

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of cold compress on comfort and pain severity during chest tube removal in patients after cardiac surgery

Protocol summary

Summary

Objective: The aim of this study is to evaluate the effect of cold compress on the severity of pain and comfort of patients undergoing heart surgery. Design: A randomized clinical trial. Setting: This study included three groups of 120 patients undergoing cardiac surgery will be performed. Each group consist of 40 patients. Allocation of samples will be done by using simple random with table of random numbers. Intervention: In the intervention group 20 minutes before removing the tube will apply cold compresses. In the placebo group, in addition to the conventional method, the ring with same body temperature will be used. The Control group will not receive any intervention. Immediately before, during and 5 minutes after removal of chest tube drainage, pain and patient comfort will be measured with visual analog scale (VAS). Inclusion criteria included: People with coronary artery disease who underwent open-heart surgery; The absence of drug addiction. Exclusion criteria included Patient dissatisfaction continued cooperation and addiction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017013025929N4**

Registration date: **2017-04-15, 1396/01/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-15, 1396/01/26

Registrant information

Name

Mehdi Molavi Vardanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Hamedan University of Medical Sciences

Expected recruitment start date

2017-02-18, 1395/11/30

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cold compress on comfort and pain severity during chest tube removal in patients after cardiac surgery

Public title

cold therapy

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: People with coronary artery disease who underwent open-heart surgery have been; The absence of drug addiction. Exclusion criteria: Patient dissatisfaction continued cooperation

Age

From **18 years** old to **60 years** old

Gender

Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: 120

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Hamedan University of Medical Sciences

Street address

hamadan

City

hamadan

Postal code

Approval date

2017-02-20, 1395/12/02

Ethics committee reference number

IR.UMSHA.REC.1395.525

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

R07.3

ICD-10 code description

Anterior chest-wall pain NOS

Primary outcomes

1

Description

pain

Timepoint

Before and 5 minute after intervention

Method of measurement

questionnaire VAS

Secondary outcomes

1

Description

comfort

Timepoint

before and 5 minutes after intervention

Method of measurement

Questionnaire VAS

Intervention groups

1

Description

In the intervention group cold compresses ring will be placed 20 minutes before removal of chest tube.

Category

Treatment - Other

2

Description

control group: certain actions will not be taken.

Category

Treatment - Drugs

3

Description

placebo group: The ring with body temperature will be used.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besaat Hospital

Full name of responsible person

Mehdi Hatami

Street address

Shahid Fahmideh street, University of Medical Sciences, Hamedan

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Hamedan University of Medical Sciences

Full name of responsible person

Akram Mirzaei

Street address

Shahid Fahmideh street, University of Medical Sciences, Hamedan

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Hamedan

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 of Hamedan University of Medical Sciences

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**

Hamadan University of Medical Sciences

Full name of responsible person

Khodayar Oshvandi

Position

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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*