

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

the effects of cold therapy and respiratory relaxation technique on pain and anxiety related to chest tube removal in patients who had open heart surgery.

Protocol summary

Study aim

the main aim of this stud is to evaluate the effect of cold application and respiratory relaxation technique on pain and anxiety related to chest tube removal. detailed aims of the study: 1- Determination and comparison of the pain caused by chest tube removal in patients in four points of time; 20 minutes before chest tube removal, before chest tube removal, immediately and 15 minutes after chest tube removal in all study groups. 2- Determination and comparison of the anxiety caused by chest tube removal in two points of time 20 minutes before chest tube removal, before chest tube removal in all study groups.

Design

randomized control trial

Settings and conduct

randomized control trial In ICU open heart surgery of Imam Khomeini Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria were having two test tubes, consciousness, age more than 18, BMI under 35, ability to report pain and anxiety, stable vital signs, not being addicted, the absence of any mental, perceptions, communicating and psycho disorders and willingness to enrol in the study. exclusion criteria: Administration of analgesic and sedatives 4 hours before the intervention, reactions to Ice unwillingness to continue

Intervention groups

In the control group, no intervention is done. In the cold application group, the designed ice bag is placed on either side of the chest tube for about 20 minutes. In respiratory relaxation group patients in a quiet were asked to do the relaxation exercise. In cold therapy and respiratory relaxation group, both interventions are done at the same time.

Main outcome variables

pain anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170827035918N2**

Registration date: **2019-05-12, 1398/02/22**

Registration timing: **retrospective**

Last update: **2019-05-12, 1398/02/22**

Update count: **0**

Registration date

2019-05-12, 1398/02/22

Registrant information

Name

zahra sajadi monfared

Name of organization / entity

Tehran University of Medical sciences/ Students\ Scientific Research Center (SSRC)

Country

Iran (Islamic Republic of)

Phone

+98 21889891614

Email address

zahrasajedi75@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

2018-06-22, 1397/04/01

Actual recruitment end date

2018-12-21, 1397/09/30

Trial completion date

2018-12-21, 1397/09/30

Scientific title

the effects of cold therapy and respiratory relaxation technique on pain and anxiety related to chest tube removal in patients who had open heart surgery.

Public title

the effects of cold therapy and respiratory relaxation technique on pain and anxiety related to chest tube removal in patients who had open heart surgery.

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

have at least two chest tube. being more than 18 and consciousness BMI under 35 ability to report pain and anxiety have normal vital signs no drug addiction without any mental diseases without any mental , perceptions and communicative problems willingness to enroll in the study

Exclusion criteria:

Administration of analgesic and sedatives 4 hours before intervention, reactions to Ice unwillingness to continue

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

permuted block randomization with a size of four was chosen for this study. firstly, with, drawing lots method, every alphabet of A, B, C, D was assigned to the control group or one of the three intervention groups. Then, two series of 24possible permutations were written separately in different pieces of papers. for example ABCD, ADBC, DCBA,.. written permutations were put in a basket, 30 pieces of papers one by one were drawn out. in this way, the sequence of blocks was determined. after the physician's decisions for removing the chest tubes, the assignments of the patient whose chest tube is going to be removed was determined according to permutation's' order in the block. for example, the first patient's group was determined according to the first permutation in the block.

Blinding (investigator's opinion)

Single blinded

Blinding description

since the researcher prepare the patient before chest tube removal by the physician, the doctor will remain blinded to the grouping.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of research duty of tehran university of Medical Sciences

Street address

research deputy of Tehran university of medical sciences, Pour Sina St, University St, Enghelab St,

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-01-07, 1396/10/17

Ethics committee reference number

IR.TUMS.VCR.REC.1396.4155

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

coronary artery diseases.

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

cardiac valve diseases

ICD-10 code**ICD-10 code description****3****Description of health condition studied**

open heart surgeries

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

theoretically: Unpleasant sensory and emotional experience associated with tissue damage. Practical: The amount of pain related to chest tube removal the patient

reports with the pain numeric rating scale.

Timepoint

the pain was assessed in 4 points of time: before the intervention, after intervention before chest tube removal, immediately after chest tube removal, and 15 minutes after chest tube removal.

Method of measurement

numeric rating scale (NRS)

2

Description

anxiety, theoretically: an unpleasant, panic and vague feeling of an unknown source. Practical : The amount of anxiety related to chest tube removal that the patient reports with the numeric rating scale.

Timepoint

Anxiety was assessed in 2 points of time: 20 minutes before chest tube removal, immediately before chest tube removal.

Method of measurement

numeric rating scale

Secondary outcomes

empty

Intervention groups

1

Description

In the control group(group number 1) chest tube is removed according to the ward regulations without any intervention.

Category

Other

2

Description

Intervention group: cold application group (intervention group number 1) while the patient in a semi-fowler position with a pillow under his/her head, the dressing of the chest tube is removed and is washed by the researcher with normal saline, then designed the ice bags which are wrapped by gauze are applied around the centre of chest tub until the skin temperature reach to 13 centigrade degrees (about 20 minutes). An infrared thermometer(without any skin contact) was used for all patients.

Category

Rehabilitation

3

Description

Intervention group: The respiratory relaxation technique(intervention group 2). Firstly respiratory relaxation technique is instructed to the patient and he/she is asked to do it for 15 minutes. In a quiet environment, the patient, with closed eyes, inhale slowly through the nose with two numbers and exhale through semi-closed lips

twice slower.

Category

Rehabilitation

4

Description

Intervention group: cold application and respiratory relaxation technique(intervention group number 3). 20 minutes before chest tube removal, ice bags are applied for the patient and at the same time, the patient is asked to do respiratory relaxation exercises for 15 minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini hospital Complex

Full name of responsible person

Zahra sajedi monfared

Street address

Imam khomeini hospital Complex, Dr. Gharib St, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Phone

+98 21 6119 0000

Email

Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

دکتر محمد علی صحراییان

Street address

research deputy of tehran university, 6th floor, Central Organization of Tehran University of Medical Sciences, Ghods St., keshavarz Blv.

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3614

Email

research@tums.ac.ir

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
zahra sajadi monfared

Position
student

Latest degree
A Level or less

Other areas of specialty/work
Nursery

Street address
NO.1079, Floor 7, Tehran University of Medical Sciences buildings, Bahonar Entrance, After Ashrafi Esfahani Exit, West Hakim Expressway

City
tehran

Province
Tehran

Postal code
1473138714

Phone
+98 21 2236 8763

Email
zahrasajedi75@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
zahra sajadi monfared

Position
دانشجو

Latest degree
A Level or less

Other areas of specialty/work
Nursery

Street address
NO.1079, Floor 7, Tehran University of Medical

Sciences buildings, Bahonar Entrance, After Ashrafi Esfahani Exit, West Hakim Expressway

City
tehran

Province
Tehran

Postal code
1473138714

Phone
+98 21 2236 8763

Email
zahrasajedi75@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
zahra sajadi monfared

Position
student

Latest degree
A Level or less

Other areas of specialty/work
Nursery

Street address
NO.1079, Floor 7, Tehran University of Medical Sciences buildings, Bahonar Entrance, After Ashrafi Esfahani Exit, West Hakim Expressway

City
tehran

Province
Tehran

Postal code
1473138714

Phone
+98 21 2236 8763

Email
zahrasajedi75@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

because the patient's information is confidential, their information will not be published unless the journal needs them for more analysis.

Study Protocol

Yes - There is 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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

study protocol will be completely and clearly published in a way that other researchers can use them to design and analyze future studies. study report will also be published in two separate articles, each article explains each primary variable.

When the data will become available and for how long

the time for publishing the data completely depends on the journal protocol.

To whom data/document is available

there is no limitation for accessing data, every student or every therapeutic member can have access to the data.

Under which criteria data/document could be used

because the researcher can not provide free public access, only people who have journal membership,

personally or from university or from an organization can have access to the data.

From where data/document is obtainable

the easiest access way is the university server which provides access to different journals. if the data was not accessible with the server, the applicant can ask for the article by sending an email to the responsible author.

What processes are involved for a request to access data/document

article access completely depends on the journal article, if there is no prohibition about making accessible from the journal, the applicant must follow this process: send an email to the responsible author and explain the reason for accessing the article, the author information is provided on the journal. the author will check the request and if the author become sure about not data abusing, only requested part of the article will be send.

Comments