

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of ice bag on vital signs and femoral region pain in patients with MI undergoing percutaneous coronary intervention

Protocol summary

Study aim

Determination of effect of ice bag on vital signs and femoral pain in patients with MI undergoing PCI

Design

This clinical trial has two groups (intervention and control,) 30 patients in each group.

Settings and conduct

This study will be done in one of Kerman University of Medical Sciences hospital (Shafa). Ice bag will be used for 20 minutes in the femoral area. Then the catheter will be removed, and the variables will be measured during and after the catheter removing.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with Myocardial infarction undergoing percutaneous ,coronary intervention, age over 18, having Iranian nationality , alert, stability of Hemodynamic situation Exclusion criteria: Using sedative and analgesic drugs, emergency status and dangerous arrhythmias, sensation to cold, having Raynaud's disease, mental and physical problems such as visual and auditory disorder, addiction to narcotic and alcohol

Intervention groups

In the intervention group, the ice bag will be used for 20 minutes in the femoral area. Then the catheter will be removed, pain and vital signs will be measured during and after the catheter removing.

Main outcome variables

-Pain - vital sign

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151107024919N7**

Registration date: **2019-06-27, 1398/04/06**

Registration timing: **retrospective**

Last update: **2019-06-27, 1398/04/06**

Update count: **0**

Registration date

2019-06-27, 1398/04/06

Registrant information

Name

Batoul Tirgari

Name of organization / entity

Kerman Medical University of Sciences

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Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of ice bag on vital signs and femoral region pain in patients with MI undergoing percutaneous coronary intervention

Public title

Application of ice bag on vital signs and reducing femoral region pain in patients with MI undergoing percutaneous coronary intervention

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
 Patients with Myocardial infarction undergoing percutaneous coronary intervention Age over 18 Having Iranian nationality Alert Stability of Hemodynamic situation

Exclusion criteria:
 Using sedative and analgesic drugs Emergency status and dangerous arrhythmias Sensation to cold Having Raynaud's disease Mental and physical problems such as visual and auditory disorder Addiction to narcotic and alcohol

Age
 From **18 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **60**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Block randomization method. Block randomization works by randomizing participants within blocks such that an equal number are assigned to each treatment. The block size is determined by the researcher and should be a multiple of the number of groups (i.e., with two treatment groups, block size of either 4, 6, or 8) The method used in this study is as follows: BABA"ABBA "AAB"BABA"BBAA" "BAAB "AAB "ABAB"BABA "AABB"BBAA"AABB "ABBA "BAAB"AABB"

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Not used

Assignment
 Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

Street address

No, 1, end of Shafa AVE., Shafa Educational Hospital

City

Kerman

Province

Kerman

Postal code

7618751151

Approval date

2018-12-10, 1397/09/19

Ethics committee reference number

IR.KMU.REC.1397.325

Health conditions studied

1

Description of health condition studied

Acute Myocardial Infarction

ICD-10 code

I21.9

ICD-10 code description

Acute myocardial infarction

Primary outcomes

1

Description

Pain

Timepoint

Before, during and after the exiting arterial catheterization

Method of measurement

Numerical Rating Scale for pain

2

Description

Vital signs

Timepoint

Before, during and after the arterial catheterization

Method of measurement

Monitor that is connected to the patient and thermometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Ice bag (in the size of 15 x 10 cm and weight 250 grams, model BEYBY BASIC model NT_304 from the company Berlyan Toba) will use for 20 minutes in the femur area

Category

Other

2

Description

Control group: They will receive routine PCI care before, during and after removing catheter that would be include: immobilization and applying sand bag of affected site.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shafa hospital

Full name of responsible person

Batool tigrari

Street address

No. 1, End of Shafa Ave., Shafa Educational hospital.

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Web page address<http://kmu.ac.ir/fa/snm>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

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Web page address<http://kmu.ac.ir/fa/vcrt>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

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**

Kerman University of Medical Sciences

Full name of responsible person

Batool tigrari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursig

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable