

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of new planning care on back pain and vascular complication after coronary angiography in the post angiography ward of Rasht (heshmat Teaching hospital), 2010

Protocol summary

Summary

The aim of this study is to assess the effect of new planning care on back pain and vascular complications after cardiac catheterization. A total of 126 patients who have undergone a nonemergency diagnostic cardiac catheterization via the femoral artery are randomly assigned into intervention or control group. The patients in the intervention group are positioned at the supine position during the first hour, at the position with head of the bed elevated by 30-45 degrees during the second hour, and at the position with head of the bed elevated by 45 degrees during the third hour, at the right and left lateral positions, equally. At the fourth hour, the patients are allowed to be out of bed after a while sitting on the edge of the bed. The sand bags are taken away two hours later. The patients in the control group will receive routine care included bed rest for 8-10 hours with immobilizing the affected leg during bed rest as well as application of a 5 kg sandbag for four hours. Primary outcome measures are incidence of vascular complications and low back pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010194971N1**
Registration date: **2010-12-24, 1389/10/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-12-24, 1389/10/03

Registrant information

Name

Mohamadtaghi Moghadabnia

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Guilan University of Medical Sciences

Expected recruitment start date

2010-11-22, 1389/09/01

Expected recruitment end date

2011-02-04, 1389/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of new planning care on back pain and vascular complication after coronary angiography in the post angiography ward of Rasht (heshmat Teaching hospital), 2010

Public title

Effect of new planning care on back pain and vascular complication after coronary angiography

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: No known coagulation abnormality,

femoral approach for the procedure, age between 18-80 years, usage of the arterial sheath 6-F size, single puncture of the femoral artery, signing written informed consent Exclusion criteria: diastolic or systolic blood pressure higher than 110 and 190 mmHg, presence of low back pain, presence of any complications developing during cardiac catheterization, arrhythmias, unconsciousness, deep vein thrombosis before the procedure

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: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Guilan University of Medical Sciences

Street address

Guilan University of Medical Sciences, opposite of Alzahra Hospital., Namjoo ave, Rasht, Guilan, Iran

City

Rasht

Postal code

Approval date

2010-09-28, 1389/07/06

Ethics committee reference number

10229

Health conditions studied

1

Description of health condition studied

back pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Vascular complication

Timepoint

Points included the time immediately after coming to the post catheterization ward, at 1 h(any30 minute), 2 h, 3 h(any30 minute), 4 h,6h.10h after cardiac catheterization and finally the next morning.

Method of measurement

The borders of hematoma measures by the ruler with Centimeter and bleeding measures by balance with Milliliter.Insignificant bleeding defines as blood loss estimated as less than 100 mL and Insignificant haematoma absence of haematoma, or a haematoma less than or equal to 5 cm in width. Significant bleeding defines as blood loss estimate as equal or greater than 100 mL. Significant hematoma also considering when a haematoma occlude width equal to or greater than 5 cm.

2

Description

Back pain

Timepoint

Points included the time immediately after coming to the post catheterization ward, at 1 h, 2 h, 3 h, 4 h, 6h, and 10 h after cardiac catheterization and finally the next morning morning

Method of measurement

visual analogue scales (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patients are positioned at the supine position during the first hour, at the position with head of the bed elevated by 30-45 degrees during the second hour, and at the position with head of the bed elevated by 45 degrees during the third hour, at the right and left lateral positions, equally. At the fourth hour, the patients are allowed to be out of bed after a while sitting on the edge of the bed. The sand bags are taken away two hours later.

Category

Prevention

2

Description

Control group: The patients will receive routine care included bed rest for 8-10 hours with immobilizing the affected leg during bed rest as well as application of a 5 kg sandbag for four hours.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmat Teaching Hospital

Full name of responsible person

Mohamadtaghi Moghadamnia

Street address

Heshmat Teaching Hospital, Bayani street, 15
Khordad ave, Rasht, Guilan, Iran

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Guilan University of
Medical Sciences

Full name of responsible person

Dr Abdolrasol Sobhani

Street address

Guilan University of Medical Sciences, opposite of
Alzahra Hospital., Namjoo ave, Rasht, Guilan, Iran

City

Rasht

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research of Guilan University of
Medical Sciences

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

Guilan University of Medical Sciences

Full name of responsible person

Marzieh Afshar Mohamadian

Position

Postgraduate Student.

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Other areas of specialty/work

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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