

# 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 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

##### Email address

f.salajegheh@kmu.ac.ir

##### 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**

Emam Blv., Afzalipour Hospital

**City**

kerman

**Province**

Kerman

**Postal code**

7616913355

**Phone**

+98 34 3132 8325

**Email**

f.salajegheh@kmu.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Faranak Salajegheh

**Street address**

Emam Blv., Afzalipour Hospital

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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

**Street address**

Emam Blv., Afzalipou Hospital

**City**

Kerman

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**Postal code**

7616913355

**Phone**

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**Person responsible for scientific 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****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

**Street address**

Emam Blv., Afzalipour Hospital

**City**

Kerman

**Province**

Kerman

**Postal code**

7616913355

**Phone**

+98 34 3132 8325

**Email**

f.salajegheh@kmu.ac.ir

**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**