

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Determination the severity (rate) of pain after closing thoracotomy incision by intracostal sutures and pericostal sutures

Protocol summary

Summary

This study aims to investigate severity(rate) of pain after thoracotomy with two different surgical techniques and is performed on 134 patients with thoracotomy indication in 2015. Patients are randomized into two groups using sealed envelopes. The first 67 patients are their chests closed with pericostal sutures (stitches are placed on top of the fifth rib and on top of the seventh rib), and the next 67 patients are their chest closed with intracostal sutures (stitches will place on top of the fifth rib and through the small holes drilled in the bed of the sixth rib). Pain severity after thoracotomy is evaluated by numeric pain rating scale during 3 days after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080323480N1**
Registration date: **2016-02-09, 1394/11/20**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-02-09, 1394/11/20

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Qom University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination the severity (rate) of pain after closing thoracotomy incision by intracostal sutures and pericostal sutures

Public title

Two different surgical techniques to close thoracotomy incision to decrease the pain after surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients with thoracotomy indication. The exclusion criteria: patients younger than 19 years and older than 100 years; chronic pain; long-term use of nonsteroidal anti-inflammatory drugs (NSAIDs) or analgesics; psychiatric illness; cancer invasion into the chest wall; preoperative chest radiation or chemotherapy; previous ipsilateral thoracotomy; neurological diseases such as diabetes-related neuropathy; a history of a previous ipsilateral thoracotomy; rib fracture during surgery; incision infection or empyema; loss of consciousness; mechanical ventilator assistance; pulmonary embolism; reoperation and Patients unwillingness to continue the trial.

Age

From **19 years** old to **100 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **134**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Closed envelopes

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qom University of Medical Sciences

Street address

Qom University of Medical Sciences, Saheli Street

City

Qom

Postal code

Approval date

2015-02-04, 1393/11/15

Ethics committee reference number

ir.muq.rec.1393.100

Health conditions studied

1

Description of health condition studied

injury of intercostal nerves

ICD-10 code

S24.5

ICD-10 code description

injury of other nerves of thorax

Primary outcomes

1

Description

pain

Timepoint

3 days after surgery

Method of measurement

numeric pain rating score

Secondary outcomes

1

Description

Air lea; hemorrhage; pneumonia; emboli and DVT; empyema; wound infection; atelectasis.

Timepoint

every day after surgery

Method of measurement

physical examination and history taking; CXRay

Intervention groups

1

Description

Intervention group 1: patients are their chests closed with pericostal sutures (stitches are placed on top of the fifth rib and on top of the seventh rib).

Category

Prevention

2

Description

Intervention group 2: patients are their chest closed with intracostal sutures (stitches will place on top of the fifth rib and through the small holes drilled in the bed of the sixth rib).

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Mohsen Eshraghi

Street address

Shahid Beheshti Hospital, Shahid Beheshti Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Qom University of Medical Sciences

Full name of responsible person

Hossein Saghafi

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Shahid Beheshti Hospital, Shahid Beheshti Blvd

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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

Vice Chancellor for research of Qom 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**

Qom University of Medical Sciences

Full name of responsible person

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Position

Medical student

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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*