Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparative study of the effect of massage therapy and cryotherapy on pain and lung volume in patients undergoing coronary artery bypass graft surgery.

Protocol summary

Summary

This study is a single-blind clinical trial with the control group in order to evaluate and compare the two techniques of Swedish massage and cryotherapy to reduce the pain and lung volume in patients undergoing coronary artery bypass graft surgery. 75 patients undergoing coronary artery bypass graft surgery were examined. The main criteria to start the study involving: the patient age is between 35 to 75 years; Thorax surgery is the first patient's experience; Cardiac output is more than 40%. Exclusion (external) criteria including: the placement of Chest tube at the time of data collection and severe emotional stress during the evaluation. Patients were divided into three groups: massage therapy, cryotherapy and control. In order to determine the severity of pain, visual analogue scale (VAS) was used also to determine the lung volumes, Spirometry unit was used. The level of pain and the lung volumes were measured for two times, 10 to 15 minutes before and 10 to 15 minutes after intervention. Massage therapy and cryotherapy intervention were done once for 20 minutes in the first 48 hours after surgery. Control patients received routine care and similar environmental intervention groups were provided for them then they were encouraged to rest in bed. The level of pain and spirometry were measured in two times, 10 to 15 minutes before and 10 to 15 minutes after rest.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015051022192N1**
Registration date: **2016-01-17, 1394/10/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-01-17, 1394/10/27

Registrant information

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Elham Ali Ahmadi

Name of organization / entity
Zahedan University of Medical Science, School of Nursing & Midwifery

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zahedan University of Medical Sciences

Expected recruitment start date

2015-06-05, 1394/03/15

Expected recruitment end date

2016-06-04, 1395/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of massage therapy and cryotherapy on pain and lung volume in patients undergoing coronary artery bypass graft surgery.

Public title

The effect of massage therapy and cryotherapy on pain and lung volume in patients undergoing open heart surgery

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:Based on previous planning the patient underwent surgery. (Elective surgery); the patient age must be between 35 to 75 years; Personal medicines such as hypnotics, benzodiazepines, sedatives, drugs and alcohol must not be used ; The minimum pain score by visual scale of pain before intervention was 40; The history of diabetes was less than 5 years; Thorax surgery is the first patient's experience; The type of graft used for patient was saphenous vein or left mammary artery; the patient does not suffer from chronic respiratory disease; Cardiac output was more than 40% based on echocardiography performed before surgery. Exclusion criteria: Patients who had a lot of pain and did not want to be touched or to continue; The placement of Chest tube was at the time of data collection; Suffering from post-operative complications such as infection, bleeding, open wound (wound dehiscence) or uncontrolled dysrhythmia; severe emotional stress during the study; Patients who have received sedatives other than the routine sedatives or the use of analgesics was less than 4 hours before the intervention.

Age

From **35 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Single-blind study because of pain and lung volumes were measured by anyone other than researcher. Research on Three Card cryotherapy, massage therapy and control written and the box has poured randomly selected.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

Pardis Zahedan Univercity Of Medical Science, Doctor Hesabi Square

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9816743463

Approval date

2015-05-31, 1394/03/10

Ethics committee reference number

IR.ZAUMS.REC.1394.101

Health conditions studied

1

Description of health condition studied

coronary artery bypass graft

ICD-10 code

151.6

ICD-10 code description

atherosclerotic cardiovascular disease

Primary outcomes

1

Description

Pain intensity

Timepoint

10 to 15 minutes before and 10 to 15 minutes after intervention

Method of measurement

In order to determine the severity of pain visual analog scale was used.

2

Description

Lung volumes

Timepoint

10 to 15 minutes before and 10 to 15 minutes after intervention

Method of measurement

Model spirometer Spiro lab III, Tuk - MIR009, ITALY

Secondary outcomes

empty

Intervention groups

1

Description

The Patients of the massage group: Swedish massage for

20 minutes, 48 hours after surgery with mild to moderate pressure, The Place of the massage depends on the willingness of the patient. Scentless and fragrance from a lubricant (glycerin) was used.

Category

Other

2

Description

The Patients of cryotherapy group: Frozen Gel packs of 10 x 14 cm with a weight of 175 g , it was put out of the fridge an hour before the intervention in a cloth cover and it was laid on the sternum dressing For 20 minutes intermittently every 5 to 10 minutes.

Category

Treatment - Other

3

Description

The patients in the control group: patients received routine care and similar environmental intervention groups were provided for them. The companions of the patient left the room for 20 minutes then the patient was encouraged to rest in bed.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ebne Abitaleb Hospital

Full name of responsible person

Changiz Azadi Ahmad Abadi

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Ali Ebne Abitaleb Hospital, Khalije Fars Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Zahedan University of Medical Science

Full name of responsible person

Hooshang Rafighdost

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City

Zahedan

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for research of Zahedan University of Medical Science

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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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