

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 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

###### Name

Elham Ali Ahmadi

###### Name of organization / entity

Zahedan University of Medical Science, School of Nursing & Midwifery

###### Country

Iran (Islamic Republic of)

###### Phone

+98 54 3343 3644

###### Email address

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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

###### **City**

Zahedan

###### **Postal code**

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. Scents 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

**Street address**

Ali Ebne Abitaleb Hospital, Khaliye Fars Blvd

**City**

Zahedan

**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

**Street address**

Pardis Zahedan University Of Medical Science, Doctor Hesabi Square,

**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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**Position**

Master Student Critical Care Nursing

**Other areas of specialty/work**

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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*