

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing Intercostals muscle flap and intracostal sutures with intracostal sutures alone for diminishing post thoracotomy pain

Protocol summary

Summary

Objectives: Comparing Intercostals muscle flap and intracostal sutures with intracostal sutures alone for diminishing post thoracotomy pain Design: From April 2012 to April 2015, 96 patients who will be admitted for thoracotomy are eligible for this prospective randomized clinical trial. Post thoracotomy pain is evaluated by two different surgical methods. All patients are randomly assigned to one of two groups. Setting and Conduct: The first group, 48 patients will receive protection of the superior intercostal nerve by rising the intercostal muscle flap and intracostal sutures will be placed through drilled holes on the rib over the inferior intercostal nerve. The second group we only use intracostal sutures for closure of thoracotomy incision. Major Inclusion and Exclusion criteria: Each patient over 19 years old will be included for this study. Chronic pain, failure in surgical technique will result in exclusion from the study. The mean duration of hospital stay is seven days and follow-up will be achieved for all patients. The most common outcome is painless condition after surgery. Interventions: First intervention includes protection of the superior intercostal nerve by rising the intercostal muscle flap and second intervention includes only intracostal sutures for closure of thoracotomy incision. Main outcome measures (variables): First variable is postoperative pain in patients, and second variable includes postoperative complications such as empyema, wound infection, atelectasis and etc.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122216077N4**

Registration date: **2016-01-13, 1394/10/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-01-13, 1394/10/23

Registrant information

Name

Ali Ramouz

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

ali.ramouz@gmail.com

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2015-03-21, 1394/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing Intercostals muscle flap and intracostal sutures with intracostal sutures alone for diminishing post thoracotomy pain

Public title

Evaluating two different thoracotomy closure suturing techniques for post thoracotomy pain relief.

Purpose

Prevention

Inclusion/Exclusion criteria
 Inclusion criteria: patients with pulmonary and non pulmonary pathology who undergone posterolateral thoractomy exclusion criteria: Below 19 years old; Chronic pain history; Addiction; Psychologic disorders; Invasion to ribs and parietal pleura; Under steroid treatment < 6 months; Neoadjuvant therapy pre operation; Brain contusion or under mechanical ventilator; Epidural catheter use; Discharge by chest tube

Age
 From **19 years** old to **139 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **96**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Single blinded

Blinding description

Placebo
 Not used

Assignment
 Parallel

Other design features
 In order to perform randomized patient selection, sealed envelopes method have been used.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Imam Reza hospital, Daneshgah street, Tabriz

City

Tabriz

Postal code

Approval date

2013-12-05, 1392/09/14

Ethics committee reference number

92854

Health conditions studied

1

Description of health condition studied

Intercostal nerve damage

ICD-10 code

S24.5

ICD-10 code description

Injury of other nerves of thorax

Primary outcomes

1

Description

Pain

Timepoint

The day of surgery. 2th weeks post surgery.

1th, 2th, 4th, 6th month post surgery

Method of measurement

1. visual pain scale 2. numeric rating score

Secondary outcomes

1

Description

Air leak, hemorrhage, pneumonia, emboli & DVT, empyema, wound infection, atelectasia

Timepoint

admission day, 1th, 2th, 4th days

Method of measurement

Chest X-Ray

Intervention groups

1

Description

Intervention group 1: In first group intercostal muscle with neurovascular bundle separated from upper rib by cutter or scalpel in opening time and salvage them from damage by rib retractor and lower rib by drilling in closing.

Category

Prevention

2

Description

Control group 2: In second group neurovascular bundle salvage just in closing time by lower rib drilling.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr. Seyed Ziaeddin Rasihashemi

Street address

Imam Reza hospital, Daneshgah street, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Seyed Ziaeddin Rasihashemi

Street address

Imam reza hospital, Daneshgah Street, Tabriz

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Tabriz

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 Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Seyed Ziaeddin Rasihashemi

Position

Assistant professor of thoracic surgery

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