

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Effect of Applying Cooling Gel Pad Compared with not using it on reducing the pain of sternal incision associated with deep breathing and coughing in cardiac surgery patient

Protocol summary

Summary

This study is a randomized Crossover trial which was performed to assess the impact of Applying Cooling Gel Pad on the pain of sternal incision associated with deep breathing and coughing in cardiac surgery patient. For this purpose, 50 eligible (more than 21 years age, patients scheduled to undergo Coronary artery bypass graft surgery and oriented) and consenting patients were recruited and randomly allocated to intervention and control group on post-surgical first day. All Patients performed four episodes of deep breathing and coughing (two with the cooling gel pack and two without cooling gel pack), every two hours. In the intervention group intensity and quality of pain, Saturation percentage Oxygen arterial blood, blood pressure and heart rate were measured before and after intervention and in the control group above measurements have done before and after deep breathing and coughing. The level of anxiety in both group were measured and compared. At the end of the fourth session, all patients were asked to describe their sensations with the cooling gel pack and their preferences for the gel pack application prior to deep breathing and coughing.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207249422N2**
Registration date: **2012-08-19, 1391/05/29**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-19, 1391/05/29

Registrant information

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Aram Feizi

Name of organization / entity

Urmia University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Urmia University of Medical Sciences

Expected recruitment start date

2012-06-22, 1391/04/02

Expected recruitment end date

2012-07-23, 1391/05/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Applying Cooling Gel Pad Compared with not using it on reducing the pain of sternal incision associated with deep breathing and coughing in cardiac surgery patient

Public title

Effect of Applying Cooling Gel Pad on the pain of sternal incision associated with deep breathing and coughing.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: more than 21 years age; able to speak and understand Persian; The minimum literacy of Reading and writing; Willing to give written informed consent; male or female patients scheduled to undergo Coronary artery bypass graft surgery with or without a valve replacement using a median sternotomy. Exclusion criteria: Mechanically ventilated patients; diseases that affect pain measurement (Delirium; Dementia or Major depression; Severe visual, hearing and verbal impairment; diabetic patient) contradictions to cryotherapy use such as (Reynaud's disease; cryoglobulinemia; sickle cell anemia; cold allergic conditions and in areas with impaired sensation); bilateral mammary harvest; postoperative complications such as (infection; bleeding; uncontrolled Atrial fibrillation or wound dehiscence).

Age

From **21 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

not used

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Urmia University of Medical Sciences

Street address

Urmia University of Medical Sciences, Resalat
Boulevard

City

Urmia

Postal code

Approval date

2012-07-18, 1391/04/28

Ethics committee reference number

6/91/4/22626پ

Health conditions studied

1

Description of health condition studied

Coronary artery disease

ICD-10 code

I20-I25

ICD-10 code description

Chronic ischaemic heart disease, unspecified

Primary outcomes

1

Description

Intensity of pain

Timepoint

Immediately before the application of cooling gel pack and after termination of DB & C sessions in intervention group and Immediately before and after DB & C sessions in control group.

Method of measurement

numeric rating scale (NRS)

Secondary outcomes

1

Description

Anxiety

Timepoint

At the beginning application of cooling gel pack and before deep breathing and coughing.

Method of measurement

State -Trait Anxiety Inventory

2

Description

Quality of pain

Timepoint

Immediately before the application of cooling gel pack and after termination of DB & C sessions in intervention group and Immediately before and after DB & C sessions in control group

Method of measurement

Modified short form MacGill pain Questionnaire

3

Description

blood pressure and heart rate

Timepoint

Immediately before the application of cooling gel pack and after termination of DB & C sessions in intervention group and Immediately before and after DB & C sessions in control group.

Method of measurement

Cardiac monitoring machine

4

Description

Spo2

Timepoint

Immediately before the application of cooling gel pack and after termination of DB & C sessions in intervention group and Immediately before and after DB & C sessions in control group.

Method of measurement

Pulse Oxy-meter

Intervention groups

1

Description

Intervention group: application of cooling gel pack before deep breathing and coughing sessions.

Category

Other

2

Description

Control group: deep breathing and coughing sessions without application of cooling gel pack

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyyed-o-alshohada Hospital

Full name of responsible person

Dr. Shahyad Salehi Ardebili

Street address

Seyyed-o-alshohada Hospital, 17 Shahrivar Street, Urmia

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urmia University of Medical Sciences

Full name of responsible person

Dr. Morteza Motazaker

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Grant name

ردیف پژوهشی معاونت تحقیقات و فن آوری

Grant code / Reference number

1052

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Urmia 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