

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Synergic effect of Cold therapy and Music therapy on pain of removing chest tube in heart bypass surgery patients

#### Protocol summary

##### Summary

The purpose of this study is to determine the synergic effects of cold therapy and music therapy to control pain during and after chest tube removal in patients undergoing heart bypass surgery. The study is a randomized clinical trial with four study groups and a factorial design. A total of 180 patients consists the sample size in this study randomly assigned into study groups (45 patients in each group) using the block sampling method. In the group A, cold therapy will use before removing the chest tube. In the group B, music therapy intervention will play before and after removal of the chest tube. For samples in the group C, the combination of music therapy and cold therapy will apply to remove a chest tube. Samples in the group D are as a control group and will not receive any intervention. Patients who have undergone heart surgery and for at least a chest tube into the pleural, they will involve in the study. If patient have severe pain, he/she will be excluded from the study. For intervention cold therapy, a ice pack with -5 temperatures will apply for 20 minutes before removing chest tube around the chest tube and chest tube will be removed by an experienced nurse. Music therapy intervention will use form 15 minutes before to 15 minutes after removal of the chest tube. In all groups, the severity of pain patients will assess before, during and 15 minutes after removal of the chest tube by using a visual analog scale.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016012626217N1**

Registration date: **2016-03-09, 1394/12/19**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-03-09, 1394/12/19

##### Registrant information

###### Name

Sajad Yarahmadi

###### Name of organization / entity

Iran University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 66 3322 5655

###### Email address

yarahmadi.s@tak.iums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Iran University of Medical Sciences

##### Expected recruitment start date

2016-03-10, 1394/12/20

##### Expected recruitment end date

2016-08-11, 1395/05/21

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Synergic effect of Cold therapy and Music therapy on pain of removing chest tube in heart bypass surgery patients

##### Public title

The effects of Cold therapy and Music therapy in pain chest tube removal

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: Minimum age of 18 and a maximum of 65 years! Having at least one a pleural chest tube for at least 24 hours! Absence of vision problems and be able to read a ruler! Have the ability to answer questions properly researcher! Absence of hearing loss! No history of mental disorder! Absence of addiction to drugs or alcohol! Body Mass Index less than 30 Kilograms per square meter! No sedative medication one hour before chest tube removal! Self ventilation! Keenness to listen folk music. Exclusion criteria: Are having pain score higher than 7 before chest tube removal! Unwillingness to continue to participate in the study! Discomfort during cold therapy! Using narcotic medication or sedative during intervention.

### **Age**

From **18 years** old to **65 years** old

### **Gender**

Both

### **Phase**

2

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **180**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Factorial

### **Other design features**

Randomization will achieve with using sample block method.

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

##### **Street address**

Rasheed Yasemi street, higher than Mirdamad, Vali Asr street, School of Nursing and Midwifery

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2016-01-21, 1394/11/01

#### **Ethics committee reference number**

IR.IUMS.REC.1394.9311449009

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Coronary and valvular heart surgery

#### **ICD-10 code**

I97.1

#### **ICD-10 code description**

Other functional disturbances following cardiac surgery

## **Primary outcomes**

### 1

#### **Description**

Amount of pain

#### **Timepoint**

Before, during the intervention and 15 minute after intervention

#### **Method of measurement**

visual analog scale

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

In cold therapy group, ice pack with temperature -5 °C will place in contact with the patient's skin for 20 minutes and chest tube will be removed after a maximum of two minutes after completion of cold therapy. The severity of patients pain in all study groups will measure before, during and 15 minutes after removal chest tube using a visual analog scale.

#### **Category**

Treatment - Other

### 2

#### **Description**

In music therapy group, a music from the list, which includes 15 tracks, are chosen by each patient and will play from 15 minutes before to 15 minutes after chest tube removal through headphone. The list includes local and traditional music and will play with maximum sound level of 60 decibel. The severity of patients pain in this study groups will measure before, during and 15 minutes after removal chest tube using a visual analog scale.

#### **Category**

Treatment - Other

### 3

#### **Description**

In patients who use the combination of music therapy and cold therapy interventions will applied for the patients before removing chest tube. The severity of

patients' pain in this study groups will measure before, during and 15 minutes after removal chest tube using a visual analog scale.

**Category**

Treatment - Other

**4**

**Description**

The control group will received routine nursing intervention for chest tube removal. The severity of patients' pain in this study groups will measure before, during and 15 minutes after removal chest tube using a visual analog scale.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Center of Cardiology shhid Ayatollah Madani

**Full name of responsible person**

Sajad Yarahmadi

**Street address**

Ayatollah Madani Heart Hospital, Boulevard Kheirabad

**City**

Khorramabad

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for research, Iran University Of Medical Science

**Full name of responsible person**

Syed Ali Javad Mosavi

**Street address**

Between Sheikh Fadlallah and Chamran expressway, Hemat expressway, Iran University of Medical Sciences

**City**

Tehran

**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, Iran 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**

Iran University Of Medical Sciences

**Full name of responsible person**

Sajad Yarahmadi

**Position**

Intensive Care Nursing Graduate Student

**Other areas of specialty/work**

**Street address**

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**Position**

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**Fax****Email**

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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*