

# 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

##### Name

Majid Kazemi

##### Name of organization / entity

Rafsanjan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3425 7663

##### Email address

dr.kazemi.n@rums.ac.ir

#### 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

**Street address**  
Imam Ali Blvd

**City**  
Kerman

**Province**  
Kerman

**Postal code**  
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**

###### **Name of organization / entity**

Rafsanjan University of Medical Sciences

###### **Full name of responsible person**

Dr.Ali Shamsi

###### **Street address**

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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

###### **Latest degree**

Master

###### **Other areas of specialty/work**

Nursery

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#### **Person responsible for scientific inquiries**

##### **Contact**

###### **Name of organization / entity**

Rafsanjan University of Medical Sciences

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Dr. Majid Kazemi

###### **Position**

Associate Professor

###### **Latest degree**

Ph.D.

###### **Other areas of specialty/work**

Nursery

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Rafsanjan University of Medical Sciences  
**Full name of responsible person**  
Majid Kazemi  
**Position**  
Associate professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
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**Phone**

## 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