

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the Outcome of Using One-way Heimlich Valve in the Treatment of Primary Spontaneous Pneumothorax in Comparison with Implantation of Chest Tube and Connection to the Bottle, A Randomized Clinical Trial

Protocol summary

Study aim

Comparison of the Outcome of Using One-way Heimlich Valve in the Treatment of Primary Spontaneous Pneumothorax in Comparison with Implantation of Chest Tube and Connection to the Bottle

Design

A double-blinded, phase 3, randomized controlled clinical trial in Shahid Madani Hospital of Alborz University of Medical Sciences in 1402. Patients will be randomly assigned to two groups with a one-to-one ratio (total sample size of 40) using the stratified block randomization method.

Settings and conduct

This study was conducted on patients with Primary Spontaneous Pneumothorax in Shahid Madani Hospital of Alborz University of Medical Sciences in Karaj in 1402. The patients will be divided into two groups of lung collapse below 50% and above 50%. Participants with the collapse below 50% will be randomly divided into two treatment groups with Chest Tube or One-way Heimlich Valve insertion, and participants with collapse above 50% will also be randomly divided into two treatment groups. After 48 hours, patients will be checked daily. Within 30 days from discharge, the patient will be examined weekly.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18 to 40 with Primary Spontaneous Pneumothorax with the lung collapse of more than 15%; No history of trauma; No complete lung collapse. Exclusion criteria: Developing complications and stop treatment; Treatment failure

Intervention groups

The first group will be treated by a Chest Tube number 16 and connection to the bottle and the second group by using a One-way Heimlich Valve.

Main outcome variables

Hospitalization duration; pain; Readmission; Complications; Severity of the shortness of breath; Treatment failure; The need for Ketorolac injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230208057359N1**

Registration date: **2023-02-13, 1401/11/24**

Registration timing: **prospective**

Last update: **2023-02-13, 1401/11/24**

Update count: **0**

Registration date

2023-02-13, 1401/11/24

Registrant information

Name

Seyed Mohammad Naghibalghora Banadaki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3726 4451

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

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 the Outcome of Using One-way Heimlich Valve in the Treatment of Primary Spontaneous Pneumothorax in Comparison with Implantation of Chest Tube and Connection to the Bottle, A Randomized Clinical Trial

Public title

Comparison of the Outcome of Using One-way Heimlich Valve in the Treatment of Primary Spontaneous Pneumothorax in Comparison with Implantation of Chest Tube and Connection to the Bottle

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients aged 18 to 40 years old with Primary Spontaneous Pneumothorax that is symptomatic and the lung collapse rate is more than 15% (the distance between the chest wall and the lung is more than 1 cm) No history of trauma in the last month No history of severe asthma or chronic obstructive pulmonary disease Not suffering from psychosis Do not require special medical services such as hospitalization in ICU Do not have complete lung collapse Not breastfeeding or pregnant

Exclusion criteria:

Patients who are eligible to enter the study but did not consent to enter the study Patients who developed complications and the patient's treatment was discontinued Patients in need of Video-assisted thoracoscopic surgery include having one lung, being a diver or a pilot, having a large Pulmonary Embolus Treatment failure after 7 days

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants with the collapse below 50% were randomly assigned to two treatment groups with chest tube insertion or One-way Heimlich Valve insertion, and participants with collapse above 50% were randomly assigned to two treatment groups with chest tube

insertion or One-way Heimlich Valve insertion (stratified randomization). For randomization, the block randomization method will be used, so that at first in the Excel software, blocks of four will be prepared as (AABB) (BBAA) (ABBA) (BAAB) (ABAB) (BABA). A indicates the group of One-way Heimlich Valve and B indicates the group of the chest tube connected to the Bottle. Then one of the blocks will be randomly selected and based on the sequence of letters in the selected block, the eligible people will be assigned to the treatment groups. This random process of selecting blocks and assigning people to treatment groups will continue until the desired sample size is reached. The preparation of the random allocation sequences of these two intervention groups and placing them in sealed envelopes and numbering with a 5-digit serial number is done by a third person who is not involved in the design of the study. All the envelopes have a 5-digit serial number, which are opened after recording background information, and the sample participants are divided into two intervention groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be double-blinded, so that the evaluator and the participants are not aware of the status of assigning participants to the study groups. It will be explained to the study subjects before the random assignment, how the work process is, and they may receive one of the two treatments randomly, and the treatment used for the individual is not known in advance. It will not be possible for the patients to distinguish these treatments from each other. Also, the outcome evaluator will be blinded about assigning participants to the study groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Alborz University of Medical Sciences

Street address

Ethics Committee Unit, Research and Technology Department of Alborz University of Medical Sciences, No 20, Safarian Alley, Golshahr Street, Karaj

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2023-01-08, 1401/10/18

Ethics committee reference number

IR.ABZUMS.REC.1401.272

Health conditions studied

1

Description of health condition studied

Primary Spontaneous Pneumothorax

ICD-10 code

J93.11

ICD-10 code description

Primary spontaneous pneumothorax

Primary outcomes

1

Description

The hospitalization duration from the start of treatment until the time of removal of the chest tube

Timepoint

When the chest tube is removed, the hospitalization duration is calculated

Method of measurement

Days recorded in the patient's file

Secondary outcomes

1

Description

Pain Severity

Timepoint

Daily examination during hospitalization and weekly after discharge for up to 4 weeks

Method of measurement

Visual Analogue Scale score (0 to 10)

2

Description

Readmission

Timepoint

Weekly from the time of discharge up to 4 weeks

Method of measurement

Based on examinations, symptoms and paraclinical measures

3

Description

Treatment failure

Timepoint

7 days after the intervention

Method of measurement

No symptom improvement or incomplete opening of the lung after 7 days is considered as treatment failure

4

Description

Complications

Timepoint

Daily examination during hospitalization and weekly after discharge for up to 4 weeks

Method of measurement

Occurrence of complications including subcutaneous Emphysema, Hematoma and wound infection through examination and clinical symptoms

5

Description

Shortness of breath severity

Timepoint

Daily examination during hospitalization and weekly after discharge for up to 4 weeks

Method of measurement

Visual Analogue Scale score (0 to 10)

6

Description

Ketorolac injection

Timepoint

Daily examination during hospitalization

Method of measurement

The number of requests and the milligrams of the injected Ketorolac

Intervention groups

1

Description

For the participants in the first intervention group, chest tube number 28 will be inserted from the fourth or fifth intercostal space in the area of the anterior to mid-axillary line and it will be connected to the bottle. Patients will receive supportive treatments such as incentive spirometry and respiratory physiotherapy, and they will be prescribed oral acetaminophen 10 mg per kilogram of weight. In case of shortness of breath, they will receive nasal oxygen.

Category

Treatment - Surgery

2

Description

For participants in the second intervention group, tube number 28 will be inserted from the fourth or fifth intercostal space in the area of the anterior to mid-axillary line and it will be and connected to the one-way Heimlich valve. Patients will receive supportive treatments such as incentive spirometry and respiratory physiotherapy, and they will be prescribed oral acetaminophen 10 mg per kilogram of weight. In case of shortness of breath, they will receive nasal oxygen.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Hospital

Full name of responsible person

Seyed Mohammad Naghibalghora Banadaki

Street address

Shahid Madani Hospital, Shahid Madani Square,
Mahan Boulevard, Taleghani Crossroad, Karaj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Razieh Lotfi

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Research and Technology Department, No.20,
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Research@abzums.ac.ir

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

Yes

Title of funding source

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Seyed Mohammad Naghibalghora Banadaki

Position

General surgery resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

General surgery resident

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Person responsible for updating data

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

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

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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