Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Designing and manufacturing of an inflatable thigh strap and evaluating its effectiveness on hemostasis during sheet removal and prevention of complications after transfemoral coronary angiography in patients referring to hospital.

Protocol summary

Study aim

This study was conducted with the aim of designing and manufacturing an inflatable thigh strap and determining its effectiveness in preventing the complications of sheet removal after transfemoral coronary angiography.

Design

Clinical trial with a control group.not blindet,randomized

Settings and conduct

This randomized clinical trial was conducted in 2021. 80 patients undergoing elective transfemoral coronary angiography referred to 502 Heart and Vascular Hospital in Tehran were included in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria included being alert, not suffering from hemophilia and coagulation disorders, age between 45 and 70 years, candidate for femoral angiography. The exit criteria are also: refusal to continue cooperation, the occurrence of complications such as bleeding, hematoma, and abnormal pain during the intervention, and use of painkillers or narcotics before, during, and after transfemoral coronary angiography.

Intervention groups

In the test group, an inflatable thigh starp was used to maintain hemostasis and prevent bleeding and hematoma immediately after the removal of the femoral sheath and hemostasis by hand in the Catheterization Laboratory by a trained nurse according to the protocol determined based on point pressure at the puncture site of the artery, the femoral was closed. The tourniquet was left in place for 4 to 6 hours and then opened. All procedures were performed under the supervision of a physician.

Main outcome variables

inflatable thigh starp, groin pain, back pain, feeling comfortable, hematoma, bleeding, leg pain, urinary incontinence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200410047011N2**
Registration date: **2022-12-13, 1401/09/22**
Registration timing: **retrospective**

Last update: **2022-12-13, 1401/09/22**
Update count: **0**

Registration date

2022-12-13, 1401/09/22

Registrant information

Name

Hojjat Niknam Sarabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

2020-11-19, 1399/08/29

Actual recruitment end date

2021-05-14, 1400/02/24

Trial completion date

2021-05-14, 1400/02/24

Scientific title
Designing and manufacturing of an inflatable thigh strap and evaluating its effectiveness on hemostasis during sheet removal and prevention of complications after transfemoral coronary angiography in patients referring to hospital.

Public title
Designing and manufacturing of an inflatable thigh strap and evaluating its effectiveness on hemostasis during sheet removal and prevention of complications after transfemoral coronary angiography.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
being alert not suffering from hemophilia and coagulation disorders age between 45 and 70 years candidate for femoral angiography
Exclusion criteria:
refusal to continue cooperation the occurrence of complications such as bleeding hematoma, and abnormal pain during the intervention use of painkillers or narcotics before, during, and after transfemoral coronary angiography.

Age
From **45 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**
Actual sample size reached: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
80 patients were included in the study by available sampling method and were divided into experimental and control groups based on the day of visit by coin toss. In this way, the patients who were visited on Sundays were included in the experimental group and they used an inflatable thigh strap, and the patients who visited on Mondays were in the control group and used sandbags according to the hospital routine.

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
Army University of Medical Sciences
Street address
Etemadzade st, Ave Fatemi, TEHRAN, IRAN
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Tehran
Province
Tehran
Postal code
1613917117

Approval date
2020-10-12, 1399/07/21

Ethics committee reference number
IR.AJAUMS.REC.1399.133)

Health conditions studied

1

Description of health condition studied
patients with coronary artery disease undergoing transfemoral coronary angiography

ICD-10 code
Y84.0

ICD-10 code description
Cardiac catheterization as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes

1

Description
Groin pain: groin pain refers to a feeling of discomfort in the area where the abdomen ends and the legs begin

Timepoint
Three trained and experienced nurses as researcher’s assistants using a chart (before and immediately after closing the FemoStop device, 15 minutes, one hour, two hours, two and a half hours, three hours, three hours and a half, four hours, four and a half hours, five hours, and six hours after closing the FemoStop device, totally of 12 times) recorded and reported all possible complications.

Method of measurement
The Visual Analog Scale will be used to measure groin pain. The Visual Analog Scale is used to measure pain. The visual analog scale is the evaluation of pain intensity as a 10 cm horizontal line numbered from 0 to 10 (zero indicates the absence of pain and 10 indicates the most severe pain possible)

2

Description
Hematoma: Localized bleeding outside the blood vessels, which occurs due to illness or trauma, including injury or

surgery, and may lead to continued bleeding from broken capillaries. The hematoma is benign and initially spreads as fluid between tissues, including the interstitial sacs, which may coagulate and solidify in the blood vessels before reabsorption.

Timepoint

Three trained and experienced nurses as researcher's assistants using a chart (before and immediately after closing the FemoStop device, 15 minutes, one hour, two hours, two and a half hours, three hours, three hours and a half, four hours, four and a half hours, five hours, and six hours after closing the FemoStop device, totally of 12 times) recorded and reported all possible complications.

Method of measurement

The Christensen scale was used to measure hematoma.

3

Description

leg pain: Prickle, cramping, fatigue and sometimes burning in the legs caused by poor blood circulation in the arteries of the legs

Timepoint

Three trained and experienced nurses as researcher's assistants using a chart (before and immediately after closing the FemoStop device, 15 minutes, one hour, two hours, two and a half hours, three hours, three hours and a half, four hours, four and a half hours, five hours, and six hours after closing the FemoStop device, totally of 12 times) recorded and reported all possible complications.

Method of measurement

The Visual Analog Scale will be used to measure leg pain. The Visual Analog Scale is used to measure pain. The visual analog scale is the evaluation of pain intensity as a 10 cm horizontal line numbered from 0 to 10 (zero indicates the absence of pain and 10 indicates the most severe pain possible).

4

Description

Bleeding: Any bleeding that comes out of the circulatory system due to damage to the blood vessels is called bleeding. Bleeding may be due to vascular disorders, platelets, coagulation factors, coagulation inhibitors, exacerbation of fibrinolysis, or a combination of these factors. Typically, a healthy person can lose 10 to 15% of their total blood volume without serious medical problems. Tolerate.

Timepoint

Three trained and experienced nurses as researcher's assistants using a chart (before and immediately after closing the FemoStop device, 15 minutes, one hour, two hours, two and a half hours, three hours, three hours and a half, four hours, four and a half hours, five hours, and six hours after closing the FemoStop device, totally of 12 times) recorded and reported all possible complications.

Method of measurement

En The amount of blood loss will be calculated based on the amount of bleeding based on the number of blood-soaked gases. Given that each 4 in 4 blood gasses in blood is about 10 ml of blood, then the amount of bleeding during 6 hours calculated by multiplying the number of gases collected in 10 Will take.

5

Description

prothrombin time (PT), Partial thromboplastin time (PTT), international normalized ratio (INR)

Timepoint

Before intervention

Method of measurement

Laboratory indicators were measured in the hospital laboratory.

6

Description

Hemodynamic indicators (systolic and diastolic blood pressure, temperature, respiratory rate, heart rate, and arterial oxygen saturation (Sao2))

Timepoint

Three trained and experienced nurses as researcher's assistants using a chart (before and immediately after closing the FemoStop device, 15 minutes, one hour, two hours, two and a half hours, three hours, three hours and a half, four hours, four and a half hours, five hours, and six hours after closing the FemoStop device, totally of 12 times) recorded and reported all possible complications.

Method of measurement

The hemodynamic indicators of the patients were recorded by the monitoring device. The temperature was measured with a thermometer.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the test group, an inflatable thigh starp was used to maintain hemostasis and prevent bleeding and hematoma immediately after the removal of the femoral sheath and hemostasis by hand in the Catheterization Laboratory by a trained nurse according to the protocol determined based on point pressure at the puncture site of the artery, the femoral was closed. The tourniquet was left in place for 4 to 6 hours and then opened. All procedures were performed under the supervision of a physician.

Category

Treatment - Devices

2

Description

Control group: according to the hospital routine, a sandbag was used instead of an inflatable thigh strap. The weight of the sandbag was 2.5 kg, which was placed in the puncture site of the femoral artery for 6 hours. In all stages, patients of the control group had to keep their legs straight. When the patient was in a semi-sitting

position, a pillow was placed on the patient’s back.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Army 502 Hospital

Full name of responsible person

Hojjat Niknam Sarabi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Prof. Zahra Farsi

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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

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Hojjat Niknam Sarabi

Position

Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Hojjat Niknam Sarabi

Position

Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Hojjat Niknam Sarabi

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Email

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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

This study was approved by the Ethics Committee of Aja University of Medical Sciences (code IR.AJAUMS.REC.1399.133). The provisions of the Declaration of Helsinki were observed in this study. Patients entered the study voluntarily and could withdraw from the study whenever they wished. Also, the purpose of the study was explained to the patients and written informed consent was obtained from all patients. The researchers were obliged to ensure that the patients did not suffer physical harm and all possible side effects of the intervention were monitored and, if necessary, appropriate measures were replaced. The confidentiality of all data and the confidentiality of the information sources used were also observed.

When the data will become available and for how long

6 months after printig results

To whom data/document is available

This study was approved by the Ethics Committee of Aja University of Medical Sciences (code IR.AJAUMS.REC.1399.133). The provisions of the Declaration of Helsinki were observed in this study. Patients entered the study voluntarily and could withdraw from the study whenever they wished. Also, the purpose of the study was explained to the patients and written informed consent was obtained from all patients. The researchers were obliged to ensure that the patients did not suffer physical harm and all possible side effects of the intervention were monitored and, if necessary, appropriate measures were replaced. The confidentiality of all data and the confidentiality of the information sources used were also observed.

Under which criteria data/document could be used

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From where data/document is obtainable

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

Send email to the responsible author, confirmation by authors, confirmation by army univarsity of medical sciences, provide data

Comments