Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The comparison of two methods of sandbag and air bag (femosup) in reduction of coronary artery angioplasty complications

Protocol summary

Summary
The purpose of this study is comparison of two methods of sandbag and air bag in reduction of coronary artery angioplasty complications after removal of sheath. Inclusion criteria are having sufficient consciousness to work with staff and have arterial sheath in the right leg. Exclusion criteria are opiate addiction, psychological disease, existence of low back pain, blood and clotting diseases. This quasi experimental study will be done on 72 patients undergoing angioplasty who hospitalized in intensive care unit. Patients will allocate to two groups of airbag and sand bag. In the sand bag group after pulling out the sheath, routine care takes place and sand bag is put on the place of artery's puncture for 6 hours. In the airbag group after the removal of the sheath the designed device (air bag) will be fastened. The extent of hematoma, the amount of tiredness, low back pain, sedative and analgesic intake and sleep status will be evaluated in two groups

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT201206306342N2**
Registration date: **2012-10-08, 1391/07/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date
2012-10-08, 1391/07/17

Registrant information
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Recruitment status
Recruitment complete

Funding source
Semnan University of Medical Sciences

Expected recruitment start date
2012-06-21, 1391/04/01
Expected recruitment end date
2012-10-21, 1391/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The comparison of two methods of sandbag and air bag (femosup) in reduction of coronary artery angioplasty complications

Public title
effect of air bag (femosup) in reducing complication after angioplasty
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Having sufficient consciousness to work with staff; have Arterial sheath in the right leg; use sheath no 6; received heparin as anticoagulant; arterial sheath is removed 5-6 hours after injection of heparin bolus dose. Exclusion criteria: Opiate addiction; psychological disease; previous use of analgesics and sedatives or tranquilizers during angioplasty; Integrilin received during angioplasty; previous used of Varfarin;

angioplasty due to myocardial infarction; hematoma forms before extraction of the sheath; existence of musculoskeletal disease and low back pain; blood and hepatic diseases; peripheral vascular disease; Clotting problems; existence of venous sheath; To access the femoral artery needle is made more than once; systolic blood pressure is above 180 mm Hg; diastolic BP is above 100 mm Hg; use of Hemcan glue after extraction of the sheath.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Semnan University of Medical Sciences

Street address
School of Nursing and Allied Health, Semnan University of Medical Sciences, Semnan, Iran

City
Semnan

Postal code

Approval date
2012-05-27, 1391/03/07

Ethics committee reference number
2744/16/91

Health conditions studied

1

Description of health condition studied
Atherosclerotic heart disease

ICD-10 code
I25.1

ICD-10 code description
Atherosclerotic heart disease

Primary outcomes

1

Description
low back pain

Timepoint
begining of intervention, 3 and 6 hours after intervention

Method of measurement
numeric rating scale of pain

2

Description
fatigue

Timepoint
begining of intervention, 3 and 6 hours after intervention

Method of measurement
numeric rating scale offatigue

3

Description
Groin discomfort

Timepoint
begining of intervention, 3 and 6 hours after intervention

Method of measurement
numeric rating scale of groin discomfort

4

Description
hematoma

Timepoint
hours of 1,2,3,4,5,6

Method of measurement
Christensen scale

5

Description
sedative intake

Timepoint
18 hours after angioplasty

Method of measurement
Patient records

6

Description
opiate intake

Timepoint
18 hours after angioplasty

Method of measurement
patient records

7

Description
sleep status

Timepoint
Day after angioplasty
Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
use of air bag (femosup) immediatly after removal of sheath
Category
Other

2

Description
use of sand bag immediatly after removal of sand bag
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Razavi Hospital
Full name of responsible person
Samira Bagheri
Street address
Razavi Hospital, Mashhad
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Raheb Ghorbani
Street address
Vice Chancellor for Research, Semnan University of Medical Sciences, Semnan
City
Semnan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan 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

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Person responsible for updating data

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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