Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Evaluation of effectiveness of betadine (Povidone-iodine) in one step and two step procedure in the treatment of patients with pleural effusion resistant to conventional treatments: a clinical trial

Protocol summary

Study aim

The aim of this study was to evaluate the effectiveness of betadine as a chemical agent for pleurisy, which will be performed in two steps.

Design

This study was performed on 40 patients with refractory pleural effusion. The present intervention involves injecting 20 cc of 10% betadine with 5 cc of lidocaine and 60 cc of normal saline. The injection is done through a catheter. Two hours after the injection, the catheter is closed and the position is changed, and after 2 hours, the catheter valve is opened again, and finally, after 24 hours, the catheter is removed. After the intervention, patients are cared for.

Settings and conduct

The present study is a clinical trial with one arm that will be performed in 1400 in Afzalipour Hospital in Kerman. In this study, which will be done as a pilot

Participants/Inclusion and exclusion criteria

In this study, patients with refractory pleural effusion with adhesions and a history of VATS and thoracoscopy met the inclusion criteria.

Intervention groups

In this study, patients with refractory pleural effusion with adhesions and a history of VATS and thoracoscopy met the inclusion criteria. The present intervention included injection of 20 cc of 10% betadine with 5 cc of lidocaine and 60 cc of normal It is saline. The injection is done through a catheter. Two hours after the injection, the catheter is closed and the position is changed, and after 2 hours, the catheter valve is opened again, and finally, after 24 hours, the catheter is removed. After the intervention, patients are cared for.

Main outcome variables

Age, sex, type of pleural effusion, duration of follow-up, effectiveness, side effects, reduction of pleural effusion, reduction of clinical symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220117053750N1**
Registration date: **2022-02-28, 1400/12/09**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-28, 1400/12/09**
Update count: **0**

Registration date

2022-02-28, 1400/12/09

Registrant information

Name

Frank Salajegheh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 8325

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Evaluation of effectiveness of betadine (Povidone-iodine) in one step and two step procedure in the treatment of patients with pleural effusion resistant to conventional treatments: a clinical trial

Public title
The Evaluation of effectiveness of betadine (Povidone-iodine) in one step and two step procedure in the treatment of patients with pleural effusion resistant to conventional treatments: a clinical trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
In this study, patients with refractory pleural effusion with adhesions and a history of VATS and thoracoscopy are eligible for the study.

Exclusion criteria:
In contrast, patients who have a mass for whom catheterization is not possible will be excluded from the study process

Age
No age limit

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
N/A

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
Kerman University of Medical Sciences

Street address
Emam Blv., Afzalipour Hospital

City
Kerman

Province
Kerman

Postal code
7616913355

Approval date
2022-01-22, 1400/11/02

Ethics committee reference number
IR.KMU.AH.REC.1400.158

Health conditions studied

1

Description of health condition studied
Resistant pleural effusion

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pleural effusion, reduction of pleural effusion

Timepoint
monthly

Method of measurement
Ultrasound of the pleural space

Secondary outcomes

1

Description
Reduce dyspnea and cough

Timepoint
One week after pleural effusion injection

Method of measurement
In this study, a data collection form (Checklist) will be used to collect data. This form consists of 4 main parts. In the first part, the demographic characteristics of patients, including age and sex, as well as the type of pleural effusion disease, which is benign and malignant, are recorded. In the second part, the form of thyroid and kidney enzymes are recorded before and after the intervention. In the third part of the form, the length of the follow-up period and the final outcome of the treatment, which includes the success of the treatment and the failure of the treatment, are recorded. Side effects and patient complaints including chest pain, fever, shortness of breath, hypotension, vision loss, and air leakage are recorded at the end of the form.

Intervention groups

1

Description
Intervention group:In this study, 20 patients received betadine in one step. 20 cc of 10% betadine is injected with 60 cc of normal saline and 5 cc of lidocaine and the catheter is removed and two weeks after betadine injection is removed with a needle. In the second group, we inject 10 cc of betadine along with 30 cc of normal

saline and 5 cc of lidocaine and hold the catheter. Two weeks later, we inject 10 cc of betadine with 30 cc of normal saline and 5 cc of lidocaine. Two hours after the injection, the catheter is closed and the position is changed, and after 2 hours, the catheter valve is opened again, and finally, after 24 hours, the catheter is removed, and the patients return two weeks later to remove the betadine. After the intervention, patients are cared for.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Afzalipour Hospital
Full name of responsible person
Faranak Salajegheh
Street address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences
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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
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Faranak Salajegheh
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
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Person responsible for updating data

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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
The clinical results obtained from the study are published in the article while maintaining the confidentiality of patient data.

When the data will become available and for how long
The information obtained from the test results will be published in the article no later than 12 months later.

To whom data/document is available
Academic and scientific researchers

Under which criteria data/document could be used
Academic and scientific researchers with the condition of maintaining the confidentiality of patients' information

From where data/document is obtainable
Email the responsible author

What processes are involved for a request to access data/document
After requesting in the email and confirmation of the researcher, the requested information will be sent via Orchid two weeks later.

Comments