

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

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2293 2190

Email address

ramin.karami@hotmail.com

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 of drain catheter for 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

ramin karami

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ramin.karami@hotmail.com

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

Full name of responsible person

ramin karami

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Position

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Latest degree

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Person responsible for updating data

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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