

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 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 for 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

#### **City**

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

##### **Street address**

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

##### **City**

Gorgan

##### **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**

##### **Street address**

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## Person responsible for scientific inquiries

### Contact

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Master of Science

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## Person responsible for updating data

### Contact

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**Other areas of specialty/work**

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**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*