

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison and combination the effect of TENS and cold application on pain during chest tube removal among coronary artery bypass grafting (CABG) patient in Shafa hospital of Kerman in 2019.

Protocol summary

Study aim

Determine and comparison of the effects of tense, cold compress and their combination on pain during extraction of chest tube in CABG patients

Design

The study is a one-way blind clinical trial in patients undergoing cardiac surgery in the ICU of the heart. The sampling method will be available and the allocation of samples will be done randomly in four groups.

Settings and conduct

The site of the study is cardiac ICU in the Shafa hospital, Kerman, Iran.

Participants/Inclusion and exclusion criteria

Entry requirements include age of over 18 years old; full awareness of time and place and person; absence of bans on receiving trance; non-sensory hearing impairment and vision and no addiction to drugs.

Intervention groups

Cold compresses, tenes, tennis compound and cold compressors

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131228015965N18**

Registration date: **2020-06-13, 1399/03/24**

Registration timing: **retrospective**

Last update: **2020-06-13, 1399/03/24**

Update count: **0**

Registration date

2020-06-13, 1399/03/24

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-19, 1397/11/30

Expected recruitment end date

2019-07-21, 1398/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison and combination the effect of TENS and cold application on pain during chest tube removal among coronary artery bypass grafting (CABG) patient in Shafa hospital of Kerman in 2019.

Public title

A Comparative Study on the Effect of Tenes, Cold Compressors and their Combination on Pain During Chest Tube Discharge

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years old Complete vigilance about time and place and departure from the study: Patient's reluctance to continue participating in the study No Tens In Ban Lack of sensory hearing and vision impairment and non-addiction to drugs

Exclusion criteria:

Patient death No desire to continue participating in the study

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

This randomized clinical trial study was performed with the participation of 120 patients undergoing open heart surgery, using block randomization method (quadruple blocks) which were assigned to four groups of 30 people by the patient's software for intervention and control

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and the person assessing the pain will be blind to the use of intervention

Placebo

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

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Imam Ali Blvd

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7717676563

Approval date

2019-01-01, 1397/10/11

Ethics committee reference number

IR.RUMS.REC.1397.174

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

Coronary artery disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

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

Pain

Timepoint

Before, during and after the removal of the chest tube

Method of measurement

VAS scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: In a cold compressed group, a 2 × 4 × 2 piece of lacquered gloves was placed in the lacquer glove and taken 5 minutes before removing the cyst tube in place

Category

Prevention

2**Description**

Intervention group 2: In tennis group 15 minutes before removing the chest tube, the electrodes of the tennis machine are connected to the sides of the chest tube in parallel with the frequency of 80-100 Hz

Category

Prevention

3**Description**

Intervention group 3: In the cold-tennis compressor group, 15 minutes before removing the chest tube, the electrodes of the tennis apparatus and at least 5 minutes before the cold compression are removed.:

Category

Prevention

4

Description

control group, embedded electrodes will be used while the machine is off and a non-cooled casket in the latex gloves will be used.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Healing Hospital

Full name of responsible person

Dr. Majid Kazemi

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Sponsors / Funding sources

1

Sponsor

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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

Fatemeh Hatefi

Position

Student

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Master

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Person responsible for updating data

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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