

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

Phone

+98 35 3822 4000

Email address

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

Masoud Rahimian

Street address

Shahid Sadughi hospital, Ghandi Blvd, Yazd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Navid Nasirzadeh

Street address

Yazd University of Medical Sciences, Bahonar Square,
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nasirizadeh@iauyazd.ac.ir

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

Full name of responsible person

Masoud Rahimian

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

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Subspecialist

Other areas of specialty/work

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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