

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Intercostals muscle flap and intracostal sutures versus intracostal sutures alone for decreasing post thoracotomy pain.

Protocol summary

Summary

From April 2012 to April 2013, forty 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. The first group, 20 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. 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.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206059948N1**

Registration date: **2012-08-30, 1391/06/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-08-30, 1391/06/09

Registrant information

Name

Majid Montazer

Name of organization / entity

Tabriz University of Medical sciences

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2013-03-21, 1392/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Intercostals muscle flap and intracostal sutures versus intracostal sutures alone for decreasing post thoracotomy pain.

Public title

Closer sutures for decreasing post thoracotomy pain by two different surgical technique.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients with pulmonary and non pulmonary pathology who have undergone posterolateral thoracotomy 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 misuse; Discharge by chest tube

Age

From **19 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of medical Science university

Street address

Research centre, Medical college, golgasht ave.,
Tabriz

City

Tabriz

Postal code

51666-14766

Approval date

2012-05-14, 1391/02/25

Ethics committee reference number

9141

Health conditions studied

1

Description of health condition studied

Injury of other nerves of thorax

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

CXR

Intervention groups

1

Description

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

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

Shahriar Hashemzadeh M.D

Street address

Thorax ward, Imam Reza Hospital, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Sokouti Mohsen MD

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Thorax ward, Imam Reza Hospital, Tabriz

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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
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 Science

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Majid Montazer Bavi Oliaii M.D

Position
Resident of thorax 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