

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of the effect cold therapy and relaxation on pain severity due to chest tube removal after coronary artery bypass graft

Protocol summary

Summary

Background: the removal of chest tube has been described as one of the worst experiences for patients after CABG. As yet there is no standard protocol for chest tube removal pain, so This study compared the effects of cold therapy and relaxation on pain of chest tube removal after coronary artery bypass graft surgery was planned. Methods: this project is a clinical trial in which 80 patients were randomly divided into two groups(intervention and control). In the control group tubes, without any intervention removed with an interval of 1 hour. In the intervention group with random assignment for tubes, Cold therapy was performed initially using and its tube was removed, and 1 hour later the other tube was removed with relaxation. For cold therapy, cold pack gel was applied and until the skin temperature reaches 13 ° C, around the tubes remain and for relaxation, the slow, deep breathing exercises for 5 minutes before chest tube removal was performed. Pain intensity with VAS was measured at three points before, immediately and 15 minutes after chest tube removal by the research assistance who was unaware of what was used for each tube. Instruments include: Cold Gel Pack 10 × 8 cm wide manufactured Baspargostar Javidan Tehran , non-contact infrared thermometer manufactured Unity Hong Kong Visual Analogue Scale (VAS) to measure pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013042813156N1**

Registration date: **2013-05-19, 1392/02/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-05-19, 1392/02/29

Registrant information

Name

Mohammad Ali Heydari Gorji

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mazandaran University of Medical Sciences

Expected recruitment start date

2013-03-10, 1391/12/20

Expected recruitment end date

2013-04-19, 1392/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect cold therapy and relaxation on pain severity due to chest tube removal after coronary artery bypass graft

Public title

Comparison of the effect cold therapy and relaxation on pain relief

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: consent to participate in the study; age greater than or equal to 18 years; orientation to time; place and person; the ability to perceive visual pain scale; the first experience of CABG surgery and having a chest tube; BMI less than 30 kg/m², have two chest tubes for at least 24 hours (one mediastinal and one left pleural). Exclusion criteria: lack of consent for continued research; cold urticaria; received mechanical ventilation support; severe visual and hearing impairments so that enable to communicate with researcher and determine the pain intensity on VAS; get analgesics less than 4 hours prior to the procedure; addiction to drugs and alcohol.

Age

From **38 years** old to **77 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Vice chancellor for research, Moalem street, Moalem square. , Sari, mazandaran, Iran.

City

sari

Postal code

4816715793

Approval date

2013-03-06, 1391/12/16

Ethics committee reference number

91-288

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

R52, R52.0

ICD-10 code description

Pain, not elsewhere classified, Acute Pain

Primary outcomes

1

Description

Pain intensity

Timepoint

Before chest tube removal, immediately after chest tube removal, 15 minute after chest tube removal

Method of measurement

Visual Analogue Scale(VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Patients in the intervention group was randomly allocated to one of two modes "left pleural cold therapy - mediastinal Relaxation" code (1) and "left pleural relaxation - mediastinal cold therapy" code (2). For cold therapy, cold pack gel was applied and until the skin temperature reaches 13 ° C, around the tubes remain and for relaxation, the slow, deep breathing exercises for 5 minutes before chest tube removal was performed. Cold therapy was performed initially using and its tube was removed, and 1 hour later the other tube was removed with relaxation.

Category

Treatment - Other

2

Description

In the control group tubes, without any intervention removed with an interval of 1 hour.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh zahra hospital

Full name of responsible person

Mohammad Ali Heydari Gorji

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Mazandaran University of Medical Science

Full name of responsible person

Dr. Ahmahali Enayati

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Mazandaran University of Medical Sciences, Vice chancellor for research, Moalem street, Moalem square. , Sari, mazandaran, Iran.

City

Sari

Grant name

در حال بررسی

Grant code / Reference number

در حال بررسی

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

Yes

Title of funding source

Vice chancellor for research of Mazandaran University of Medical Science

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

Mazandaran University of Medical Sciences

Full name of responsible person

Mohammad Ali Heydari Gorji

Position

PHD/ faculty member

Other areas of specialty/work

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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