Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the results of pleurodesis treatment with 50% glucose with pleurodesis with bleomycin in patients with malignant pleural effusion referring to educational centers

Protocol summary

Study aim

The practical purpose of this study was to determine a safe and less complicated and cost-effective treatment method for the treatment of pleurisy in patients with malignant pleural effusion.

Design

A clinical trial with a control group with a parallel simple double-blind randomized phase group of phase 3 on 64 patients.

Settings and conduct

Admitted patients with malignant pleural effusion in Isfahan medical sciences hospitals, including Al-Zahra, Seyed Al-Shohada, Amin and ... Double blind so that: In this study, the order is written by the professor as *pleurodesis No. 1 * and * pleurodesis No. 2 *, and only the executing nurses were aware of this formula, and the relevant assistant for the execution is unaware of the drug being injected into the chest.

Participants/Inclusion and exclusion criteria

Patient with metastatic malignancies cause to pleural effusion. Diagnosis of malignant pleural effusion based on pleural fluid cytology. Symptomatic and recurrent pleural effusion due to malignancy. History of lung diseases such as COPD, sclerotherapy Hypersensitivity to bleomycin

Intervention groups

One group for pleurodesis uses bleomycin and one group for pleurodesis uses 50% glucose.کار

Main outcome variables

Age; Gender; The type of material used in Plourdes; Time required to hold the chest tube; Time of hospitalization of patients; Postoperative complications of pleurisy with bleomycin; Recurrent pleural effusion; Symptoms of patients after pleurisy with bleomycin; Plovers success rate; Frequent injection of 50% glucose or bleomycin in Plordes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201013049017N1**
Registration date: **2021-02-12, 1399/11/24**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-12, 1399/11/24**
Update count: **0**

Registration date

2021-02-12, 1399/11/24

Registrant information

Name

Hamid Talebzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the results of pleurodesis treatment with 50% glucose with pleurodesis with bleomycin in patients with malignant pleural effusion referring to educational centers

Public title
Pleurodesis treatment with 50% glucose

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patient with metastatic malignancies cause to pleural effusion. Diagnosis of malignant pleural effusion based on pleural fluid cytology. Symptomatic and recurrent pleural effusion due to malignancy. No history of allergy to bleomycin .

Exclusion criteria:
Reluctance to participate in the study

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the Convenience Sampling method, 64 eligible individuals were selected and then assigned to groups A and B using a 4-item randomized block method. For this purpose, in blocks of 4, two allocations to group A and two allocations to group B were considered and there were a total of 6 cases. The four blocks created were selected so that the sample size reached 64 people. In order to conceal random allocation, the method of opaque sealed envelopes with the random sequence was used. In this method, first, a random sequence is created by one of the mentioned methods, and based on the sample size of the research, a number of opaque envelopes are prepared and each of the random sequences created is recorded on a card and the cards are inside the envelopes. Were placed in order. At the time of enrollment, one of the envelopes was opened and the assigned group was revealed in order of eligible participants.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the order is written by the professor as * pleurodesis No. 1 * and * pleurodesis No. 2 *, and only the performing nurses were aware of this formula, and the relevant assistant for the execution is unaware of the drug being injected into the chest.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Esfahan University of Medical Sciences

Street address
No. 4, Hezar Jerib St., Isfahan University of Medical Sciences and Health Services- Vice Chancellor for Research and Technology,Isfahan, Iran.

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Approval date
2020-03-11, 1398/12/21

Ethics committee reference number
IR.MUI.MED.REC.1398.712

Health conditions studied

1

Description of health condition studied
Malignant pleural effusion

ICD-10 code
J91.0

ICD-10 code description
Malignant pleural effusion

Primary outcomes

1

Description
Investigation of the location and severity of pleural effusion

Timepoint
Before starting the intervention: Installation of chest tube number F 28 in the area of the hypothetical middle axillary line from the fifth or sixth intercostal space in the appropriate position24 to 48 hours after chest tube implantation: Preparation of chest graph in both face and profile positions

Method of measurement
CT-Scan

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group (A): There are 32 people in this group. the solution containing 200 cc of 50% glucose and 12.5 ml of 2% lidocaine is injected into the pleural cavity through the chest tube between the teeth, injected and the chest tube for 2 hours. It is recommended that they change their position every 15 minutes for the first 2 hours. If the chest radiograph after pleurodesis shows satisfactory lung dilation and less than 100 ml of 24-hour drainage without air leakage, the patient's chest tube is removed and the patient is discharged. Patients will be referred for follow-up immediately after pleurodesis and after removal of the Chest Tube and then at one-month intervals for 3 months. At each visit, patients are evaluated for clinical signs and symptoms associated with pleural effusion, including shortness of breath, cough, chest pain, and pulmonary sounds, followed by chest radiographs in the first and second months, and The third will be performed after pleurisy and the patients' recovery will be evaluated.

Category

Treatment - Drugs

2

Description

Intervention group(B): In this group is 32 people Plunders solution containing 12.5 cc of lidocaine 2 ٪ is mixed with 50 cc of normal saline and bleomycin (1 mg / kg) and injected into the Chest Tube using a 50 cc syringe and then for Clamps for 2 hours.It is recommended that they change their position every 15 minutes for the first 2 hours.If the chest radiograph after pleurodesis shows satisfactory lung dilation and less than 100 ml of 24-hour drainage without air leakage, the patient's chest tube is removed and the patient is discharged.Patients will be referred for follow-up immediately after pleurodesis and after removal of the Chest Tube and then at one-month intervals for 3 months.At each visit, patients are evaluated for clinical signs and symptoms associated with pleural effusion, including shortness of breath, cough, chest pain, and pulmonary sounds, followed by chest radiographs in the first and second months, and The third will be performed after pleurisy and the patients' recovery will be evaluated.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al Zahra University Hospital

Full name of responsible person

Hamid Talebzadeh

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Recruitment center

Name of recruitment center

Seyed Al-Shohada Teaching Hospital (Omid)

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Recruitment center

Name of recruitment center

Kashani Teaching Hospital

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4

Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

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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
Esfahan 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
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Position
Associated professor of thoracic surgeon
Latest degree
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Other areas of specialty/work
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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