Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison on effectiveness of different methods of changing position on side effects of sheet removal after femoral angiography in patients referring to hospital

Protocol summary

Study aim
Comparison on effectiveness of different methods of changing position on side effects of sheet removal after femoral angiography in patients referring to hospital 502

Design
Clinical trial with a control group, not blinded, randomized

Settings and conduct
This study will be performed in 2018-2019 on patients with coronary artery disease under cardiac catheterization through femoral in angiography and angiography departments of Nezaja Hospital 502.

Participants/Inclusion and exclusion criteria
72 patients who had the criteria to enter the study, including satisfaction, age, no history of blood disease and lack of back pain and alertness, and did not use narcotic and unusual drugs.

Intervention groups
In the intervention group in the first hour after angiography, patients will be cared for lying down and keeping their legs still. In the second hour with a flat angle of 15 degrees, in the third hour they will be in a semi-sitting position with an angle of 30 degrees and in the fourth hour onwards with a 45 degree angle of the bed. It should be noted that at all stages of the intervention, the sandbag will be placed on the dressing area of the arterial access site and the patients' feet will be flat. From the third hour onwards, a pillow will be placed in the patient's lumbar region for more comfort. In control patients, routine post-angiographic care involves bed rest while keeping the affected limb immobile. In this group, patients are angiographed all the time during study hours (6 hours) lying on their backs with flat head and flat feet, and placed a sandbag weighing approximately 3.5 kg on the arterial site to prevent bleeding. will be . During this time, patients can only bend and straighten their legs.

Main outcome variables
Change in position; groin pain; back pain; feeling comfortable; hematoma; bleeding; leg pain; urinary incontinence

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200410047011N1**
Registration date: **2020-04-30, 1399/02/11**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-30, 1399/02/11**
Update count: **0**

Registration date
2020-04-30, 1399/02/11

Registrant information

Name
Hojjat Niknam Sarabi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-20, 1398/10/30

Expected recruitment end date
2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison on effectiveness of different methods of changing position on side effects of sheet removal after femoral angiography in patients referring to hospital

Public title

Comparison of the effectiveness of different modes of position change on the effects of sheet removal after femoral angiography

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The satisfaction to participate in the study Absence of hemophilia and coagulation disorders The patient's age is between 45 and 70 years old Femoral elective angiography candidate Not treated with streptokinase Routine use of half a promethazine ampoule and half a diazepam ampoule as a sedative No history of low back pain

Exclusion criteria:

The patient's unwillingness to continue to participate in the study Complications such as bleeding, hematoma, and abnormal pain during the procedure Painkillers or drugs before, during and after coronary angiography via the femoral

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: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

72 patients will be selected based on the criteria for entering the study and based on the target method and will be assigned to two test and control groups (36 people in each group) by simple random method. In this way, the patients will be placed in two groups of test and control based on the coin toss on the couple and individual days of the week.

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

Ethics Committee of the AJA University of Medical Sciences is the medical school of Islamic Republic

Street address

Tehran - West Fatemi St. - Shahid Etemadzadeh St. - Army University of Medical Sciences

City

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Province

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1411718541

Approval date

2020-04-21, 1399/02/02

Ethics committee reference number

IR.AJAUMS.REC.1399.011

Health conditions studied

1

Description of health condition studied

Femoral angiography in cardiovascular patients

ICD-10 code

ICD-10 code description

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

Before the intervention - after the intervention - the first / second / third / fourth / fifth and Sixth hours after the intervention

Method of measurement

Visual analog scale will be used to measure groin pain. Visual analog scale is used to measure pain. The visual analog scale of 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

Changing position: Fowler's condition is the patient's standard condition in which the patient is in a semi-sitting position (60-45 degrees) and the knees may be bent or straight. Fowler's position includes angles between 30 and 90 degrees. The upper Fowler

represents a vertical position of about 90 degrees; the Fowler shows an angle of 45 to 60 degrees; the half Fowler, 30 to 45 degrees, and the lower Fowler, where the head is slightly elevated.

Timepoint

Before the intervention - after the intervention - the first / second / third / fourth / fifth and Sixth hours after the intervention

Method of measurement

In the intervention group,in the first hour after angiography, patients will be cared for lying down and keeping their legs still. In the second hour with a flat angle of 15 degrees, in the third hour they will be in a semi-sitting position with an angle of 30 degrees and in the fourth hour onwards with a 45 degree angle of the bed. It should be noted that at all stages of the intervention, the sandbag will be placed on the dressing area of the arterial access area and the patients' feet will be flat. The infection occurs. In this group, patients are angiographed all the time during study hours (6 hours) lying on their backs with flat head and flat feet, and placed a sandbag weighing approximately 3.5 kg on the arterial site to prevent bleeding. will be . During this time, patients can only bend and straighten their legs. In both groups, groin pain, patient comfort, hematoma, bleeding, leg pain, and urinary incontinence before and after sheet discharge were examined 6 times at one-hour intervals (8 times in total). Will take.

3

Description

Feeling comfortable: Comfort (feeling comfortable) is a feeling of physical or mental comfort, which is often characterized by a lack of difficulty. People who are uncomfortable experience discomfort.

Timepoint

Before the intervention - after the intervention - the first / second / third / fourth / fifth and Sixth hours after the intervention

Method of measurement

Visual scale was used to measure patient comfort. This visual scale is one of the tools developed by Colcaba Nursing Theorist to measure patient comfort. Studies show that visual scales are commonly used to measure mental perceptions such as pain and comfort. Patients were asked to rate their comfort according to the line and the numbers written.

4

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

Before the intervention - after the intervention - the first / second / third / fourth / fifth and Sixth hours after the intervention

Method of measurement

The Christensen scale will be used to measure hematoma

5

Description

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

Timepoint

Before the intervention - after the intervention - the first / second / third / fourth / fifth and Sixth hours after the intervention

Method of measurement

Visual analog scale will be used to measure leg pain. Visual analog scale is used to measure pain. The visual analog scale of 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)

6

Description

Urinary incontinence: Urinary retention is the inability to urinate. This complication is one of the main causes of benign prostatic , hyperplasia. Other causes of urinary retention include infections, neurological problems, constipation, and the effects of certain medications and amphetamines. This disorder of the urinary system means a small or incomplete emptying of the bladder. Sometimes the muscles of the bladder and bladder sphincter are not released and the urine is difficult to pass and causes the bladder to be completely emptied. Residual urine can lead to infection

Timepoint

Before the intervention - after the intervention - the first / second / third / fourth / fifth and Sixth hours after the intervention

Method of measurement

We measure the severity of urinary retention based on visual scale and the duration of urinary retention in minutes, before and after the intervention. It should be noted that the severity of urinary retention in the postoperative stage was measured 10 minutes after the intervention, and given that there is no objective scale for measuring urinary retention, the patient's statements were used as a measure. The severity of urinary retention in patients after angiography was recorded in two time periods, including before the intervention and at the end of the intervention, based on the patient's personal statements, quantitatively through a scaled visual scale.

7

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

Before the intervention - after the intervention - the first / second / third / fourth / fifth and Sixth hours after the intervention

Method of measurement

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

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients will be cared for in the first hour after angiography, lying down and keeping their legs still. In the second hour with a flat angle of 15 degrees, in the third hour they will be in a semi-sitting position with an angle of 30 degrees and in the fourth hour onwards with a 45 degree angle of the bed. It should be noted that at all stages of the intervention, the sandbag will be placed on the dressing area of the arterial access site and the patients' feet will be flat. From the third hour onward, a pillow will be placed in the patient's lumbar region for more comfort. In case of bleeding, pain and dissatisfaction, the patient will return to the supine position and will be pressed 5 cm above the dressing area by hand. It remains and the routine treatment protocol continues. It is important to note that all patients prophylactically use anticoagulants such as aspirin 80 mg and Plavix 300 mg single dose for angiography as directed by their physician.

Category

Treatment - Other

2

Description

Control group: In control group patients, routine post-angiographic care involves bed rest while keeping the affected limb immobile. In this group, patients are angiographed all the time during study hours (6 hours) lying on their backs with flat head and flat feet, and placed a sandbag weighing approximately 3.5 kg on the arterial site to prevent bleeding. will be . During this time, patients can only bend and straighten their legs. In both groups, groin pain, patient comfort, hematoma, bleeding, leg pain, and urinary incontinence before and after sheet discharge were examined 6 times at one-hour intervals (8 times in total). Will take.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

502 Nazaja Hospital

Full name of responsible person

Hojat Niknam Sarabi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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
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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
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
Providing research results to the subjects and officials of the research environment, if desired and requested, in accordance with the rights of the authors (according to paragraph 35 of the Helsinki Statement at the end of the study, participants have the right to be informed of the study results and the benefits of the results. Access to studies that have been found to be beneficial in terms of study or other appropriate care and benefits.
When the data will become available and for how long
Access available 6 months after printing results
To whom data/document is available
Providing research results to the subjects and officials of the research environment, if desired and requested, in accordance with the rights of the authors (according to paragraph 35 of the Helsinki Statement at the end of the study, participants have the right to be informed of the study results and the benefits of the results. Access to studies that have been found to be beneficial in terms of study or other appropriate care and benefits.

Under which criteria data/document could be used

Providing research results to the subjects and officials of the research environment, if desired and requested, in accordance with the rights of the authors (according to paragraph 35 of the Helsinki Statement at the end of the study, participants have the right to be informed of the study results and the benefits of the results. Access to studies that have been found to be beneficial in terms of study or other appropriate care and benefits.

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 other authors / Confirmation by Army University of Medical Sciences / Provide data

Comments