Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of success rate of pleurodesis with negative pressure suction and bleomycin in malignant pleural effusions

Protocol summary

Study aim
Effect of pleurodesis with negative pressure suction plus bleomycin in malignant pleural effusions

Design
Before and after interventional study , without control group, without randomization, without blindness

Settings and conduct
In patients with malignant pleural effusion referring to Shahid Sadoughi hospital of Yazd, who have been studied not randomly and without blindness, 15 ml of lidocaine 2% with 1 mg/kg bleomycin is injected. Before intervention and four weeks later, a simple decubitus chest x-ray is taken and the amount of malignant pleural effusion is measured and compared with the amount of pleural effusion before the chest tube and pleurodesis are compared with bleomycin with suction using 20cmH2O negative pressure.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Cytologically confirmed malignant pleural fluid, No sensitivity to bleomycin, No history of previous chemotherapy with bleomycin Exclusion criteria: Previous history of pleurodesis, History of coagulation disorders, Patient dissatisfaction

Intervention groups
In patients with malignant pleural effusion, 15 ml of lidocaine 2% is injected into the chest tube, and bleomycin 1 mg/kg is injected into the chest tube with 50 ml normal saline to be diluted. Then the clamp is released and an hour later, the clamp is opened and lung fluid is pulled out using 20cmH2O negative pressure.

Main outcome variables
The amount of pleural effusion

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180813040779N1**
Registration date: **2018-08-26, 1397/06/04**
Registration timing: **prospective**

Last update: **2018-08-26, 1397/06/04**
Update count: **0**

Registration date
2018-08-26, 1397/06/04

Registrant information

Name
Masoud Rahimian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 35 3822 4000

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m.rahimian@ssu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2019-02-20, 1397/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of success rate of pleurodesis with negative pressure suction and bleomycin in malignant pleural effusions

Public title
Effect of pleurodesis and bleomycin in malignant pleural

effusions

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Cytologically confirmed malignant pleural fluid No sensitivity to bleomycin No history of previous chemotherapy with bleomycin

Exclusion criteria:

Previous history of pleurodesis History of coagulation disorders Patient dissatisfaction

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yazd University of Medical Sciences

Street address

Shahid Sadughi hospital, Ghandi Blvd, Yazd

City

Yazd

Province

Yazd

Postal code

8944163114

Approval date

2017-07-02, 1396/04/11

Ethics committee reference number

IR.SSU.MEDICINE.REC.1396.264

Health conditions studied

1

Description of health condition studied

Pleural effusion

ICD-10 code

J90

ICD-10 code description

Pleural effusion, not elsewhere classified

Primary outcomes

1

Description

The amount of pleural effusion

Timepoint

Before the intervention and four weeks after the intervention

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In patients with malignant pleural effusion, 15 ml of lidocaine 2% is injected into the chest tube, and bleomycin 1 mg/kg is injected into the chest tube with 50 ml normal saline to be diluted. Then the clamp is released and an hour later, the clamp is opened and lung fluid is pulled out using 20cmH2O negative pressure.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadughi hospital of Yazd

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Yazd 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
Yazd University of Medical Sciences
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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
I will decide after collecting of all data
When the data will become available and for how long
Six months after publishing the results.
To whom data/document is available
All researchers
Under which criteria data/document could be used
With email request
From where data/document is obtainable
Masoud Rahimian
What processes are involved for a request to access data/document
Just email
Comments