

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison the influence of sand bag and closure pad on vascular complication of patients undergoing Angiography and admitted at Imam Ali Hospital (2015)

Protocol summary

Summary

Study design: Randomized Using random draw, patients are placed in one of the groups Study population: patients undergoing coronary angiography The main criteria for inclusion: full consciousness, the use of the right femoral artery, aged between 18-80 years, the lack of bleeding disorders, and lack of groin infection, normal coagulation tests (PT, PTT, and INR), not receiving anticoagulant and glomerular filtration rate above 50 mg / dl. Main exclusion criteria: primary hemostasis more than 30 minutes Sample size: 250 In the intervention and control group the closure pad and sand bag will be used respectively. Vascular complications in both groups will be monitored, immediately and up to 24 hours after homeostasis. Intervention: in intervention group one of two groups of pregnant women using sand bags blocking pad, placed. Vascular complications in both groups, will be monitored immediately and until 24 hours after homeostasis. Randomization: Random allocation Intervention time: after completion of angiography Primary outcome: : the amount of hematoma and bleeding at the angiography site

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404134736N5**
Registration date: **2015-08-19, 1394/05/28**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-08-19, 1394/05/28

Registrant information

Name

Alireza Khatony

Name of organization / entity

Kermanshah University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the influence of sand bag and closure pad on vascular complication of patients undergoing Angiography and admitted at Imam Ali Hospital (2015)

Public title

Comparison of sand bag and closure pad on the reducing bleeding and hematoma

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: non-emergency angiography, full consciousness, the use of the right femoral artery for

vascular access, age between 18-80 years, the use of sheath No. 6 (fr), the absence of pregnancy and lactation in females, absence of disorder bleeding disorder such as hemophilia, lack of infection of the groin, no peripheral arterial diseases such as Raynaud's, normal blood pressure, normal blood coagulation tests (PT, PTT, INR), not receiving anticoagulant and glomerular filtration rate above 50mg/dl respectively. Exclusion criteria: the primary hemostasis more than 30 minutes

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **250**

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

Ethic Committee of Kermanshah University of Medical Sciences

Street address

Shahid Beheshty Blvd., Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

Approval date

2015-06-23, 1394/04/02

Ethics committee reference number

kums.rec.1394.30

Health conditions studied

1

Description of health condition studied

Coronary Artery Diseases

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease Coronary (artery): • atheroma • atherosclerosis • disease • sclerosis

Primary outcomes

1

Description

amount of bleeding

Timepoint

Immediately after angiography and every half an hour up to 24 hours.

Method of measurement

Weighing gases of angiography site

2

Description

Hematoma size

Timepoint

Immediately after angiography and every 6 hours up to 24 hours

Method of measurement

Checkered ruler

Secondary outcomes

empty

Intervention groups

1

Description

Intervention 1: closure pad will be used. In this group amount of bleeding will be measured immediately and every half an hour for 24 hours and hematoma size will be measured immediately and every 6 hours for 24 hours

Category

Prevention

2

Description

Intervention 2: Sand bag will be used. In this group amount of bleeding will be measured immediately and every half an hour for 24 hours and hematoma size will be measured immediately and every 6 hours for 24 hours.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital

Full name of responsible person

Mostafa Bahremand

Street address

Imam Ali Hospital

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akhatony@gmail.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafy

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Shahid Beheshty Blvd., Kermanshah University of Medical Sciences

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Kermanshah

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, Kermanshah 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**

Kermanshah University of Medical Sciences

Full name of responsible person

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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