

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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

Name

Akbar Raeisi Estabragh

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

I51.6

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

systolic 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 saturation

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

City

Shiraz

2

Recruitment center

Name of recruitment center

Faghihi Hospital

Full name of responsible person

Dr Mohamad Ghazinour

Street address

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City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Gholamrza Hatam

Street address

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City

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

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Fahimeh Soltani Shirazi

Position

MSc. of nursing, lecturer

Other areas of specialty/work

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Full name of responsible person

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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