

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

The Effect of Cold Application and Inhalation of Lavender Essential Oil on Pain and Anxiety during Chest Tube Removal in Cardiac Surgery Patients

Protocol summary

Summary

The aim of this study is to investigate the effect of cold application and Inhalation of Lavender Essential Oil on pain and anxiety during Chest tube removal (CTR). Design of this study is randomized, clinical trial with a factorial design. Pain intensity in five stages (before, immediately, 5, 10 and 15 minutes after CTR), pain quality and anxiety in two stages (before and immediately after CTR) were measured. Sample 80 patients who are undergoing cardiac surgery in cardiac surgery intensive care unit of Imam Reza hospital at Mashhad. Verbal and written informed consent is obtained from each of the patients for the present study. The patients were assigned to four randomized groups that included cold application, aromatherapy with inhalation of lavender essential oil, cold application in combination of inhalation of lavender essential oil and control groups. For cold was used from cold gel packs manufacturing Dispotch Italy company and for aromatherapy was used from essential oils made in GIAH essence pharmaceutical company (Gorgan - Iran) after analyzed by gas chromatography.

General information

Acronym

cardiac chest tube removal or CRT

IRCT registration information

IRCT registration number: **IRCT2015080523515N1**

Registration date: **2015-09-05, 1394/06/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-09-05, 1394/06/14

Registrant information

Name

Narges Mohammadi

Name of organization / entity

Mashhad Univesity of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences Vice chancellor for research

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Cold Application and Inhalation of Lavender Essential Oil on Pain and Anxiety during Chest Tube Removal in Cardiac Surgery Patients

Public title

The effect of cold and aromatherapy on reduce of pain and anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion: Subjects were of Iranian nationality.Willingness to participate.Upper 18 years old. Oriented to person, place and time.First time experience with cardiac surgery

and chest tube removal. Lack of allergy to cold, plants and essential oils. Having chest tubes for 24 hours at least. Exclusion: Received mechanical ventilation support. Received Continuous infusion of sedatives and analgesics. Any difficulty breathing, nausea, vomiting, oversensitivity and dissatisfaction during aromatherapy or cold application.

Age

From **18 years** old to **80 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)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Science

Street address

Ghoraishy Building, University St

City

mashhad

Postal code

Approval date

2014-10-25, 1393/08/03

Ethics committee reference number

930222

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

2

Description of health condition studied

pain

ICD-10 code

R52

ICD-10 code description

Pain, not elsewhere classified

Primary outcomes

1

Description

Pain Intensity

Timepoint

Before intervention, Immediately, 5 minutes, 10 minutes 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

3

Description

Anxiety

Timepoint

Before chest tube removal, Immediately after chest tube removal

Method of measurement

Spielberger Situational Anxiety Questionnaire

Secondary outcomes

1

Description

Vital Sign

Timepoint

Before Intervention, immediately after chest tube removal

Method of measurement

Monitoring

Intervention groups

1

Description

On the first postoperative morning, patients' readiness for CTR was determined by a physician according to standard criteria. In cold therapy group, cooling gel packs were used to reduce the body temperature around the

chest tube during undressing when the skin temperature reached 13 °C, pack was removed and the nurse removed pericardial tube within 1-2 minutes.

Category

Other

2

Description

In Aromatherapy group, 1-2 drops of Lavender essence were poured on cotton was fixed at a 10 cm distance from the patients' nose to Collar dress patient and the patient was asked to breathe slowly for 20 minutes and then pericardial tube removed within 1-2 minutes.

Category

Other

3

Description

In Cold & Aromatherapy group both intervention (cold gel packs application and inhalation of lavender essential oils for 20 minutes) was conducted.

Category

Other

4

Description

In control group, chest tube was removed as ward routine.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Narges Mohammadi

Street address

Falahi 38/18- Ghasem Abad- Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Farzaneh Hasanzadeh

Street address

Nursing & Midwifery Faculty Mashhad

City

Mashhad

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

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

Mashhad University of Medical Sciences

Full name of responsible person

Narges Mohammadi

Position

Msc- critical care nursing student

Other areas of specialty/work

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Person responsible for scientific 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