

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of necessity of obtaining chest x-ray after chest tube removal in patients with pneumothorax

Protocol summary

Study aim

Evaluation of necessity of obtaining chest x-ray after chest tube removal in patients with pneumothorax

Design

Clinical trial with an intervention group, with a parallel group; single blind, random

Settings and conduct

This study is conducted in Imam Reza Birjand Hospital, South Khorasan Province. 54 patients are randomly divided into two intervention groups (A) and (B).

Participants/Inclusion and exclusion criteria

Our study population, patients with pneumothorax hospitalized in Imam Reza Hospital, who had a chest tube implanted for them and whose chest tube was removed at the time of discharge, will be included in the study if they agree to conduct the research. Exclusion criteria: pleural effusion in the patient; the need to reinsert the chest tube after discharge (for example, due to accidents, lung diseases, etc.); hemothorax in the patient; symptoms immediately after removing the chest tube; mechanical ventilation and surgical intervention will be performed in the patient except chest tube insertion.

Intervention groups

The intervention groups are as follows: Group one (A): after pulling the chest tube, if there are no symptoms, CXR will be taken 2 hours later and if it is normal, they will be discharged, and in the second group (B): the group that After chest tube removal, if there are no clinical symptoms, they will be observed in the hospital for at least 4 hours, depending on the doctor's opinion, and then they will be discharged.

Main outcome variables

Taking a chest x-ray and inserting a chest tube

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190618043934N20**

Registration date: **2023-09-13, 1402/06/22**

Registration timing: **prospective**

Last update: **2023-09-13, 1402/06/22**

Update count: **0**

Registration date

2023-09-13, 1402/06/22

Registrant information

Name

Zabihullah Mohaghegh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3232 3232

Email address

oabstudent@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of necessity of obtaining chest x-ray after chest tube removal in patients with pneumothorax

Public title

It is necessary to take a chest X-ray after removing the chest tube

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Chest tube removal during patient discharge Patient consent to participate in the study

Exclusion criteria:

Pleural effusion in the patient The need to reinsert the chest tube after discharge (for example, due to accidents, lung diseases, etc.) Hemothorax in the patient Symptoms immediately after removing the chest tube Mechanical ventilation Surgical intervention except for the installation of the chest tube

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider

Sample size

Target sample size: 27

Randomization (investigator's opinion)

Randomized

Randomization description

The placement of people in each group will be simple random and in a blocked method, in one of the two groups A (after pulling the chest tube if there are no symptoms, CXR was taken 2 hours later and they were discharged if they were normal.), group B (the group who were observed in the hospital for at least 4 hours after pulling the chest tube if there were no clinical symptoms, depending on the doctor's opinion, and then they were discharged). In this way, first, various blocks of four (AABB, BBAA, ABAB, BABA, ABBA and BABA) are created on different cards. One of these blocks will be randomly selected using the lottery method and the patients will be divided into one of two groups A or B. Then randomization is done for other patients as well. This will be done by the study manager.

Blinding (investigator's opinion)

Single blinded

Blinding description

Outcome evaluator: The study administrator (final year medical student) examines and records the desired variables without knowing the placement of patients in two groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Birjand University of Medical Sciences, Ghaffari Blvd, Birjand, South Khorasan, Iran.

City

Birjand

Province

South Khorasan

Postal code

9717811674

Approval date

2022-02-07, 1400/11/18

Ethics committee reference number

IR.BUMS.REC.1400.372

Health conditions studied

1

Description of health condition studied

Pneumothorax

ICD-10 code

J93.11

ICD-10 code description

Primary spontaneous pneumothorax

Primary outcomes

1

Description

Recurrent pneumothorax

Timepoint

Before entering the study and 5 days after discharge from the hospital

Method of measurement

Physical examination by the study manager and questions about the clinical symptoms of the patients

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First intervention group: After chest tube removal, if there are no symptoms, CXR will be taken 2 hours after them, and if they are normal, they will be discharged.

Category

Treatment - Surgery

2

Description

Intervention group: The second intervention group: the group that after pulling the chest tube, if there are no clinical symptoms, they are observed in the hospital for at least 4 hours, depending on the doctor's opinion, and then they are discharged.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital_Birjand

Full name of responsible person

Mahshid Masbogh

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School of Medicine, Birjand University of medical sciences, Ghahhari Blvd,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Zabihullah Mohaqiq

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no need to publish individual patient information

Study Protocol

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

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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