

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of thoracotomy surgeries outcome in two methods of closing the chest wall with intracostal sutures and pericostal sutures in thoracotomy candidate patients

Protocol summary

Study aim

The aim of this study is to compare intercostal sutures and periosteal sutures in patients undergoing thoracotomy.

Design

A clinical trial with two intervention groups, with parallel groups, three-blind, randomized, on 30 patients. Blocks of 4 were used for randomization.

Settings and conduct

The study is carried out in Semnan Kosar Hospital and in an interventional way and the patients are divided into two groups. One group, those whose chest is closed with pericostal sutures (PS) and another group, the group whose chest is closed with intracostal sutures (IS). In the PS group, Closing the chest is done by passing the suture close to the upper edge of the fifth rib and around it, as well as close to the lower edge of the sixth rib and around it, and finally pulling them together, and in the IS group, with the help of Manual drill, 4 holes are created in the selected (lower) rib, then the stitches pass through these two holes and go around the upper rib.

Participants/Inclusion and exclusion criteria

People under 18 years old and over 80 years old, history of previous injury to the chest, either trauma or surgery, neurological diseases, history of chemotherapy, history of radiotherapy, history of stroke and impaired consciousness, are excluded from the study.

Intervention groups

In the two studied groups, after thoracotomy surgery, the chest is closed in two different ways; In one group with intracostal sutures and in the other group with pericostal sutures

Main outcome variables

Comparison of the amount of pain in two groups ; Comparison of the amount of palliative requests in two groups; Comparison of the ability to work with an incentive spirometry device in two groups; Comparison

of hospitalization duration in two groups;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230222057498N1**

Registration date: **2023-05-24, 1402/03/03**

Registration timing: **prospective**

Last update: **2023-05-24, 1402/03/03**

Update count: **0**

Registration date

2023-05-24, 1402/03/03

Registrant information

Name

amirhosein Mobaraki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3328 0179

Email address

amirhosein.m.23@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-05, 1402/03/15

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of thoracotomy surgeries outcome in two methods of closing the chest wall with intracostal sutures and pericostal sutures in thoracotomy candidate patients

Public title

results of intracostal sutures in closing the chestwall after thoracotomy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients candidate for thoracotomy 18-75 years of age

Exclusion criteria:

History of chest trauma or thorax surgeries Neurological disorders Alchole or drugs abuse History of chemotherapy and radiotherapy

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description

After randomization by 4 block method, only the thoracic specialist surgeon knows about the surgery method, and the patient, clinical caregiver, researcher and analyst do not know about the surgery method.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

kosar hospital , Amin Street , Nirogah Square , Golestan Town , Semnan

City

Semnan

Province

Semnan

Postal code

3519899951

Approval date

2023-02-06, 1401/11/17

Ethics committee reference number

IR.SEMUMS.REC.1401.300

Health conditions studied**1****Description of health condition studied**

Post thoracotomy complications

ICD-10 code

J95.8

ICD-10 code description

Other intraoperative and postprocedural complications and disorders of respiratory system, not elsewhere classified

Primary outcomes**1****Description**

Pain level after surgery based on VAS

Timepoint

24 hours, 48 hours, 72 hours after surgery and 7 days after discharge from the hospital

Method of measurement

VAS

2**Description**

The amount of housing request

Timepoint

24 hours, 48 hours, 72 hours after surgery and 7 days after discharge from the hospital

Method of measurement

Hospital admission file and questionnaire

3**Description**

Ability to work with incentive spirometry

Timepoint

24 hours, 48 hours, 72 hours after surgery and 7 days after discharge from the hospital

Method of measurement

incentive spirometry device

4

Description

Length of hospitalization

Timepoint

Before the patient is discharged

Method of measurement

Hospital admission file

5

Description

Time to return to work and normal activities

Timepoint

after the patient is discharged

Method of measurement

call

6

Description

Examination and comparison of thoracotomy area sensation

Timepoint

30 days after surgery

Method of measurement

call

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group where the chest is closed by the intracostal method

Category

Treatment - Surgery

2

Description

Intervention group: The group where the chest is closed by the pericostal method

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center**Name of recruitment center**

Semnan Kosar Hospital

Full name of responsible person

Amirhosein Mobaraki

Street address

kosar hospital , Amin Street , Nirogah Square ,
Golestan Town , Semnan

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3519899951

Phone

+98 23 3344 1022

Email

kosarhos@semums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Hamidreza Hemmati

Street address

kosar hospital , Amin Street , Nirogah Square ,
Golestan Town , Semnan

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3519899951

Phone

+98 23 3142 2118

Email

dr.hemmati2007@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Semnan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Shahrzad Izadi

Position

Assistant professor, specialist doctor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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kosar hospital , Amin Street , Nirogah Square ,
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shahrzad.izadi@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Hamidreza Hemmati

Position

Associate professor, specialist doctor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data**Contact****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Amirhosein Mobaraki

Position

Student , medical intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All the information related to the data collected from the
participants, study protocol, data analysis, will be
published after the end of the study.

When the data will become available and for how long

From the March of 2024

To whom data/document is available

All researchers and workers in the industry

Under which criteria data/document could be used

The condition of using the data is that if it is used in
scientific research, the name of the researchers of this
project should be included.

From where data/document is obtainable

information of Dr.Amirhosein Mobaraki : Phone number :
0098 9124805078 Email : Amirhosein.m.23@gmail.com
address : kosar hospital , Amin Street , Nirogah Square ,
Golestan Town , Semnan

What processes are involved for a request to access data/document

First, with one of the mentioned methods, he informs the
researcher what information he needs; Then, if possible,
the information will be sent to them one week later.

Comments