

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Evaluation of the effect of local cold pack application on vascular access site bleeding and hematoma after sheath removal in patients undergoing Angioplasty & Stenting

Protocol summary

Summary

The aim of the study is determining "the effect of cold-pack therapy on bleeding and hematoma after sheath removal in patients undergoing percutaneous coronary interventions". This is an interventional study with parallel approach by repeated measures, with a control group and before and after design. The population of this study consist patients' undergoing angioplasty and stenting procedure. Inclusion Criteria: non-emergency angioplasty or stenting by femoral artery approach with a sheath size of 6 or 7 French; age between 18-80 years; the absence of active bleeding disorders; INR< 2; Not receiving thrombolytic drugs and only one try for entrancing sheaths in femoral artery. Exclusion Criteria: integrilin administration during the procedure; systolic and diastolic blood pressure over 190 and 110 respectively; complications during catheterization; need for cardio-pulmonary resuscitation (CPR); chest pain with ECG changes; hemodynamic impairment during the study; no sense of arterial pulses lower than sheath access point; presence of hematoma at the beginning of study in puncture site; foreign patients who are unable to cooperate. After transferring the patient to the CCU, ACT will be assess by the researcher and if it is less than 180 seconds, the sheath will be removed and immediately hand pressure will be applied equally by the same researcher assistance to both groups at the puncture site for 20 minutes. The next step in the intervention group cold-pack will be placed for 30 minutes in sheath removing site and patients in control group will receive routine protocol (local pressure with sand bags during 4 hours and 6 hours complete bed rest). Bleeding and hematoma will be examined consistently until the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014122920472N1**

Registration date: **2015-02-11, 1393/11/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-11, 1393/11/22

Registrant information

Name

Samane sadat Javadi

Name of organization / entity

Shahid Sadoughi University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 35 3724 0173

Email address

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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences and Health Services

Expected recruitment start date

2015-01-05, 1393/10/15

Expected recruitment end date

2015-07-06, 1394/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of local cold pack application on vascular access site bleeding and hematoma after sheath removal in patients undergoing Angioplasty & Stenting

Public title
Evaluation of the effect of local cold pack application on bleeding and hematoma after Angioplasty

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion Criteria: non-emergency angioplasty or stenting by femoral artery approach with a sheath size of 6 or 7 French; age between 18-80 years; the absence of active bleeding disorders; INR < 2; Not receiving thrombolytic drugs and only one try for entraining sheaths in femoral artery. Exclusion Criteria: integrilin administration during the procedure; systolic and diastolic blood pressure over 190 and 110 respectively; complications during catheterization; need for cardio-pulmonary resuscitation (CPR); chest pain with ECG changes; hemodynamic impairment during the study; no sense of arterial pulses lower than sheath access point; presence of hematoma at the beginning of study in puncture site; foreign patients who are unable to cooperate

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: **66**

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

Shahid Sadoughi University of Medical Sciences and Health Services

Street address

Yazd, Ba Honar square, Shahid Sadoughi University of Medical Sciences and Health Services

City

Yazd

Postal code

Approval date

2014-11-08, 1393/08/17

Ethics committee reference number

163518 /17/1/پ

Health conditions studied

1

Description of health condition studied

Angioplasty and Senting

ICD-10 code

Z95.5

ICD-10 code description

Presence of coronary artery prosthesis Status following coronary angioplasty NOS

Primary outcomes

1

Description

Hematoma

Timepoint

Immediately after Hemostasis (before using ice packs), 0.5, 1, 2, 4 and 6 hours after the onset of ice packs and in the morning after Angioplasty and Stenting

Method of measurement

Rule-based cm2

2

Description

Bleeding

Timepoint

Immediately after Hemostasis (before using ice packs), 0.5, 1, 2, 4 and 6 hours after the onset of ice packs and in the morning after angioplasty and stenting

Method of measurement

Scale with a sensitivity of 0.01 grams

Secondary outcomes

1

Description

Blood Pressure

Timepoint

During the study

Method of measurement

Monitoring

Intervention groups

1

Description

For reduce the effect of the intervention on the results, the selected samples are Angioplasty and stenting by a specialist, then the patient is transferred to the CCU. ACT will be reviewed by the researcher and if less than 180 seconds, the sheath is removed and immediately hand pressure applied equally by the same researcher assistance to both groups at the exit sheath for 20 minutes. The next step will be placed in the intervention group ice bag for 30 minutes on the sheath exit and bleeding and hematoma measure and record during and immediately after hemostasis (before using ice packs), 0.5, 1, 2, 4 and 6 hours after the onset of use ice packs, also the morning after angioplasty and stenting. The patient gets out of bed 6 hours after sheath removal to help the researcher. The dressing can be done at the patient's groin. Over time, the use of ice packs, bleeding is observed in the site of sheath removal .

Category

Prevention

2

Description

In the control group, sand bags can be placed on the sheet removal site for 4 hours and the patient out of bed after 6 hours. In the control group, bleeding and hematoma measure and record during and immediately after hemostasis (before using sand bag), 0.5, 1, 2, 4 and 6 hours after the onset of use sand bag , also the morning after angioplasty and stenting. The patient gets out of bed 6 hours after sheath removal to help the researcher. The dressing can be done at the patient's groin. Over time, the use of sand bags, bleeding is observed in the site of sheath removal .

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Afshar Hospital

Full name of responsible person

Samane sadat Javadi

Street address

Afshar Hospital, Jomhori blvd,Yazd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences and Health Services

Full name of responsible person

Amir Hooshang Mehrparvar

Street address

Nursing and Midwieri school, Bu ali street, Safaee, Yazd

City

Yazd

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Sadoughi University of Medical Sciences and Health Services

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

Shahid Sadoughi University of Medical Sciences and Health Services

Full name of responsible person

Samane sadat Javadi

Position

BS in Nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

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Other areas of specialty/work

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00

Fax

Email

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