Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of effects of two changing position on severity of back pain, comfort, blood pressre, bleeding and hematoma after coronary angiography in Valiasre hospital of Qom, 2009

Protocol summary

Summary

Background: Back pain and discomfort is frequently reported following coronary angiography (CC) due the prolonged bed rest after the procedure. Aim: The aim of this study was to compare the effect of 2 changing Positions on back pain, comfort, bleeding and hematoma after CC. Participants: A sample of 75 patients, who had undergone a non-emergency 6-French CC via the femoral artery from April to August, 2009. Exclusion criteria were: known bleeding disorders, experiencing back pain before the procedure, admission to the Coronary Care Unit after the procedure. Methods: In a single-blind randomized controlled trial, each patient was randomly divided into three equal groups. Patients in the first (control) group were managed as routine; they were restricted to a 6h bed rest in supine position with the affected leg straight and immobilized and a sand bag on the puncture site for at least 1h. The patients' position in the second and third groups was intermittently changed during the first 6 h after angiography. The severity of back pain, level of comfort, amount of bleeding and hematoma were measured at regular intervals after the procedure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138807182560N1**
Registration date: **2009-11-17, 1388/08/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2009-11-17, 1388/08/26

Registrant information

Name

Mohammad reza Yeganehkhah

Name of organization / entity

Qom University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 21 6630 4368

Email address

yeganehkhah@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Qom University of Medical Sciences

Expected recruitment start date

2009-04-21, 1388/02/01

Expected recruitment end date

2009-08-22, 1388/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effects of two changing position on severity of back pain, comfort, blood pressre, bleeding and hematoma after coronary angiography in Valiasre hospital of Qom, 2009

Public title

Comparison of effects of two positioning on back pain and comfort after coronary angiography

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1) Patients' ages between 18-80 years 2) Had undergone a non-emergency 6 French diagnostic angiography via the femoral artery 3) Had complete alert 4) Ability of patient to assess the pain & comfort with visual analogue scale 5) Had no active bleeding disorders 6) Had no chronic lower back pain Exclusion criteria: 1) Had active bleeding at catheter insertion site after angiography 2) Development of artery disorders during angiography 3) Had systolic blood pressure greater than 190mmHg or diastolic blood pressure greater than110mmHg 4) Admission to the coronary care unit or intensive care unit 5) CPR during angiography 6) PT higher than 16 Sec 7) Had no pulse in feet 8) Inability of patient to help for changing 9) Had vomiting greater than 4 times during first 6 hours after angiography

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Qom University of Medical Sciences and Health Services

Street address

Qom University of Medical Sciences and Health Services, Saheli st., Qom., Iran.

City

Qom

Postal code

37185

Approval date

2009-04-05, 1388/01/16

Ethics committee reference number

272/34/پ

Health conditions studied

1

Description of health condition studied

back pain and discomfort after coronary angiography

ICD-10 code

R29.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

reduced back pain and promote physical comfort without increasing vascular complications

Timepoint

every 2 hours(three time after coronary angiography) and next morning at 08:00h

Method of measurement

Visual Analogue pain Scale(VAS), Visual Analogue comfort Scale, ruler

Secondary outcomes

empty

Intervention groups

1

Description

Patients in the first (control) group were managed as routine

Category

N/A

2

Description

The patients in the second group were positioned as follows: in the supine position with the affected leg straight and immobilized and a sand bag on the puncture site for first hour, in the supine position with the affected leg straight and immobilized and head of bed [HOB]15° elevated during the second hour, in the supine position with the affected leg straight and immobilized and HOB 30° elevated during the third hour, in the supine position with the affected leg straight and immobilized and head of bed [HOB]45° elevated during the fourth hour, in the supine position with the affected leg straight and immobilized and head of bed [HOB]30° elevated during the fifth hour, in the supine position with the affected leg straight and immobilized and head of bed [HOB]15° elevated during the sixth hour. After that, the patients were allowed to come out of bed [OOB], to sit on the chair beside the bed for10min and then to walk around and undertake self care activities. In the second group, the sand bag was taken away 1h after the procedure.

Category

Treatment - Other

3

Description
The patients in the third group were positioned as follows: in the supine position with the affected leg straight and immobilized and a sand bag on the puncture site for first hour, in the semi right lateral position with the affected leg straight and immobilized during the second hour, in the supine position with the affected leg straight and immobilized during the third hour, in the semi left lateral position with the affected leg straight and immobilized during the second hour, in the supine position with the affected leg straight and immobilized during the fourth hour, in the semi right lateral position with the affected leg straight and immobilized during the fifth hour, in the supine position with the affected leg straight and immobilized during the sixth hour. While the patients in the third group were in semi lateral position, they were given a thin supportive pillow (10cm×40cm×70cm) under one side of their body, either left or right, from the shoulder to the gluteus area. We changed the place of the pillow every 1 hour in the right or the left side of the body. In seventh hour, the patients were allowed to come out of bed [OOB], to sit on the chair beside the bed for10min and then to walk around and undertake self care activities. In the third group, the sand bag was taken away 1h after the procedure.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
post ward angiography of Valiasre hospital of Qom
Full name of responsible person
Ali Honarman
Street address
City
Qom

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qom University of Medical Sciences and Health Services,
Full name of responsible person
Salimi, Ali
Street address
Qom University of Medical Sciences and Health Services, Saheli st., Qom., Iran
City
Qom
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qom University of Medical Sciences and Health Services,
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Qom University of Medical Sciences and Health Services
Full name of responsible person
Yeganeh khah, Mohammad Reza
Position
MSc in Community Health Nursing
Other areas of specialty/work
Street address
No. 12, 2 Senobar lane., Sepideh Ave., Bahrami st., Saeedi highway
City
Tehran
Postal code
1373765613
Phone
+98 21 6630 4368
Fax
Email
yeganeh3603@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Qom University of Medical Sciences and Health Services
Full name of responsible person
Yeganeh khah, Mohammad Reza
Position
MSc in Community Health Nursing
Other areas of specialty/work
Street address
No. 12, 2 Senobar lane., Sepideh Ave., Bahrami st., Saeedi highway
City
Tehrah
Postal code
3173765613
Phone

+98 21 6630 4368

Fax

Email

yeganeh3603@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Qom University of Medical Sciences and Health Services

Full name of responsible person

Yeganeh khah, Mohammad Reza

Position

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Fax

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yeganeh3603@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty