Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

Country

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,Iimmediately 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 Univesity 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 Univesity 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 Medicsl Sciences

Full name of responsible person
Narges Mohammadi

Position
Msc- critical care nursing student

Other areas of specialty/work

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Position
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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