

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the efficacy of N-acetylcysteine and bromhexine in patients with pneumothorax

Protocol summary

Study aim

Evaluation of time required for lung expansion and chest tube resection to compare N-Acetylcysteine and bromhexine in the treatment of pneumothorax

Design

A cross-group trial, without control group and blind strain, randomized on 50 patients in 3 phase, used a lottery container containing 50 balls for randomization

Settings and conduct

After the approval of the plan in the research council of the university and obtaining the code of ethics, sampling will begin among the patients admitted to the surgical ward of Pasteur Hospital in Bam who have the conditions to participate in the study. Randomization will be done first and then people will be randomly divided into 2 groups. Upon arrival, the patient will be photographed on the chest and if the amount of pneumothorax is significant, the patient will be included in the study. N-acetylcysteine and bromhexine are then used as mucolytic drugs

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with traumatic pneumothorax.
Exclusion criteria: patients with chronic obstructive pulmonary disease, asthma, cystic fibrosis, bronchitis, bronchiectasis, Interstitial lung disease (ILD), AIDS, intubation patients

Intervention groups

Group 1 consists of 25 people: N-acetylcysteine use and routine treatment under the supervision of a surgeon
Group 2 includes 25 people: taking bromhexine and routine treatment under the supervision of a surgeon

Main outcome variables

The time required for the chest xray to normalize and result in the exit of the chest tube

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220529055014N1**

Registration date: **2022-06-15, 1401/03/25**

Registration timing: **prospective**

Last update: **2022-06-15, 1401/03/25**

Update count: **0**

Registration date

2022-06-15, 1401/03/25

Registrant information

Name

Meysam Abyazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6600 2873

Email address

meab17811@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of N-acetylcysteine and bromhexine in patients with pneumothorax

Public title

Effect of N-acetylcysteine and bromhexine pneumothorax

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patient admitted to the surgical ward Satisfaction with participation in the study Patients with traumatic pneumothorax to a significant extent
Exclusion criteria:
Patients with chronic obstructive pulmonary disease (copd) Asthma cystic fibrosis bronchitis bronchiectasis AIDS Patients who have undergone intubation

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 50

Randomization (investigator's opinion)
Randomized

Randomization description
First determine a total sample size then randomly Assign a set of them to group A and the rest to group B. For example, in a study with a sample size of 50 people, 25 balls for intervention group A and 25 balls for group Intervention B is placed inside a lottery container and then the balls are randomly recorded without being replaced from the container and the resulting sequence is recorded.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Bam University of Medical Sciences

Street address

Bam - Sardaran Shahid Square - Shahid Rajaei Boulevard

City

Bam

Province

Kerman

Postal code

7661791453

Approval date

2022-05-18, 1401/02/28

Ethics committee reference number

IR.MUBAM.REC.1401.025

Health conditions studied

1

Description of health condition studied

Pneumothorax

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Normalization of symptoms in chest xray

Timepoint

About a week after starting treatment

Method of measurement

Counting the number of days hospitalized

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, pneumothorax patients are treated orally for one week by implanting chest tube and taking bromhexine tablets, a product of Aveh Sina Pharmaceutical Company, at a dose of 8 mg once a day. Then the patient is photographed chest and in case of recovery of pneumothorax, the time required for chest tube exit is recorded and examined

Category

Treatment - Drugs

2

Description

Intervention group: In this group, pneumothorax patients are treated by chest tube implantation and N-acetylcysteine, a product of Aveh Sina Pharmaceutical Company, at a dose of 600 mg as a solution in 30cc of water, every 12 hours orally for one week. Take. Then the patient is photographed chest and in case of recovery of pneumothorax, the time required for chest tube exit is recorded and examined

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pasteur Hospital of Bam

Full name of responsible person

Fatemeh kamali

Street address

Kerman, Bam, km 5 of Bam road, Barvat

City

Bam

Province

Kerman

Postal code

0344431940

Phone

+98 34 4431 9404

Email

Pastor@mubam.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bam University of Medical Sciences

Full name of responsible person

Sajjad Khosravi

Street address

Bam - Persian Gulf Highway - University Campus

City

Bam

Province

Kerman

Postal code

7661771967

Phone

+98 34 4421 9074

Email

sci@mubam.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Bam 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

Bam University of Medical Sciences

Full name of responsible person

Hossein Rezaei

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Biostatistics

Street address

Bam - Persian Gulf Highway - University Campus

City

Bam

Province

Kerman

Postal code

7661771967

Phone

+98 34 4421 9074

Email

Hossein.rezaei.aliabadi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bam University of Medical Sciences

Full name of responsible person

Mojtaba Khojandi

Position

Faculty Member

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Bam - Persian Gulf Highway - University Campus

City

Bam

Province

Kerman

Postal code

7661771967

Phone

+98 34 4421 9074

Email

Mojtabakhajandi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Bam University of Medical Sciences

Full name of responsible person

Hossein Rezaei

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Biostatistics

Street address

Bam - Persian Gulf Highway - University Campus

City

Bam

Province

Kerman

Postal code

7661771967

Phone

+98 34 4421 9074

Email

Hossein.rezaei.aliabadi@gmail.com

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

Clinical information (including therapeutic outcomes) and demographics Pneumothorax patients treated with N-acetylcysteine and bromhexine

When the data will become available and for how long

About a year

To whom data/document is available

Public

Under which criteria data/document could be used

Detailed study information can be made available to interested researchers Treat patients

From where data/document is obtainable

Author responsible for the study

What processes are involved for a request to access data/document

Competent and enthusiastic researchers can document the data after publication Work of the responsible author by providing academic information and self-identification To receive

Comments