

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Effect of changing position and early mobilization on back pain and vascular side effects in patients after coronary angiography

Protocol summary

Study aim

evaluate effect of changing position and early mobilization on back pain and vascular side effects in patients

Design

This experimental design are conduct on the 120 patients hospitalized for coronary angiography. Each Patient is assign randomly to either the control group(n= 60), which remain supine position 6 hours of bed rest after coronary angiography or experimental group(n= 60).

Settings and conduct

This clinical trial will be conducted in Tehran's Shahid Taleghani Hospital , in which the data analyzer will be blinded.

Participants/Inclusion and exclusion criteria

All subject of the research scheduled one day before for non emergency cardiac angiography via femoral artery. They are older than 18- years old with full conscious and ability for performing the project. The systolic blood pressure are not higher than 190 mmHg or diastolic higher than 110 mmHg. According to the patients data they should not have known bleeding disorders, peripheral vascular disease, experiencing back pain before the procedure, allergy to contrast materials

Intervention groups

control group will remain supine position 6 hours of bed rest after coronary angiography without changeling position. The experimental group will remain 4 hours of bed rest after coronary , also is changed position hourly, varying between supine, elevated to 30 degrees and semi position (elevated to 45 degrees) during the first 4 hours after coronary angiography. The vascular side effects were registered before and after angiography on immediate return to the ward, at first hour every 15 minutes and then hourly up to 6 hours and also in next morning after angiography. The back pain in both groups was assessed on immediate return to the ward and then after 2, 4 and 6 hours following cardiac angiography and

the next morning.

Main outcome variables

intensity and extent back pain and vascular side effects

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20180723040562N1**

Registration date: **2019-05-21, 1398/02/31**

Registration timing: **retrospective**

Last update: **2019-05-21, 1398/02/31**

Update count: **0**

Registration date

2019-05-21, 1398/02/31

Registrant information

Name

Neda Haghighi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5582 8977

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neda.khoshkho@kiauo.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2010-08-20, 1389/05/29

Expected recruitment end date

2012-10-21, 1391/07/30

Actual recruitment start date

2016-09-21, 1395/06/31

Actual recruitment end date

2018-06-09, 1397/03/19

Trial completion date

2018-06-09, 1397/03/19

Scientific title

Effect of changing position and early mobilization on back pain and vascular side effects in patients after coronary angiography

Public title

Effect of changing position and early mobilization on back pain and vascular side effects in patients after coronary angiography

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

scheduled one day before for non emergency cardiac angiography via femoral artery older than 18- years old
The systolic blood pressure was not higher than 190 mmHg
The diastolic blood pressure was not higher than 110 mmHg
full conscious and ability for performing the project
The desire to participate in the study not have known bleeding disorders, peripheral vascular disease, kidney disease ,experiencing back pain before the procedure, allergy to contrast materials
Having previous history of angiography

Exclusion criteria:

Having a back pain when you start a study
Desire to leave the study

AgeFrom **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample sizeTarget sample size: **120**Actual sample size reached: **120****Randomization (investigator's opinion)**

Randomized

Randomization description

A randomized randomization was performed using a random number table.

Blinding (investigator's opinion)

Single blinded

Blinding description

The samples studied were blind about they are in the intervention or control group

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Faculty, Shaheed Beheshti University of Medical Sciences & Health Services

Street address

Faculty, Shaheed Beheshti University of Medical Sciences & Health Services, Velanjak

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2017-01-02, 1395/10/13

Ethics committee reference number

IR.SBMU.PHNM.1395.591

Health conditions studied**1****Description of health condition studied**

back pain

ICD-10 code

M70

ICD-10 code description

Soft tissue disorders related to use, overuse and pressure

Primary outcomes**1****Description**

score of NPS

Timepoint

Q 2 hours

Method of measurement

The back pain in both groups was assessed on immediate return to the ward and then after 2, 4 and 6 hours following cardiac angiography and the next morning.

Secondary outcomes**1****Description**

vascular side effect

Timepoint

The vascular side effect were registered before and after angiography on immediate return to the ward, at first hour every 15 minutes and then hourly up to 6 hours and also in next morning after angiography

Method of measurement

Christenson's guidelines

Intervention groups

1

Description

Intervention group: remained 4 hours of bed rest after coronary, also was changed position hourly, varying between supine, elevated to 30 degrees and semi position (elevated to 45 degrees) during the first 4 hours after coronary angiography.

Category

Prevention

2

Description

Control group: The control group received routine care after angiography, ie rest in the bed for 6 hours, resting in the back, and not changing the condition.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Masoumeh Neishabouri

Street address

Taleghani hospital, Erabi Ave, Velenjak, Tehran

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taleghani@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Masoumeh Neishabouri

Street address

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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

Shahid Beheshti 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

Mazandaran University of Medical Sciences

Full name of responsible person

Masoumeh Neishabouri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Some of the data, such as information on the main outcome or the like, can be shared.

When the data will become available and for how long

2019

To whom data/document is available

Researchers working in academic and academic institutions, students and medical science

Under which criteria data/document could be used

It is permissible to cite the results of research for scholars and researchers in the medical sciences department who are willing to continue working in the mentioned hospital.

From where data/document is obtainable

Masoumeh Neishabouri mn.neishabouri@gmail.com

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

About a month

Comments