

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The Comparative Study of the Effects of Sand Bag Keeping Time and Changing Body Position on Acute Complications of Coronary Angiography.

Protocol summary

Summary

This study aimed to evaluate the effect of duration of sandbag and change position on the acute complications of coronary angiography in patients referred to angiography Tohid Hospital in Sanandaj, 1394 will be conducted. This triple blind clinical trial with a sample size of 75 patients undergoing coronary angiography, a 3-block design and randomized into 3 groups: control, sandbag's intervention group and Changing body Position's intervention group will be carried out. patients in the control group, will receive routines care include of 8 hours motionless in supine position, with head angle of zero degrees, rest in bed and preserving a 4 kg sandbag on the site of catheter insertion for 6 hours. patients in sandbag's intervention group will receive routines care except that in the third hour after entering to the heart ward, sandbag will be removed from the position. patients in Changing body Position's intervention group will receive routines care except that the following positions during bed rest will be applied. During the first and second hours supine position and head angle of zero degrees, during the third and fourth positions supine head angle of 45 degrees, during the fifth and sixth hours left and right latera position with head angle of 15 degrees and in the seventh and eighth in the sitting position will be cared for. The acute angiographic complications in three groups, including urinary retention, bruising, thrombosis, bleeding, hematoma, back pain, groin pain, the the discomfort in 0, 3, 6, 8 and 24 hours after the entering the patient to the heart ward will be studied and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015091424018N1**

Registration date: **2015-11-14, 1394/08/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-14, 1394/08/23

Registrant information

Name

Parvin Mahmoodi

Name of organization / entity

Kurdistan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 87 3328 0414

Email address

mahmoodi.parvin@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences

Expected recruitment start date

2015-10-07, 1394/07/15

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparative Study of the Effects of Sand Bag Keeping Time and Changing Body Position on Acute Complications of Coronary Angiography.

Public title

Evaluation of Coronary Angiography

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: under non-emergency catheterization; age between 18-65 years; blood pressure less than 100/180 mmHg; the absence of active bleeding disorders; prothrombin time less than 16 seconds and time; Partial thromboplastin less than 90 seconds; no history of diabetes with disabilities; consent to participate in the study; angiography via the femoral artery; arterial puncture for the route only once; no DVT before the procedure; treatment with thrombolytic drugs and anticoagulant (taking warfarin); taking pain medication before the procedure; lack of peripheral vascular disease; no history of urinary problems; lack of sensitivity to contrast; no drug addiction; lack of chronic low back pain lack of blood and liver disease will be. Exclusion criteria: active bleeding from the catheter entry with hemodynamic impairment and the need for blood transfusion; blood coagulation disorders; history of chronic low back pain; the need for cardiopulmonary resuscitation during angiography; chest pain with ECG changes; non-invasive blood pressure (NIBP) systolic or diastolic over and over mmHg 180 mmHg 100; disability and impaired level of consciousness in such a way that the patient is able to transform the work; rupture of the femoral artery during angiography; after a dangerous rhythm disorder Angiography; heparin injection during or after the procedure; the patient's hemodynamic status was while studying will be unhappy.

Age

From **18 years** old to **65 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)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kurdistan University of Medical Sciences

Street address

Kurdistan University of Medical Sciences,sanandaj,
kurdistan

City

sanandaj

Postal code

Approval date

2015-09-30, 1394/07/08

Ethics committee reference number

MUK.REC.1394.194

Health conditions studied

1

Description of health condition studied

complication of coronary angiography

ICD-10 code

I70.8

ICD-10 code description

Atherosclerosis of other arteries(coronary arteries)

Primary outcomes

1

Description

bleeding

Timepoint

at 0, 3, 6, 8 and 24 hours after angiography

Method of measurement

Measurement scales with a sensitivity of 0.1 g

2

Description

hematoma

Timepoint

at 0, 3, 6, 8 and 24 hours after angiography

Method of measurement

with Trans Parente and graph paper

3

Description

bruise

Timepoint

at 0, 3, 6, 8 and 24 hours after angiography

Method of measurement

with Trans Parente and graph paper

4

Description

pain(include of back pain and groin pain)

Timepoint

at 0, 3, 6, 8 and 24 hours after angiography

Method of measurement

NRS

5

Description

urinary retention

Timepoint

at 0, 3, 6, 8 and 24 hours after angiography

Method of measurement

Based on asking from the patient

6**Description**

convenience

Timepoint

at 0, 3, 6, 8 and 24 hours after angiography

Method of measurement

VAS

7**Description**

thrombosis

Timepoint

at 0, 3, 6, 8 and 24 hours after angiography

Method of measurement

The sensory and motor symptoms, absence of peripheral pulse, the white appearance and painful physical examination

Secondary outcomes

empty

Intervention groups**1****Description**

control group: patients in the control group, will receive routines care include of 8 hours motionless in supine position, with head angle of zero degrees, rest in bed and preserving a 4 kg sandbag on the site of catheter insertion for 6 hours.

Category

Prevention

2**Description**

sandbag's intervention group: patients in sandbag's intervention group will receive routines care except that in the third hour after entering to the heart ward, sandbag will be removed from the position.

Category

Prevention

3**Description**

Changing body Position's intervention group: patients in Changing body Position's intervention group will receive routines care except that the following positions during bed rest will be applied. During the first and second hours supine position and head angle of zero degrees, during the third and fourth positions supine head angle of 45 degrees, during the fifth and sixth hours left and

right latera position with head angle of 15 degrees and in the seventh and eighth in the sitting position will be cared for.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tohid Hospital

Full name of responsible person

Parvin Mahmoodi

Street address

number7, Diman 4 alley, Hazhar street, Andishe town, Janbazan blv, Sanandaj, Kurdistan

City

Sanandaj

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kurdistan University of Medical Sciences

Full name of responsible person

Parvin Mahmoodi

Street address

Number7, Diman 4 alley, Hazhar street, Andishe town, Janbazan blv, Sanandaj, Kurdistan

City

Sanandaj

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kurdistan 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**

Kurdistan University of Medical Sciences

Full name of responsible person

Sina Valiee

Position

Ph.D of Nursing Education

Other areas of specialty/work

Street address

Number 4, Negin alley, Keshavarz town, Sanandaj

City

Sanandaj

Postal code

Phone

00

Fax

Email

sinavallee@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Parvin Mahmoodi

Position

MS Student of Medical Surgical of Nursing

Other areas of specialty/work

Street address

Number7,Diman 4 alley, Hazhar street, Andishe town, Janbazan blv, Sanandaj, Kurdistan

City

Sanandaj

Postal code

6616814915

Phone

+98 87 3328 0414

Fax

+98 87 3328 1240

Email

mahmoodi.parvin@gmail.commahmoodi.parvin@muk.ac.irmahmoodi.parvin@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Parvin Mahmoodi

Position

MS Student of Medical Surgical of Nursing

Other areas of specialty/work

Street address

Number7,Diman 4 alley ,Hazhar street, Andishe town, Janbazan blv,Sanandaj,Kurdistan

City

Sanandaj

Postal code

6616814915

Phone

+98 87 3328 0414

Fax

+98 87 3328 0414

Email

mahmoodi.parvin@gmail.commahmoodi.parvin@muk.ac.ir

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