

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effect of local coldness, heat and intermittent cold heat application on chest pain severity during respiratory exercise after open heart surgery in patients with coronary artery disorders

Protocol summary

Summary

Objective: comparing the effect of local coldness, heat and intermittent cold heat application on chest pain severity during respiratory exercise in patients after open heart surgery. Study design: randomized clinical trial. Inclusion criteria: Patients after open heart surgery; communication ability Exclusion criteria: Patients undergoing mechanical ventilator; sensitivity to local coldness or heat; occurring crisis condition; alteration in patient status Sample size: 80 patients. Blinding: not blinded Centers: single Study phase: 2 Intervention: Local coldness, heat and intermittent coldness-heat application. Intervention time: 10 minutes. Method: for performing the study, the research samples placed randomized to one of following group. The randomization is performed according to randomized block design. The first group: application of local coldness. The second group: application of local heat. The third group: intermittent cold - heat application. The fourth group: routine care. The chest pain severity was measured before intervention and each 5 minutes during respiratory exercises, immediately after intervention or routine care (after 10 minutes of respiratory exercises), and 5 minutes after intervention or routine care. In intermittent cold heat application, at first 5 minutes' coldness and then 5 minutes' heat will apply.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201609245134N10**

Registration date: **2016-10-26, 1395/08/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-26, 1395/08/05

Registrant information

Name

Ali Fakhr-Movahedi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research and technology, Semnan University of medical sciences

Expected recruitment start date

2016-10-06, 1395/07/15

Expected recruitment end date

2017-04-04, 1396/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of local coldness, heat and intermittent cold heat application on chest pain severity during respiratory exercise after open heart surgery in patients with coronary artery disorders

Public title

Effect of local coldness and heat on chest pain severity after open heart surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Patients after open heart surgery; communication ability Exclusion criteria: Patients undergoing mechanical ventilator; sensitivity to local coldness or heat; occurring crisis condition; alteration in patient status

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

For performing the study, the research samples placed randomized in study groups. The randomization is performed according to randomized block design.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan university of medical sciences

Street address

Basij Blvd; The central headquarters of the mobilization of the Boulevard, Semnan University of medical sciences, Vice President for research and technology

City

Semnan

Postal code

Approval date

2016-09-13, 1395/06/23

Ethics committee reference number

IR.SEMUMS.REC.1395.96

Health conditions studied

1

Description of health condition studied

Chest pain on breathing

ICD-10 code

R07.1

ICD-10 code description

Painful respiration

Primary outcomes

1

Description

Chest pain severity during respiratory exercises

Timepoint

before intervention and each 5 minutes during respiratory exercises, immediately after intervention or routine care (after 10 minutes of respiratory exercises), and 5 minutes after intervention or routine care

Method of measurement

Visual analog scale of pain

Secondary outcomes

empty

Intervention groups

1

Description

The first group: application of local coldness

Category

Other

2

Description

The second group: application of local heat

Category

Other

3

Description

The third group: intermittent cold - heat application

Category

Other

4

Description

The fourth group: routine care

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar hospital

Full name of responsible person

Dr. Abolfazle Abdollahpour

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Golestan town, Amin Blvd., Kosar Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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University of medical sciences

Full name of responsible person

Dr. Ali Rashidy-pour

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technology, Basij Blvd

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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

Vice Chancellor for research and technology, Seman
University of medical sciences

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

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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