

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

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9176699199

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+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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1394491388

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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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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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