Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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
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Grant name
درحال 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

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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