

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Investigating the combined effect of reflex massage and respiratory relaxation on pain following chest tube removal in heart surgery patients

Protocol summary

Study aim

Determining the combined effect of reflex massage and respiratory relaxation on pain following chest tube removal in heart surgery patients

Design

A clinical trial with a control group and parallel groups, double-blind, randomized, on 140 patients, in an accessible method based on the goal and as a block randomization.

Settings and conduct

Determination of groups, invitation to participate in the study, an explanatory meeting for each person, obtaining informed consent, statistical population: all heart surgery patients with pleural chest tube. Research environment: special care department of Shahid Beheshti Hospital, Shiraz.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Consent to participate in the study, age 18 or older, having a pleural chest tube, awareness of time, place and person, ability to understand the visual scale of pain, no severe vision and hearing impairment, no neuropathy and sensory disorders caused by diabetes. Not addicted to drugs and alcohol. Exclusion criteria: unwillingness to continue participating in the study, being connected to a ventilator, receiving narcotic pain medication for less than 4 hours

Intervention groups

1- Control group: removal of the chest tube by routine method 2- Respiratory relaxation group: removal of the chest tube using respiratory relaxation methods 3- Foot reflex massage group: to reduce pain from massage according to the standard 4- Combination group of respiratory relaxation and massage Reflexive: pain control by combining respiratory relaxation + reflex foot massager together

Main outcome variables

intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131228015965N22**

Registration date: **2023-11-28, 1402/09/07**

Registration timing: **retrospective**

Last update: **2023-11-28, 1402/09/07**

Update count: **0**

Registration date

2023-11-28, 1402/09/07

Registrant information

Name

Majid Kazemi

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

dr.kazemi.n@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-15, 1402/01/26

Expected recruitment end date

2023-10-18, 1402/07/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the combined effect of reflex massage and respiratory relaxation on pain following chest tube removal in heart surgery patients

Public title

Evaluation of the combined effects of two methods of reflexology massage and respiratory relaxation on pain following chest tube removal in heart surgery patients

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Consent to participate in the study Age 18 or older Patients who only have a pleural chest tube Awareness of time, place and person The ability to understand the visual scale of pain Absence of severe vision and hearing impairment Not having neuropathy and sensory disorders caused by diabetes Not addicted to drugs and alcohol

Exclusion criteria:

Unwillingness to continue participating in the study Being connected to a ventilator Receive narcotic pain medication less than 4 hours

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

This study was a randomized clinical trial with the participation of 140 patients undergoing open heart surgery, using the block randomization method (blocks of four), who were assigned to four intervention and control groups of 35 patients by the software.

Blinding (investigator's opinion)

Double blinded

Blinding description

This research is This research is a randomized clinical trial with a control group and a blind side; in which the evaluator of pain intensity will be unaware of the type of intervention.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Rafsanjan University of Medical Sciences

Street address

Imam Ali Boulevard, Central Organization

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2023-03-06, 1401/12/15

Ethics committee reference number

IR.RUMS.REC.1401.236

Health conditions studied

1

Description of health condition studied

Coronary Artery Disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

intensity of pain

Timepoint

Before, immediately, 15 minutes after the intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Control group: In this group, chest tube removal will be done in a routine way.

Category

Other

2

Description

Intervention group 1: Respiratory relaxation group, in which 5 minutes before the removal of the chest tube,

slow and deep breathing exercises will be performed, in such a way that the patient closes his eyes, slow and deep breath through the nose and slow exhalation. will do with bud lips.

Category

Other

3**Description**

Intervention group 2: Foot reflex massage group, in which the center of the anterior third of the patient's left foot between the arch of the foot and the toes, a knuckle under the second toe and the thumb moments before the chest tube exits for ten minutes in a circular manner (like crushing a sugar cube with your thumb) will be massaged with gentle pressure.

Category

Other

4**Description**

Intervention group 3: The combination group of respiratory relaxation and reflex massage, which in this group will be performed together to control pain during chest tube removal before performing the procedure of respiratory relaxation + foot reflex massage.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Beheshti Hospital, Shiraz

Full name of responsible person

Majid Kazemi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Rafsanjan University of Medical Sciences

Full name of responsible person

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http://rums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Rafsanjan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Rafsanjan University of Medical Sciences

Full name of responsible person

Majid Kazemi

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Position

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available