Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Hamidreza Hemmati
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kosar hospital , Amin Street , Nirogah Square , Golestan Town , Semnan
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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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Person responsible for updating data

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Student , medical intern
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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