

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of ice bag on pain associated with chest tube removal after cardiac surgery.

Protocol summary

Summary

The aim of this study is to investigate the effect of Ice application on intensity and quality of pain during Chest tube removal (CTR). Design of this study is single-blinded randomized crossover. The subjects act as their own controls. Pain intensity in three stages and pain quality in two stages by helping the researcher will be measured. Sample is 51 patients who are undergoing cardiac surgery in Mashhad University Hospital. Verbal and written informed consent is obtained from each of the patients for the present study. Patient have two chest tubes (pericardial and thoracic tube) that distance between them is more than 8-10 cm, patient able to verbally report their pain and understand visual analog scale. The patients were excluded that don't desire to participate in the study or had received narcotics 2 hours ago. Patients randomly assigned to three groups, Group 1: Ice and placebo bags application group; Group 2: Ice bag application and without application; Group 3: placebo application and without application. Ice bags (zero to -5 - 0° C) and placebo (18 - 22° C) is designed by the researcher. Ice and placebo bags will apply to the area surrounding the chest tubes for 20minutes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105146484N1**
Registration date: **2011-06-07, 1390/03/17**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-06-07, 1390/03/17

Registrant information

Name

Fatemeh Gandomkar

Name of organization / entity

Mashhad University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences Vice chancellor for research

Expected recruitment start date

2011-01-20, 1389/10/30

Expected recruitment end date

2011-06-20, 1390/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of ice bag on pain associated with chest tube removal after cardiac surgery.

Public title

The effect of ice on reduce of pain

Purpose

Supportive

Inclusion/Exclusion criteria

Eligible participants include adult patients who had cardiothoracic surgery; Could speak Persian and able to verbally report their pain; Have two chest tube (pericardial and thoracic tube); Orient to place, person and time; Don't have co morbidity to effect pain such as,

delirium, severe depression, severe visual defect; Had chest tube at least 24 hours; Don't connect to ventilator and are Iranian and Muslim; Patient had pericardial and pleural chest tube that distance between them is more than 8-10 cm. Exclusion criteria include patient refusal; Sedative drugs infusion; Chest tubes were removed more than three minutes of discontinuation of the intervention; Time between remove two chest tube is less than 30 minutes; Take opioid drugs 2 hours ago chest tube removal.

Age

To 80 years old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 51

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

1

Registry name

no

Secondary trial Id

no

Registration date

empty

2

Registry name

no

Secondary trial Id

no

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Mashhad University of Medical Science

Street address

Ghoraishy Building, University St, Mashhad

City

Mashhad

Postal code

Approval date

2011-01-03, 1389/10/13

Ethics committee reference number

89359

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 and 15 minutes after chest tube removal

Method of measurement

Visual Analog Scale

2

Description

Pain Quality

Timepoint

Before chest tube removal, Immediately after chest tube removal

Method of measurement

Modify Short Form McGill Pain Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

This clinical trial consists of three groups. The patients are divided to three groups randomly assigned; Group 1: tubes (pericardial and thoracic tube) randomly assigned for Ice bag (zero to 5 ° C) and placebo bag (22-18 ° C) application. Ice and placebo bags designed by the researcher. Ice and placebo bags apply to the area surrounding the chest tubes for 20minutes. Time between two chest tubes removal is 30 minutes.

Category

Other

2

Description

Group 2: Tubes (pericardial and thoracic tube) randomly assigned for Ice bag (zero to 5 ° C) and control (without anything application). Ice bag applies to the area surrounding the chest tube for 20minutes. Time between two chest tubes removal is 30 minutes.

Category

Other

3

Description

Group 3: Tubes (pericardial and thoracic tube) randomly assigned for placebo bag (zero to 5 ° C) and control (without anything application) placebo bag (22-18 ° C) applies to the area surrounding the chest tube for 20minutes. Time between two chest tubes removal is 30 minutes.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Seyed Reza Mazloun

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences Vice chancellor for research

Full name of responsible person

Dr. Jalil Tavakol Afshari

Street address

Ghoraishy Building, University St, Mashhad.

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences Vice chancellor for research

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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Full name of responsible person

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Position

PhD of Nursing

Other areas of specialty/work

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Web page address**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