

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of Local heat therapy on Comfort And Physiological parameters in the Patients with Acute Coronary Syndrome

Protocol summary

Study aim

The aim of this study was to evaluate the effect of topical therapy on comfort and physiological parameters in patients with acute coronary syndrome.

Design

This study is a control clinical trial. Eighty patients admit to the cardiac coronary care unit who are qualify for study are randomly divide into intervention and control groups.

Settings and conduct

Numerous studies have been conducted on the efficacy of heat therapy on the comfort and physiological Indexes of patients with acute coronary syndrome who reported different results. In this study, 80 patients hospitalized in cardiac care units of hospitals affiliated to Arak University of Medical Sciences were randomly divided into control and intervention groups. To evaluate comfort and physiological parameters in the intervention group, local heat treatment will be performed at 50 ° C and in the control group will be performed local heat treatment at 37 ° C. The participant and the data collector are kept blind about which participant is in which group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. The presence of a definitive diagnosis by a specialist physician of acute coronary syndrome 2. No musculoskeletal or thoracic or gastrointestinal diseases at the time of the disease. 3. Absence of swelling, scars, scratches and redness in the chest area 4. BMI between 18/5 and 25 Exclusion criteria: 1. Hypotension 2.Cardiac arrhythmia 3. Decrease of oxygen saturation of arterial blood

Intervention groups

In the experimental group, topical heat treatment with a temperature of 50 ° C will be performed in the posterior part of the chest. In the placebo group patients will receive topical heat therapy in the posterior part of the chest at 37 ° C.

Main outcome variables

Comfort; physiological parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180519039711N5**

Registration date: **2020-03-04, 1398/12/14**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-04, 1398/12/14**

Update count: **0**

Registration date

2020-03-04, 1398/12/14

Registrant information

Name

Mohamad Golitaleb

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3506

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m.golitaleb@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-09, 1398/10/19

Expected recruitment end date

2020-07-09, 1399/04/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Local heat therapy on Comfort And Physiological parameters in the Patients with Acute Coronary Syndrome

Public title

The effect of Local heat therapy on Comfort And Physiological parameters

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The presence of a definitive diagnosis by a specialist physician of acute coronary syndrome No musculoskeletal or thoracic or gastrointestinal diseases at the time of the disease. Absence of swelling, scars, scratches and redness in the chest area BMI between 18/5 and 25

Exclusion criteria:

Hypotension Cardiac arrhythmia Decrease of oxygen saturation of arterial blood

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting qualified samples, informed consent form is obtained. Eighty patients will be randomly assigned to either the intervention or control groups, initially 8 blocks of 10 different T and C letters (which represent the intervention and control groups). Belong to the control group). These blocks were then randomly selected to obtain an 80-fold combination of blocks, respectively. The resulting combination of letters is placed individually in 80 closed envelopes, with each patient opening one envelope in order to determine which group the patient falls into.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will be unaware of the type of intervention. Also, the nurse will not be informed about the type of intervention. Therefore, the study will be double blind.

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

Education and Research Deputy of Arak University of Medical Sciences, Basij Square, Arak, Iran

City

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Markazi

Postal code

7558538149

Approval date

2019-11-23, 1398/09/02

Ethics committee reference number

IR.ARAKMU.REC.1398.235

Health conditions studied**1****Description of health condition studied**

acute coronary syndrome

ICD-10 code

120-125

ICD-10 code description

Ischaemic heart diseases

2**Description of health condition studied**

acute coronary syndrome

ICD-10 code

121

ICD-10 code description

Acute myocardial infarction-Subsequent myocardial infarction

Primary outcomes**1****Description**

comfort

Timepoint

Before and after intervention

Method of measurement

Kulkaba general comfort questionnaire

Secondary outcomes**1****Description**

heart beat

Timepoint

Before and after intervention

Method of measurement

Cardiac monitoring

2

Description

Systolic blood pressure

Timepoint

Before and after intervention

Method of measurement

Cardiac monitoring

3

Description

Diastolic blood pressure

Timepoint

Before and after intervention

Method of measurement

Cardiac monitoring

4

Description

Arterial Oxygen Saturation Percentage

Timepoint

Before and after intervention

Method of measurement

Pulse Oximeter

Intervention groups

1

Description

Intervention group: In the experimental group, topical heat treatment with a temperature of 50 ° C will be performed in the posterior part of the chest. The hot pack is placed in the 4 to 11 chest area and the patient is placed in the supine position on the hot pack. The duration of the heat treatment is 23 minutes. Heat treatment is performed every 12 hours for 2 days.

Category

Other

2

Description

Control group: In the placebo group patients will receive topical heat therapy in the posterior part of the chest at 37 ° C. The hot pack is placed in the 4 to 11 chest area and the patient is placed in the supine position on the hot pack. The duration of the course is 23 minutes. Heat treatment is performed every 12 hours for 2 days.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Kabir Hospital

Full name of responsible person

Mohamad Golitaleb

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2

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
Mahtab Farahani

Position
Nursing Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Shared data including demographic and disease information, type and method of intervention, information about sleep quality of participants before and after intervention.

When the data will become available and for how long

Start the access period 6 months after the results are published.

To whom data/document is available

Researchers and people working in nursing education as well as nursing clinical staff.

Under which criteria data/document could be used

The data can be used for education, research and clinical nursing. The applicant must be in the nursing field The data applicant only uses data for teaching, research and clinical nursing.

From where data/document is obtainable

Mohamad golitaleb, Department of critical care nursing, school of nursing, Arak university of medical sciences E mail: Mohamadgolitaleb@gmail.com
Tel: +989379366279

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

After ensuring that the data applicant is in the nursing field, we will be immediately responded to the request form by email.

Comments