Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 3o 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

Email address

neda.khoshkho@kiau.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, kideny 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
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target 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 coronaryو also was changed position hourly, varying between supine, elevated to 3o 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Masoumeh Neishabouri
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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
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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