Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of cold therapy on pain, ventilation, oxygenation and hemodynamic parameters in patients undergoing coronary artery bypass graft surgery

Protocol summary

Summary

Pain with Deep Breathing & Cough (DB & C) post cardiac surgery remains an issue for nurses. This pain prevents patients from performing these activities which in turn places them at risk for pulmonary complications. Incisional pain can be managed with both pharmacologic & non pharmacologic therapies. However, pharmacologic therapies can have systemic side effects. Cold pack application is a low cost, low risk & accessible non pharmacologic pain management strategy. This research was conducted to determine the effect of cold therapy on pain, ventilation, oxygenation and hemodynamic parameters in patients undergoing coronary artery bypass graft surgery. In this research 25 patients in a randomized crossover trial were assigned to either begin the DB & C sessions with or without cold pack. Participants then alternated with respect to the cold pack. Pain scores & other variables after DB & C (two stages in any method) were compared with & without cold pack. Cold pack was applied over the chest dressing for 20 minutes before second stage of DB & C in cold pack method. Exclusion criteria: allergic or sensitive to cold, cognitive impairments, having chest tube at time of data collection, develop sever postopration complication and receiving pain medications.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201038600N1**
Registration date: **2012-02-14, 1390/11/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-02-14, 1390/11/25

Registrant information

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Name of organization / entity
Shiraz university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellery of research, Shiraz University of Medical Sciences

Expected recruitment start date

2011-08-16, 1390/05/25

Expected recruitment end date

2011-09-21, 1390/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of cold therapy on pain, ventilation, oxygenation and hemodynamic parameters in patients undergoing coronary artery bypass graft surgery

Public title

Effect of cold bag on pain relief

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients undergoing CABG by sternotomy. Exclusion criteria: Allergic or sensitivity to cold, cognitive impairments, having chest tube at the

time of data collection, developing severe post-op complication and receiving pain medications

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **25**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee, Shiraz University of Medical Sciences

Street address
Shiraz University of Medical Sciences, Zand blvd

City
Shiraz

Postal code
71435-1987

Approval date
2011-08-15, 1390/05/24

Ethics committee reference number
CT-90-5645

Health conditions studied

1

Description of health condition studied
coronary artery bypass graft

ICD-10 code
151.6

ICD-10 code description
atherosclerotic cardiovascular disease

Primary outcomes

1

Description
pain

Timepoint
2 stages with two hour interval between them in any method

Method of measurement
numerical rating scale

2

Description
sistolic and diastolic blood pressure

Timepoint
2 stages with two hour interval between them in any method

Method of measurement
analogue manometer

3

Description
pulse

Timepoint
2 stages with two hour interval between them in any method

Method of measurement
By touching and counting pulse

4

Description
Maximum inspiratory volume

Timepoint
2 stages with two hour interval between them in any method

Method of measurement
incentive spirometry

5

Description
arterial o2 suturation

Timepoint
2 stages with two hour interval between them in any method

Method of measurement
pulse oximetry

6

Description
respiratory rate

Timepoint
2 stages with two hour interval between them in any method

Method of measurement
By counting

Secondary outcomes

empty

Intervention groups

1

Description
Control group (without cold pack method): Not using cold pack (no intervention) before the first and second stages.
Category
N/A

2

Description
Intervention group (with ice bag method): Not using cold pack (no intervention) before the first stage and Using cold pack on sternotomy dressing for 20 minutes before the second stage.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi hospital
Full name of responsible person
Dr Mohamad Ghazinour
Street address
Namazi Hospital, Zand blvd, Namazi Square
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2

Recruitment center
Name of recruitment center
Faghihi Hospital
Full name of responsible person
Dr Mohamad Ghazinour
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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Street address
Shiraz University of Medical Science, Zand blvd
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Shiraz
Grant name
Grant code / Reference number
CT-90-5645
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
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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