

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effectiveness of cold application in combination with Indomethacin suppository on chest tube removal pain undergone open heart surgery patients.

Protocol summary

Summary

Background : Chest tube removal is a painful procedure. there is no study on indometacin in combination with cold on chest tube removal pain. Aim: to examine the effect of cold application in combination with Indomethacin suppository on chest tube removal pain in patients undergone open heart surgery . Material and Methods: In this single blind randomized control trial 66 open heart surgery paients with chest tube were allocated in two groups randomly. Experimental group received 100 mg Indomethacin suppository one hour before Chest tube removal. A +4º c cold pack was placed on chest tube site 20 minutes before removing chest tube. In control group 100 mg Indomethacin suppository was prescribed one hour before chest tube removal. we use same cold pack with room temprature as placebo and placed it on chest tube site 20 minutes before removing chest tube. Pain intensity was evaluated by the visual analog scale 20 minutes before, after and 15 minutes after chest tube removal. Key words: pain, cold therapy, Indomethacin, chest tube.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205169664N2**
Registration date: **2012-06-06, 1391/03/17**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-06-06, 1391/03/17

Registrant information

Name

Mitra Payami Bousari

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

all funds is supplied by Vice-chancellor for Research of Zanjan University of Medical Sciences

Expected recruitment start date

2011-04-04, 1390/01/15

Expected recruitment end date

2011-11-06, 1390/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of cold application in combination with Indomethacin suppository on chest tube removal pain undergone open heart surgery patients.

Public title

The effectiveness of cold application in combination with Indomethacin suppository on chest tube removal pain undergone open heart surgery patients.

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: patients undergo sternomy surgery, range of age :18-69, oriented to time and place, able to answer to questions, not addicted to drug , no smoking , Indometacin suppository or other kind of sedative have not being prescribed at least 6 hours before intervention also having no opioids prescription 12 hours before intervention, having at least one chest tube in pluera, having physician order for removing chest tube , exclusion criteria: sudden change in patient status during the intervention, pain in other organs which affect chest tube removal pain such as heart pain

Age

From **18 years** old to **69 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zanjan University of Medical Sciences & health services

Street address

Azadi Square,Zanjan University of Medical Sciences and Health Services

City

Zanjan

Postal code

45156-13191

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

8912315

2

Ethics committee

Name of ethics committee

Ethics committee of Vice-chancellor for Research of

Zanjan university of medical sciences and health

Street address

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City

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Postal code

45156-13191

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

8912315

Health conditions studied

1

Description of health condition studied

chest tube removal pain

ICD-10 code

I00-I99

ICD-10 code description

Primary outcomes

1

Description

pain of chest tube removal

Timepoint

20 minutes before CTR , just after and 15 minutes after CTR

Method of measurement

visual analog scores (VAS)

Secondary outcomes

1

Description

vital sign including Blood pressure, pulse, respiratory rate

Timepoint

20 minutes before CTR, just after and 15 minutes after intervention

Method of measurement

mm/hg for BP, number for Pulse and respiratory rate announced by vital sign monitoring system Pooyandegan rahe Saadat made by iran

Intervention groups

1

Description

In Intervention group 100 mg Indomethacin suppository will be administered one hour before Chest tube removal. In intervention group a 4º c cold pack will be placed on chest tube site 20 minutes before removing chest tube. pain intensity evaluated by the visual analog scale three times:20 minutes before, just after and 15

minutes after chest tube removal. In control group: 100 mg Indomethacin suppository will be administered one hour prior to Chest tube removal. In control group same cold pack with room temperature (as placebo) will be placed on chest tube site 20 minutes before removing chest tube. pain intensity evaluated by the visual analog scale three times: 20 minutes before, just after and 15 minutes after chest tube removal.

Category

Treatment - Other

2

Description

control group: 100 mg Indomethacin suppository will be administered one hour prior to Chest tube removal. In control group same cold pack with room temperature (as placebo) will be placed on chest tube site 20 minutes before removing chest tube. pain intensity evaluated by the visual analog scale three times: 20 minutes before, just after and 15 minutes after chest tube removal.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Aallinasab Hospital

Full name of responsible person

Dr. Eskanddar Nourizadeh, Cardiologist of Aallinasab hospital of Tabriz

Street address

Tabriz, Aallinasab hospital affiliated to social security services

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research of Zanjan University of Medical Sciences and Health Services

Full name of responsible person

Dr. Alireza Biglari

Street address

Zanjan, Zanjan University of Medical Sciences and Health Services, Research

City

Zanjan

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 Zanjan University of

Medical Sciences and Health Services

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

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Full name of responsible person

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Position

PhD, Assistant professor

Other areas of specialty/work

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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