

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of using sand and ice bag on bleeding, hematoma and local pain after percutaneous coronary intervention

Protocol summary

Study aim

Determining the effect of ice bag application on hemorrhagy, hematoma and local pain in Percutaneous Coronary Intervention (PCI) patients.

Design

Clinical trials with control and intervention group, with parallel and randomized groups.

Settings and conduct

This study was conducted in the Angiography section of Imam Reza Hospital in Mashhad.

Participants/Inclusion and exclusion criteria

Age is over 18 years old, non-drug addiction according to one's own words, enough to be alert, not having vascular disease except coronary, Failure to receive the procedure, INR less than 1.8, BMI 18 and 30,

Intervention groups

In the control group (sand bag alone), the sheet arterial will be removed 4 hours after completion of the procedure and after applying the manual pressure to coagulate, the dressing is placed on the floor and patients are placed in the supine position for up to 4 hours and during this time, a sand bag with a fixed weight of 3 kg is placed on an angiographic position. After that, the sandbag is removed and the patient is trained it can rest for up to three hours without moving, then sleep to the healthy feet. In contrast, in the test group (use together of sand and ice bags), the arterial sheet will be removed 4 hours after completion of the procedure and after applying the manual pressure to coagulate, the dressing is placed on the floor And on that ice bag with a cloth (weighing less than 100 grams) then a sand bag with a weight of 3 kg is placed on it for 15 minutes after 15 minutes, the ice pack is removed slowly without removing the bag of sand from the bottom of the sand bag for 45 minutes, the sandbag is in place alone. This cycle is repeated four times (a total of 4 hours), then a sandbag is removed.

Main outcome variables

Determine the effect of ice bag on bleeding, hematoma

and local pain after PCI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180315039107N1**

Registration date: **2018-04-21, 1397/02/01**

Registration timing: **retrospective**

Last update: **2018-04-21, 1397/02/01**

Update count: **0**

Registration date

2018-04-21, 1397/02/01

Registrant information

Name

Maryam Valikhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4223 2352

Email address

valikhanim931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

2017-11-22, 1396/09/01

Actual recruitment end date

2018-02-19, 1396/11/30

Trial completion date

empty

Scientific title
The effect of using sand and ice bag on bleeding, hematoma and local pain after percutaneous coronary intervention

Public title
The effect of ice bag on the hematoma, bleeding and pain of patients pci

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Non-drug addiction according to one's own words Age over 18 years no puncture More than once to enter the catheter Enough to be alert Not having vascular disease expect coronary Failure to receive Integrilin during the procedure INR less than 1.8 BMI between 18 and 30 Not addictive to sedative medicines
Exclusion criteria:
Very old age (up to 85y)

Age
From 18 years old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 60
Actual sample size reached: 60

Randomization (investigator's opinion)
Randomized

Randomization description
Accidental numbers

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
Ethics committee of Mashhad University of Medical Sciences
Street address
Crossroad of the Doctora., mashhad city
City
Mashhad

Province
Razavi Khorasan
Postal code
91778-99191
Approval date
2017-11-22, 1396/09/01
Ethics committee reference number
IR.MUMS.REC.1396.312

Health conditions studied

1

Description of health condition studied
percutaneous coronary intervention through the femoral artery
ICD-10 code
123
ICD-10 code description
انفارکتوس میوکارد

Primary outcomes

1

Description
The amount of bleeding
Timepoint
After completed the procedure , after the removal of the sheet every half hour to three hours, then every hour to three hours and then 12 hours after the removal of the sheet.
Method of measurement
In grams: Measure the weight of bloody gauze using a digital balance and a fraction of the weight of the dry gas.In Cc: To measure the amount of area of bloody gauze with the help of a chessboard.

2

Description
Hematoma
Timepoint
After the completion of the procedure, after removal of the sheet, at 5, 6 and 12 hour after the removal of the sheet.
Method of measurement
Touching the bump caused by hematoma and estimating the hematoma area by measuring the small diameter and large diameter and inserting numbers in the formula: $1/2ab3.14$

3

Description
local pain
Timepoint
After completed the procedure , after the removal of the sheet every half hour to three hours, then every hour to three hours and then 12 hours after the removal of the sheet.
Method of measurement

Pain Numerical rating scale(PNRS)

Secondary outcomes

empty

Intervention groups

1

Description

Using a bag of ice weighing less than 100 grams plus sand bag after removing the sheet in 4 cycles per hour (15 minutes of ice and sand and 45 minutes sand bag) totaling 4 hours. Ice bag in the form of a plastic bag containing freezing materials (made by Kavian Pars Company size 10 * 20 cm)

Category

Treatment - Devices

2

Description

Control group: Use a bag of sand to weigh 3 kilograms after the removing the sheet for up to 4 hours in succession

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

(مرکز آموزشی، پژوهشی و درمانی امام رضا(ع)

Full name of responsible person

سید موسی مهدی زاده

Street address

میدان امام رضا(ع)، مرکز آموزشی، پژوهشی و درمانی امام رضا(ع)

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Email

MahdizadehM@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

دکتر محسن تفقدي

Street address

University of Mashhad- next to Hivizadeh Cinema -
Mashhad University of Medical Sciences- Deputy of
Research & Technology University

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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

Mashhad University of Medical Sciences

Proportion provided by this source

80

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

MahdizadehM@mums.ac.ir

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyyed mousa mahdizadeh

Position

Faculty of Nursing and Midwifery, Mashhad

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Maryam Valikhani

Position

دانشجوی کارشناسی ارشد پرستاری

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only the original outcome information

When the data will become available and for how long

Starting the access period from 1397

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

Analysis of delivered data is allowed

From where data/document is obtainable

Valikhanim931@mums.ac.ir Maryam Valikhani

What processes are involved for a request to access data/document

In less than one month, information is provided to the applicant by email.

Comments