Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Assessment affection of cold gel pack application on the sternal incision and pleural chest tube insertion site on the pulmonary function and pain due to coughing and deep breathing in coronary artery bypass graft surgery patients

Protocol summary

Summary

Study Objective: Assessment affection of cold gel pack application on the sternal incision and pleural chest tube insertion site on the pulmonary function and pain due to coughing and deep breathing in coronary artery bypass graft surgery patients The trial will be conducted randomized parallel design Study Population: Patients undergoing open heart surgery in Madani hospital A) Inclusion Criteria 1- The patient consent to participate in the study. 2- The patient is over 40 years old. 3- The patient is able to read and write. 4- The patient can speak Farsi and Azari. 5- The patient orient to person, place and time. 6- The patient is able t use pain scale. 7- The patient has been underwent coronary artery bypass surgery (with or without valve replacement) with median sternutomy located. B) Exclusion criteria 1- The patient has a history of allergy or sensitivity to cold. 2- The patient has a history of Raynaud 's syndrome , sickle cell anemia , Cryoglobulinemia , diabetes and delirium. 3- The patient has severe visual, hearing and speech impairment. 4- The patient is connected to a ventilator at the time of data collection. 5- The patient has been ill at the time of data collection. 6- The patient has postoperative complications such as infection , bleeding , uncontrolled atrial fibrillation and opening the wound edges. The sample size: 25 people for each groups. In this study, patients who underwent coronary artery bypass surgery with median sternutomy randomly used cooling gel bag or gel bag with room temperature. Data on the afternoon of the first day of practice will be collected. The pain in both groups will be measured before of use of the gel pack and at the end coughing and deep breathing by the researcher with numerical pain rating scale. lung volumes are measured by Spirometery in three times before surgery and before and after applying the gel and coughing and deep. study time: 20 minutes. Expected Outcome: change in pain and pulmonary function results.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201502049422N9**
Registration date: **2015-03-15, 1393/12/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-03-15, 1393/12/24

Registrant information

Name
Aram Feizi
Name of organization / entity
Urmia University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Urmia Medical Science University

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessment affection of cold gel pack application on the sternal incision and pleural chest tube insertion site on the pulmonary function and pain due to coughing and deep breathing in coronary artery bypass graft surgery patients

Public title
Effects of cold on the pain
Purpose
Treatment
Inclusion/Exclusion criteria
A) Inclusion Criteria 1- The patient consent to participate in the study. 2- The patient is over 40 years old. 3- The patient is able to read and write. 4- The patient can speak Farsi and Turkish. 5- The patient orient to person, place and time. 6- The patient is able t use pain scale. 7- The patient has been underwent coronary artery bypass surgery (with or without valve replacement) with median sternutomy located. B) Exclusion criteria 1- The patient has a history of allergy or sensitivity to cold. 2- The patient has a history of Raynaud 's syndrome , sickle cell anemia , Cryoglobulinemia , diabetes and delirium. 3- The patient has severe visual, hearing and speech impairment. 4- The patient is connected to a ventilator at the time of data collection. 5- The patient has been ill at the time of data collection. 6- The patient has postoperative complications such as infection , bleeding , uncontrolled atrial fibrillation and opening the wound edges.
Age
From **40 years** old to **100 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz Medical Science University
Street address
Central Building of Medical science, Golgasht Avenue, Azadi Street, Tabriz, East Azarbaijan
City
Tabriz
Postal code
Approval date
2015-01-26, 1393/11/06
Ethics committee reference number
93160

Health conditions studied

1

Description of health condition studied
Pain in patients undergoing coronary artery surgery
ICD-10 code
R07.1
ICD-10 code description
Chest pain on breathing

2

Description of health condition studied
pulmonary function tests
ICD-10 code
R94.2
ICD-10 code description
Abnormal results of pulmonary function studies

Primary outcomes

1

Description
pain
Timepoint
before and 20 minutes after intervention
Method of measurement
numeric pain scale

2

Description
pulmonary function results
Timepoint
before of operation /before of use of ice packed/ 20 minutes after use of ice packed
Method of measurement
spirometry

Secondary outcomes

empty

Intervention groups

1

Description

In this study, the cooling gel pack with dimensions (10 × 25 cm) that is placed at room temperature and the timer is set for 20 minutes for the control group. Then, gel pack is placed in the dressing on the sternum incision site and around the pleural chest tube. A pillow or folded sheet will be given to the patient to support and immobilize the wound site before coughing or deep breathing. Gel pack is removed in 20 minutes and head of the bed elevated to 45-90 degrees for coughing and deep breathing. Pain intensity will be measured by a researcher using numerical pain scale, before and after applying gel pack at the end of coughing and deep breathing in the control group. The lung volumes are measured by using spirometry three times; before surgery, before and after applying the gel pack and coughing and deep breathing. Data will be collected in the afternoon of the first day after the operation.

Category

Treatment - Other

2

Description

In this study, the cooling gel pack with dimensions (10 × 25 cm) that has been frozen for at least one hour (reaching a pack's temperature between 0 to - 5°C) is removed from the freezer and the timer is set for 20 minutes in the intervention group. Then, gel pack is placed in the dressing on the sternum incision site and around the pleural chest tube. A pillow or folded sheet will be given to the patient to support and immobilize the wound site before coughing or deep breathing. Gel pack is removed in 20 minutes and head of the bed elevated to 45-90 degrees for coughing and deep breathing. Pain intensity will be measured by a researcher using numerical pain scale, before and after applying the gel pack at the end of coughing and deep breathing in the intervention group. The lung volumes are measured by using spirometry three times; before surgery, before and after applying the gel pack, and coughing and deep breathing. Data will be collected in the afternoon of the first day after the operation

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Madani hospital

Full name of responsible person

Feizi Aram

Street address

Madani hospital, In front of Research and Development complex of University, University Street, Tabriz, East Azarbaijan

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urima Medical Sience University

Full name of responsible person

Mohebi Iraj

Street address

Research and Technology Assistance Building,University Staff,End of The Emergency Center,Resalat Blvd., Urmia, West Azarbaijan

City

Urmia

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Urima Medical Sience University

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

Madani hospital, Tabriz Medical Science University

Full name of responsible person

Noorellahi Davod

Position

Msc in Critical Care Nursing

Other areas of specialty/work

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Madani hospital, In front of Research and Development complex of University, university street, Tabriz, East Azarbaijan

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Person responsible for scientific inquiries

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Web page address

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