

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The effect of foot reflexology massage on pain, anxiety and physiological parameters during chest tube removal after open heart surgery

Protocol summary

Study aim

Determination the effect of foot reflexology on pain, anxiety and vital signs of patients during chest tube removal in the intensive care unit of heart surgery

Design

Semi-experimental clinical trial, with a sample size of 90 people, with control, test and placebo groups, parallel groups, without blindness and randomized by lottery method

Settings and conduct

The study in the intensive care units of the heart surgery of Jamaran and the Baqiatallah. In all three groups vital signs, pain , and trait and state anxiety score were measured before intervention . in the test group, anterior 1/3 and in the placebo group, posterior 1/3 of the left foot were massage for 10 minutes, and in the control group any intervention was done, few moments before the chest tube removal. After the chest tube removal , pain, state anxiety scores Immediately and vital signs were measured immediately, 5 minutes, 10 minutes and 15 minutes after the chest tube removal.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients admitted to the intensive care unit of cardiac surgery, underwent coronary artery bypass graft and cardiac valve surgeries, have at least one chest tube, candidate for chest tube removal, range of age between 40 to 80 years, male gender, Pain scores over 4, trait anxiety score over 33, consciousness, Reading and writing literacy exclusion criteria: History of chronic pain, taking pain relief medication, sensory-motor disorders, opium addiction, feet-related problems, taking opioid medications until 4 hours ago, psychiatric disorders, psychological disorders

Intervention groups

Intervention group 1: massage on 1/3 anterior of foot,
Intervention group 2: massage on 1/3 posterior of foot,
Control group: Routine procedure

Main outcome variables

Hemodynamic parameters include blood pressure, heart

rate, respiratory rate and oxygen saturation, anxiety, pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100105002992N5**

Registration date: **2018-10-02, 1397/07/10**

Registration timing: **retrospective**

Last update: **2018-10-02, 1397/07/10**

Update count: **0**

Registration date

2018-10-02, 1397/07/10

Registrant information

Name

Saeed Babajani Vafsi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2012-10-21, 1391/07/30

Expected recruitment end date

2012-12-20, 1391/09/30

Actual recruitment start date

2012-10-24, 1391/08/03

Actual recruitment end date

2013-01-04, 1391/10/15

Trial completion date

2013-02-03, 1391/11/15

Scientific title

The effect of foot reflexology massage on pain, anxiety and physiological parameters during chest tube removal after open heart surgery

Public title

The effect of reflexology (reflexology) on pain and anxiety and vital signs caused by chest tube removal

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients hospitalized in heart surgery intensive care unit Under the heart valves or coronary artery bypass graft surgeries Having at least one chest tube Candidate for chest tube removal (based on routine criteria in the admitted ward) Male gender Age ranges between 40 to 80 years Having reading and writing literacy Be wake up and consciousness (GCS = 15) Numerical rate scores of pain greater than 4 (NRS> 4) Personality anxiety score greater than 33 (based on Spielberger questionnaire)

Exclusion criteria:

A history of chronic pain (such as rheumatoid arthritis, etc.) A history of taking pain relief medications (analgesics, anti-inflammatory drugs and opioids) A history of opium addiction A history of psychological disorders A history of taking neurology and psychiatry medications Taking opium medications until 4 hours ago A history of sensory-motor disorders A history of feet related problems and abnormalities (such as Corns and calluses, burns, amputations, skin diseases, etc.)

Age

From **40 years** old to **80 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Actual sample size reached: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with inclusion criteria, written in letters A ,B and C, were assigned into each test, placebo and control groups, respectively, through the lottery method.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Baqiatallah University of Medical Sciences

Street address

Molasadra Ave. Baqiyatallah University of Medical Sciences

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Postal code

1234567890

Approval date

2013-05-18, 1392/02/28

Ethics committee reference number

IR.Bmsu.REC.1392.25

Health conditions studied**1****Description of health condition studied**

anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes**1****Description**

pain

Timepoint

Before and immediately after intervention (every 5 minutes for 15 minutes)

Method of measurement

Numeric Rating Scale (NRS)

Secondary outcomes**1****Description**

Physiological parameters (vital signs and oxygen saturation percent)

Timepoint

Before intervention and after intervention every 5 minutes up to 15 minutes

Method of measurement

Vital signs monitoring

2

Description

anxiety

Timepoint

Before (state and trait anxiety) and immediately after intervention (state anxiety)

Method of measurement

Spielberger's The State-Trait Anxiety Inventory (STAI)- 40 question form

Intervention groups

1

Description

First intervention group (test): Before the chest tube removal, in the test group, the center of one third anterior left foot between the arch of the foot and the fingers (fin) of the patient's left leg deeply and in a rotary manner (such as crushing a sugar cubes with a thumb) massage was given for 10 minutes.

Category

Treatment - Other

2

Description

Second intervention group (placebo): In the placebo group, the third (heel) of the patient's left leg deeply and in a rotary manner (such as crushing a sugar cubes with a thumb) massage was given for 10 minutes.

Category

Placebo

3

Description

Control group: In the control group there was no intervention and routine care was performed.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Jamaran Hospital - cardiac surgery intensive care unit

Full name of responsible person

Saeed Babajani Vafsi

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No. 22, Bimarestan Alley, Jamaran Ave, Bahonar Blvd.

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2

Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Zahra Ghasemi

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<https://www3.bmsu.ac.ir/Services/Departments/?ObjId=201&Pageld=3180>

Grant name

Grant code / Reference number

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

Yes
Title of funding source
Bagheiat-allah 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

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Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available