

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

The effect of time of complete bed rest and keep the sand bag on the rate of hemorrhage and hematoma after coronary angiography.

Protocol summary

Summary

The aim of this study is to assessing an effect of time of complete bed rest and keeps the sand bag on the rate of hemorrhage and hematoma after coronary angiography. This randomized clinical trial conducted on 222 patients undergone selective angiography which divided in 3 groups. Patients with age>18, only one trial for femoral artery access with angiography sheath 6 French was included in study and patients with any kind of coagulopathy and emergency procedures are excluded. In control group, Patients receiving routine post angiography care. (10 hours in complete bed rest by Sand bag in first 4 hours) In group A, Patients receiving 8 hours complete bed rest by using Sand bag in first 2 hours. In group B, Patients receiving 7 hours complete bed rest by using Sand bag in first 4 hours. By completing bed rest and sand bag insertion, Patients evaluated on vital sign, angiography puncture site and back pain. In This study, bleeding and hematoma are considered as a primary outcome and back pain as a secondary outcome variable.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015081323609N1**

Registration date: **2015-11-25, 1394/09/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-25, 1394/09/04

Registrant information

Name

Khalil Rasouly

Name of organization / entity

Shahid Sadoughi University Of Medical Sciences and Health Services, Yazd, Iran.

Country

Iran (Islamic Republic of)

Phone

+98 35 3725 1668

Email address

rasouly.kh@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Sadoughi University of Medical Science, Yazd, Iran.

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of time of complete bed rest and keep the sand bag on the rate of hemorrhage and hematoma after coronary angiography.

Public title

The effect of time of complete bed rest and keep the sand bag on the rate of hemorrhage and hematoma after coronary angiography.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: were are considered, All patients undergoing transfemoral cardiac catheterization by six French sheath and transferred to ward; age>18 and

patients by one puncture trial for femoral artery access. Exclusion criteria: were considered; patients receiving anticoagulant by INR>; age>75; previous history of angiography; chronic lower back pain; previous surgery in the Iliac or Femoral arteries; abnormal prothrombin time(PT>90) and platelet lower than 100000.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **222**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization is done by table of random numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Sadoughi University of Medical Science, Yazd, Iran.

Street address

Nursing and Midwifery College, Boo Ali Street, Safaee, Yazd.

City

Yazd

Postal code

Approval date

2015-08-23, 1394/06/01

Ethics committee reference number

ir.ssu.rec.1394.69

Health conditions studied

1

Description of health condition studied

Bleeding

ICD-10 code

D69.9

ICD-10 code description

Haemorrhagic condition, unspecified

2

Description of health condition studied

Back pain

ICD-10 code

M54.9

ICD-10 code description

Dorsalgia, unspecified

Primary outcomes

1

Description

Bleeding

Timepoint

1. Immediately after angiography procedure. 2. every 15 minute in first hour. 3. every 30 minute in second hour. 3. every hour still mobilization.

Method of measurement

Amount of bleeding is measured by weight of blood loaded gauze.

2

Description

size of hematoma

Timepoint

1,2,4 and 6 hour after mobilization

Method of measurement

palpable mass on angiography puncture site which measured by transparent ruler.

Secondary outcomes

1

Description

Back pain

Timepoint

1,2,4,6,8 and 10 hour after angiography procedure.

Method of measurement

Visual analog scale is used for back pain assessment

Intervention groups

1

Description

In control group, Patients receiving routine post angiography care.(10 hours in complete bed rest by Sand bag in first 4 hours).

Category

Prevention

2

Description

In group A, Patients receiving 8 hours complete bed rest by using Sand bag in first 2 hours.

Category

Prevention

3

Description

In group B, Patients receiving 7 hours complete bed rest by using Sand bag in first 4 hours.

Category

Prevention

Recruitment centers

1

Recruitment center**Name of recruitment center**

Afshar heart center, Yazd, Iran.

Full name of responsible person

Khalil Rasouly

Street address

Afshar heart center, Yazd, Iran.

City

Yazd

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice chancellor for research, Shahid Sadoughi University of Medical Science, Yazd, Iran.

Full name of responsible person

Amir Houshang Mehrparvar

Street address

Nursing and Midwifery College, Boo Ali Street, Safaee, Yazd.

City

Yazd

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, Shahid Sadoughi University of Medical Science, Yazd, Iran.

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**

Shahid Sadoughi University of Medical Science, Yazd, Iran.

Full name of responsible person

Khalil Rasouly

Position

Master of Sciences in Intensive Care Nursing.

Other areas of specialty/work**Street address**

Nursing and Midwifery College, Boo Ali Street, Safaee, Yazd.

City

Yazd

Postal code**Phone**

+98 35 3824 1751

Fax**Email**

khalilrasouly@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Sadoughi University of Medical Science, Yazd, Iran.

Full name of responsible person

Khalil Rasouly

Position

Master of Science in Intensive Care Nursing

Other areas of specialty/work**Street address**

Nursing and Midwifery College, Boo Ali Street, Safaee, Yazd.

City

Yazd

Postal code**Phone**

+98 35 3824 1751

Fax**Email**

khalilrasouly@yahoo.com

Web page address**Person responsible for updating data****Contact****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