound-guided

compression by hand.

**Category**

Treatment - Devices

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Ghaem Hospital

**Full name of responsible person**

Zahra Kermani

**Street address**

Ghaem Hospital, Ahmadabad Street, Dr. Ali Shariati Square

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9176699199

**Phone**

+98 51 3840 0000

**Email**

Z-k-65@yahoo.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

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Mashhad

**Province**

Razavi Khorasan

**Postal code**

1394491388

**Phone**

+98 51 3841 1538

**Email**

vcresearch@mums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Zahra Kermani

**Position**

Residents

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Radiology

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**Contact**

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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**Latest degree**

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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**

Not applicable

**Informed Consent Form**

Yes - There is 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

**Title and more details about the data/document**

The total data to be included are the primary and secondary effects to be shared.

**When the data will become available and for how long**

6 months after printing results

**To whom data/document is available**

Our data will only be available to researchers working in science center and university.

**Under which criteria data/document could be used**

Our data will be available for scholars working in science center and university.

**From where data/document is obtainable**

Zahra Kermani provides the analysis code to the applicants via email: Z-k-65@yahoo.com

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

Applicants can respond to the email of the respondent and receive a response within a week.

**Comments**