Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

To compare chest tube and pigtail drain procedures in the treatment of uncomplicated and non-traumatic pneumothorax patients referred to Shariati Hospital 2025

Protocol summary

Study aim
Determining the effectiveness of pigtail catheter in treating patients with spontaneous pneumothorax and comparing it with patients treated with chest tube

Design
cohort

Settings and conduct
Pneumothorax is diagnosed based on plain chest radiography or chest CT and treatment will involve LBCT 24-28 F or PC 10-14 F. This procedure is performed in the operating room or bedside. The catheter is placed in the 5th-6th intercostal space in the anterior axillary line. pain will be assessed 2h after catheter insertion and at 1day interval, and the amount of pain medication will be recorded. The success of the procedure will be considered as complete lung opening and patient discharge following the first catheter insertion

Participants/Inclusion and exclusion criteria
simple pneumothorax

Intervention groups
Patients with spontaneous uncomplicated pneumothorax Exclusion criteria include the following: -Patients with traumatic or iatrogenic pneumothorax -Patients with tension pneumothorax, hemothorax, hydrothorax, empyema, hemodynamic instability, or associated injuries -Patients with a previous history of pneumothorax

Main outcome variables
Clinical symptoms asked of the patient, side of the pneumothorax as determined by imaging, gender, age, length of stay, length of time with catheter from when the catheter is inserted until it is removed, treatment success rate, which is the p of patients who have their lungs opened after the first catheter and not need another procedure compared to the total number of patients who have had that procedure, postoperative complications, duration of drainage, duration of procedure, time required for lung opening based on imaging studies, size of catheter used, amount of pain relievers prescribed the total dose of these medications prescribed to the patient, and the need or lack of need for other procedures or treatments.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251112067967N1**
Registration date: **2025-11-14, 1404/08/23**
Registration timing: **registered_while_recruiting**

Last update: **2025-11-14, 1404/08/23**
Update count: **0**

Registration date
2025-11-14, 1404/08/23

Registrant information
Name
Ramin Karami
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-03-21, 1404/01/01

Expected recruitment end date
2026-03-20, 1404/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
To compare chest tube and pigtail drain procedures in the treatment of uncomplicated and non-traumatic pneumothorax patients referred to Shariati Hospital 2025

Public title
To compare chest tube and pigtail drain procedures in the treatment of uncomplicated and non-traumatic pneumothorax patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
simple pneumothorax
Exclusion criteria:
complicated pneumothorax or traumatic
Age
From **15 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
simple randomization 56 patients are divided into two equal groups: a chest tube group and a pigtail drain group, in a one-to-one ratio.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Educational, Research and Treatment Center of Dr. Shariati Hospital - Tehran University of Medical S
Street address
Tehran, North Kargar Street, Jalal Al-Ahmad Intersection, opposite the Faculty of Economics, Dr. Shariati Educational, Research and Treatment Center
City
tehran
Province
Tehran
Postal code
1411713135
Approval date
2024-05-13, 1403/02/24
Ethics committee reference number
IR.TUMS.SHARIATI.REC.1403.036

Health conditions studied

1

Description of health condition studied
non complicated non traumatic pneumothorax
ICD-10 code
J93.11
ICD-10 code description
Primary spontaneous pneumothorax

Primary outcomes

1

Description
Clinical symptoms asked of the patient, side of the pneumothorax (right/left lung) as determined by imaging studies, patient gender, age at admission, length of stay, length of time with catheter from when the catheter is inserted until it is removed, treatment success rate, which is the percentage of patients who have their lungs opened after the first catheter and do not need another procedure compared to the total number of patients who have had that procedure, postoperative complications, duration of drainage, duration of procedure, time required for lung opening based on imaging studies, size of catheter used, amount of pain relievers prescribed including the total dose of these medications prescribed to the patient, and the need or lack of need for other procedures or treatments.
Timepoint
The patient's pain level will be assessed 2 hours after catheter placement and at 1-day intervals, and the amount of pain medication prescribed, including nonsteroidal anti-inflammatory drugs (NSAIDs) and opioids, will be recorded. Success will be defined as complete lung opening and patient discharge after the first catheter placement, and failure will be defined as the need for a second catheter after the first catheter is removed.
Method of measurement
The patient's pain level will be assessed 2 hours after catheter insertion and at one-day intervals, and the amount of analgesics prescribed, including nonsteroidal anti-inflammatory drugs (NSAIDs) and opioids, will be recorded. The success of the procedure will be defined as complete lung opening and patient discharge following the insertion of the first catheter, and failure of the

procedure will be defined as the need for a second catheter after the first catheter is removed.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: insertion pf drain catheter fpr simple pneumothorax
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
shariati hospital
Full name of responsible person
dr reza eslamian
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Tehran, North Kargar Street, Jalal Al-Ahmad Intersection, opposite the Faculty of Economics, Dr. Shariati Educational, Research and Treatment Center
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
none
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
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ramin karami
Position
resident
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Other areas of specialty/work
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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
Yes - There is 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
Yes - There is a plan to make this available

Title and more details about the data/document
All data is shareable.

When the data will become available and for how long
Access period immediately after publication

To whom data/document is available
All applicants, including medical engineers

Under which criteria data/document could be used
there is no limits

From where data/document is obtainable
Please contact me personally via email.

What processes are involved for a request to access data/document
There will be no process and it will be immediate.

Comments