

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of Changing weight of sand bag on some complications of femoral artery puncturation and patients comfort on patient undergoing coronary angiography in Kordkooy Amir-almomenin Hospital1392

Protocol summary

Summary

1)Objectives: To assess the effect of Changing weight of sand bag on the bleeding, hematoma, back pain, urinary retention and Patient comfort after cardiac catheterization. 2) Design: This is a quasi-experimental study, including four groups of 35 patients (140 samples with random sampling). 3)Setting and conduct:Patients were randomly assigned to intervention and control groups are examined. 4)Participants including major eligibility criteria:Inclusion criteria: non-emergency catheterization; withdrawal of arterial sheath immediately after angiography; aged 18-65; informed consent to participate in the study. Exclusion criteria: the need for cardiopulmonary resuscitation during angiography; vascular injury during the procedure; patient unwillingness to participate in the study. 5)Intervention:The control group received a common protocol, will be the use of sandbags is 4 kg to 6 hours. Patients in the intervention group of sandbags weighing 3/5, 3 and 2/3 will be used for 6 hours. 6)main outcome measures (variables): the amount of bleeding, hematoma, back pain, urinary retention and Patient comfort were measured in 0, 1, 2, 4, 6,8 and 24 hours after angiography. Data were collected by the use of personal information questionnaire and Numeric Pain Intensity Scale and Christenson check list for investigating the amount of bleeding and hematoma and Visual comfort scale .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013052213424N1**
Registration date: **2013-06-25, 1392/04/04**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-06-25, 1392/04/04

Registrant information

Name

Afiyeh Kor

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6689 7622

Email address

korafiyeh1@gmail.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Golestan University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2013-07-23, 1392/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Changing weight of sand bag on some complications of femoral artery puncturation and patients comfort on patient undergoing coronary angiography in Kordkooy Amir-almomenin Hospital1392

Public title

Effect of Changing weight of sand bag on some complications of coronary angiography

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: non-emergency catheterization of the femoral artery and catheter 6fr build a company; withdrawal of arterial sheath immediately after angiography; aged 18-65; systolic blood pressure less than 180 and a diastolic pressure of less than 100; the lack of bleeding disorders Off; Pt <16, ptt <50, INR <1/8; the absence of peripheral vascular disease; no history of previous low back pain; lack of experience difficulty passing urine; loss of cerebrovascular accidents and motor and neuromuscular problems; lack of angioseal, BMI 18/5-29; informed consent to participate in the study. Exclusion criteria: the need for angiography during cardiopulmonary resuscitation; chest pain with new ECG changes; hemodynamic changes associated with active bleeding and need for blood transfusion; dangerous arrhythmias immediately after cardiac catheterization; vascular injury during the procedure; hemostasis time after the procedure; a long (over 20 minutes); use of pain medications; heparin infusion during or after catheterization; manipulating both the femoral artery and arterial catheter in place for more than 2 times; patient unwillingness to participate in the study.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of the Golestan University of Medical Sciences

Street address

Golestan University of Medical Sciences, 5 km road Gorgan - Sari, Gorgan, Golestan, Iran

City

Gorgan

Postal code

49165-568

Approval date

2013-02-19, 1391/12/01

Ethics committee reference number

356191122716

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

cardiac catheterization

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

bleeding

Timepoint

On arrival the patient, every 2 hours for 8 hours and then 24 hours later

Method of measurement

Christenson check list

2**Description**

Hematoma

Timepoint

On arrival the patient, every 2 hours for 8 hours and then 24 hours later

Method of measurement

Christenson check list

3**Description**

pain

Timepoint

On arrival the patient, every 2 hours for 8 hours and then 24 hours later

Method of measurement

Numeric pain scale

4**Description**

Urinary retention

Timepoint

On arrival the patient, every 2 hours for 8 hours and then 24 hours later

Method of measurement

Question of patient

5

Description

Comfort

Timepoint

On arrival the patient, every 2 hours for 8 hours and then 24 hours later

Method of measurement

Visual scale Comfort

Secondary outcomes

1

Description

protromobin time (PT)

Timepoint

Before intervention

Method of measurement

second

Intervention groups

1

Description

control group: patients who received routine care, including the use of sandbags is 4 kg to 6 hours.

Category

Prevention

2

Description

Intervention group 1:The sandbags 3/5 kg was used for 6 hours

Category

Prevention

3

Description

Intervention group 2:The sandbags 3 kg was used for 6 hours

Category

Prevention

4

Description

Intervention group 1:The sandbags 2/3 kg was used for 6 hours

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir-al-momenin hospital

Full name of responsible person

Afiyeh Kor

Street address

Jangal St, KordKooy, Golestan, Iran

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Kordkooy

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Golestan University of Medical Sciences

Full name of responsible person

Dr MJ Golalipour

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Golestan University of Medical Sciences, 5 km road Gorgan - Sari, Gorgan, Golestan

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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

Vice chancellor for research, Golestan 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

Golestan University of medical Sciences

Full name of responsible person

Afiyeh Kor

Position

Bachelor of Science

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