

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Bed Angle Change on Back Pain and Urinary Retention after Coronary Angiography

Protocol summary

Study aim

Determining the effect of bed angle change on back pain and urinary retention after coronary angiography

Design

A randomized clinical trial with two groups of test and control , with 120 subjects as sample size, a purpose-based sampling method and dividing subjects into two groups of test and control

Settings and conduct

This clinical trial study was conducted on 120 patients after cardiac angiography .In this study, patients after angiography were placed in two back positions with angle of 0 degrees and 30 degrees. They were compared for the severity of back pain and urinary retention.The location of the study was the Shahid Sadoghi hospital in Yazd city.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Patient's candidate for angiography, aged over 18 years. Perform angiography via femoral artery .Insert the needle only once .Use the Sheath number 6 and 7. Non-Inclusion criteria:Patients with back pain history and prostate hypertrophy.

Intervention groups

Patients in intervention group were placed in bed at 30 degree angle at the time of arrival and up to 4 hours later. Patients in control group: were placed in bed at zero degree angles at the time of arrival and up to 4 hours later.

Main outcome variables

Back pain; urinary retention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181212041938N1**

Registration date: **2019-08-11, 1398/05/20**

Registration timing: **retrospective**

Last update: **2019-08-11, 1398/05/20**

Update count: **0**

Registration date

2019-08-11, 1398/05/20

Registrant information

Name

Maasoumeh Barkhordari-Sharifabad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-05, 1397/02/15

Expected recruitment end date

2018-09-06, 1397/06/15

Actual recruitment start date

2018-05-10, 1397/02/20

Actual recruitment end date

2018-10-12, 1397/07/20

Trial completion date

2018-10-12, 1397/07/20

Scientific title

The Effect of Bed Angle Change on Back Pain and Urinary Retention after Coronary Angiography

Public title

Effect of Bed Angle on Back Pain and Urinary Retention after Angiography

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient's candidate for angiography, aged over 18 years
 Perform angiography via femoral artery Insert the needle only once Use the Sheath number 6 and 7

Exclusion criteria:
 Patients with back pain history Patients with prostate hypertrophy

Age
 From **18 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **120**
 Actual sample size reached: **120**

Randomization (investigator's opinion)
 Randomized

Randomization description
 The randomization of this study is simple randomization. Randomization unit was individual. The samples were determined and assigned to two groups by random number table. Researcher closes our eyes and randomly point to a spot on the chart .the path in the random numbers table was from left to right. Even numbers considered for the intervention group and odd numbers for the control group. The sample size was 120.On average, 150 patients were admitted to the ward per month. The expected duration of study was 4 months. Therefore, the research population was 400 Patients candidate for angiography. The numbers were below 400 in the random number table. .If the number was odd; they would be in the intervention group and if the number was even; they would be in the control group. This was done until 60 individuals were selected for intervention group and 60 for the control group. It should be noted that if we encountered a duplicate number, that number would be deleted.Also a random extra list of 10 people was prepared for both groups. If one of the selected individuals did not meet the inclusion or exclusion criteria or was not willing to participate in the study, another subject replaced. The daily sampling was performed .From the first day of the study; patients were enrolled based on the number one referral for angiography. If the number is selected who had inclusion criteria and agreed to participate in the study, they were studied in the intervention or control group.

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 Islamic Azad University - Isfahan (Khorasgan) Branch

Street address

Islamic Azad University Isfahan (Khorasgan) Branch., University Blvd., Jey St., Isfahan town

City

Isfahan

Province

Isfahan

Postal code

815513998

Approval date

2018-04-18, 1397/01/29

Ethics committee reference number

IR.IAU.KHUISF.REC.1397.083

Health conditions studied

1

Description of health condition studied

Cardiac catheterization

ICD-10 code

Y84.0

ICD-10 code description

Cardiac catheterization

Primary outcomes

1

Description

Back pain

Timepoint

Measurement of pain intensity immediately and four hours after angiography

Method of measurement

Numerical Visual Scale of Pain

2

Description

Urinary Retention

Timepoint

Measurement of urinary retention immediately and tow hours after angiography

Method of measurement

According to the patient's statements

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients were placed in bed at 30 degree angle at the time of arrival and up to 4 hours later.

Category

Treatment - Other

2

Description

Control group: Patients were placed in bed at zero degree angle at the time of arrival and up to 4 hours later.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital

Full name of responsible person

Farzane Sedighi

Street address

Shahid Sadoughi Hospital., Abn Sina Blvd., Safaie., Yazd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Farzane Sedighi

Position

Graduated Master of Nursing Intensive Care

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

Masoumeh Barkhordari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable