Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

The Effects of Topical Heat Therapy on Chest Pain due to Percutaneous Coronary Intervention

Protocol summary

Study aim

Determining the mean score of chest pain after percutaneous coronary intervention (PCI) in patients in the intervention and control group. Comparison of mean score of chest pain after PCI in patients in the intervention and control group.

Design

This is a randomized, double blind, controlled clinical trial with a parallel group in which 139 patients will be selected by purposeful sampling, and they are divided into two groups by block method. Random allocation software will be used to assign patients to intervention (A) and control (B) groups.

Settings and conduct

This study will be performed on patients admitted to coronary care unit of Farshchian hospital in Hamadan due to myocardial infarction who need percutaneous coronary intervention (PCI). After PCI, a warm bag with a temperature of 50°C is used for the intervention group (A) and similar bags with a temperature of 5.37°C for the control group (B). The amount of chest pain will be measured by a visual analogue scale. This is a double-blind study in which patients as well as the data collector are unaware of what is being done in groups A or B.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Successful angioplasty. Having normal hemodynamic conditions. Ability to speak Persian. Exclusion criteria: Wound and injury in the chest. History of mental illness. Addiction to alcohol and narcotics. History of gastrointestinal diseases. Occurrence of any severe complications (such as cardiac arrest, myocardial infarction, heart attack, and severe heart failure).

Intervention groups

In the intervention group, local heat therapy with the temperature of 50°C for 23 minutes in the left posterior chest, two times a day is used. In the control group, local heat therapy with the temperature of 37.5°C will be performed the same way.

Main outcome variables

The frequency and severity of chest pain will be measured by (VAS).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190920044823N1**
Registration date: **2019-12-05, 1398/09/14**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-05, 1398/09/14**
Update count: **0**

Registration date

2019-12-05, 1398/09/14

Registrant information

Name

Mahdi Abedini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3834 1026

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-01, 1398/09/10

Expected recruitment end date

2020-02-29, 1398/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effects of Topical Heat Therapy on Chest Pain due to Percutaneous Coronary Intervention

Public title
Effect of Heat Therapy on Chest Pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Successful angioplasty Having normal hemodynamic conditions Ability to speak Persian

Exclusion criteria:
Wound and injury in the chest History of mental illness Addiction to alcohol and narcotics History of gastrointestinal diseases Occurrence of any severe complications (such as cardiac arrest, myocardial infarction, heart attack, and severe heart failure)

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **138**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be selected according to inclusion and exclusion criteria and will be randomly divided into intervention and control groups. Random allocation software will be used to assign patients to intervention (A) and control (B) groups. According to the sequence of allocation schedules, letter A or B, concealed in sequentially numbered, sealed, opaque envelopes, and kept by researcher assistance who is responsible for sampling and has no any role in collecting information.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding in the control group is done using similar pads that have a temperature of 37.5 degrees. The outcome assessor will be unaware of which patients are in the intervention or control group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Arak University of Medical Sciences

Street address
Vice-Chancellor for Research, Arak University of Medical Sciences, Basij Square, Sardasht, Arak

City
Arak

Province
Markazi

Postal code
3819693345

Approval date
2019-07-28, 1398/05/06

Ethics committee reference number
IR.ARAKMU.REC.1398.118

Health conditions studied

1

Description of health condition studied
Unstable angina

ICD-10 code
I20

ICD-10 code description
Angina pectoris

2

Description of health condition studied
Acute myocardial infarction

ICD-10 code
I21

ICD-10 code description
ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description
Chest pain score

Timepoint
Every 6 hours in a day will be assessed chest pain.

Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Mortality.

Timepoint

Six month after the start of the study.

Method of measurement

Number of deaths using checklists.

2

Description

Recurrent angioplasty.

Timepoint

Six month after the start of the study.

Method of measurement

Number of new angioplasty cases using checklists.

Intervention groups

1

Description

Intervention group:Topical heat therapy on posterior chest, is performed using a warm pad that has a temperature of 50 degrees celsius. The heat pad is made of hydrophilic silicon with dimensions of 25 x 30 cm which is covered with tarpaulin. This pad is warmed by a special device called Heater Hot pack.

Category

Treatment - Other

2

Description

Control group: Patients in the control group will receive the same pad (that has a temperature of 37.5 degrees Celsius) in the same way.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Hospital

Full name of responsible person

Mahdi Abedini

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Shah Hosseini Street

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6517839131

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Mahdi Abedini

Position

Master,s student critical care nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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Bachelor
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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
Not applicable
Title and more details about the data/document
Demographic characteristics and chest pain score
When the data will become available and for how long
Start the access period 6 months after the publication of the results.
To whom data/document is available
All individuals can access the information.
Under which criteria data/document could be used
Nothing.
From where data/document is obtainable
Korosh Rezaei; k.rezaei@arakmu.ac.ir; Arak University of Medical Sciences; 00989183677622.
What processes are involved for a request to access data/document
Two weeks after the applicant's request.
Comments