

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of 1 liter versus 1.5 liter therapeutic thoracentesis, in symptomatic malignant pleural effusion

#### Protocol summary

##### Summary

1.Objectives: Therapeutic thoracentesis is the first line treatment of symptomatic malignant pleural effusion. But there is no consensus on the amount of removed volume, required for maximum benefit. In this project we planned to compare the 1 liter versus 1.5 liter (both recommended by existing guidelines) therapeutic thoracentesis. 2.Design: The patients will be assigned randomly by research supervisor to one liter group or one and a half liter group (using random number table). The researcher, patient and technician responsible for spirometry will not be aware of the thoracentesis volume. 3.Setting and conduct: The patients with moderate to severe symptomatic malignant pleural effusion who require therapeutic thoracentesis will be assigned randomly to one or 1.5 liter group. In each group, the MRC breathlessness scale and modified Borg scale will be obtained and spirometry and six minute walk test will be performed just before thoracentesis. These objectives will also be performed within 24 hours after thoracentesis. 4.Participants including major eligibility criteria: Inclusion criteria: Malignant pleural effusion documented by positive cytology or pleural biopsy; Moderate to severe dyspnea; Moderate to severe pleural effusion on thoracic CT-scan Exclusion criteria: Age less than 18; Uncooperative patient; unstable hemodynamics and or severe distress; Intubated patients; chest tube insertion; Bleeding diathesis; Severe ascitis; Impaired mental status; Decompensated cardiac/renal/hepatic failure. 5.Intervention: Therapeutic thoracentesis (One liter or one and a half liter). 6.main outcome measures (variables): Lung volumes; MRC breathlessness scale; Modified Borg scale; Six minute walk test.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014120120024N1**

Registration date: **2015-01-05, 1393/10/15**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-01-05, 1393/10/15

##### Registrant information

###### Name

Soheil Peiman

###### Name of organization / entity

Tehran University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6693 9922

###### Email address

s-peiman@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Tehran University of Medical Sciences Floor 6, Central building of Tehran university of medical sciences, Ghods street, Keshavaez blv, Tehran

##### Expected recruitment start date

2014-11-01, 1393/08/10

##### Expected recruitment end date

2015-05-01, 1394/02/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of 1 liter versus 1.5 liter therapeutic

thoracocentesis, in symptomatic malignant pleural effusion

## Public title

Therapeutic thoracocentesis in malignant pleural effusion

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: 1. Known malignancy (documented by cytology or pleural biopsy) ; 2. Moderate to severe dyspnea (requiring therapeutic thoracocentesis); 3. Malignant pleural effusion is the most possible cause of symptoms; 4. Awake and cooperative patients; 5. Moderate to severe pleural effusion on thoracic Computed tomography scan (more than 3 cm in anterior-posterior of thoracic cage); Exclusion criteria: 1.Age less than 18 2. Uncooperative patient; 3. Toxic patients with unstable hemodynamics and or Severe distress; 4. Intubated patients; 5. Chest tube insertion; 6. Bleeding diathesis; 7. Severe ascitis; 8. Impaired mental status; 9. Decompensated cardiac/renal/hepatic failure.

## Age

From **18 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **32**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

##### Street address

6th floor,Vice Chancellor for Research, Tehran University of Medical Sciences central building, Keshavarz blvd. Ghods street.

##### City

Tehran

##### Postal code

## Approval date

2014-10-06, 1393/07/14

## Ethics committee reference number

130/1591

## Health conditions studied

### 1

#### Description of health condition studied

Malignant pleural effusion

#### ICD-10 code

J91

#### ICD-10 code description

Pleural effusion in conditions classified elsewhere

## Primary outcomes

### 1

#### Description

Lung volumes

#### Timepoint

Just before the thoracocentesis and again within 24 hours after it

#### Method of measurement

COSMED spirometer

### 2

#### Description

Severity of Dyspnea

#### Timepoint

Just before the thoracocentesis and again within 24 hours after it

#### Method of measurement

Modified Borg Dyspnea Scale

### 3

#### Description

Functional quality of dyspnea

#### Timepoint

Just before the thoracocentesis and again within 24 hours after it

#### Method of measurement

MRC breathlessness scale

### 4

#### Description

Arterial oxygen saturation of hemoglobin

#### Timepoint

Just before the thoracocentesis and again within 24 hours after it

#### Method of measurement

Pulse oximeter

### 5

#### Description

Exercise Induced Oxygen Desaturation

### Timepoint

Just before the thoracocentesis and again within 24 hours after it

### Method of measurement

6 minute walk test

## Secondary outcomes

### 1

#### Description

Duration of hospitalization

#### Timepoint

Discharge documents

#### Method of measurement

Days of admission

### 2

#### Description

Mortality within 28 days

#### Timepoint

28 days after Thoracentesis

#### Method of measurement

Documents note and/or telephone follow up

## Intervention groups

### 1

#### Description

One liter Therapeutic Thoracentesis after topical anesthesia and sterilization by posterior inter-costal approach

#### Category

Treatment - Other

### 2

#### Description

One and a half liter Therapeutic Thoracentesis after topical anesthesia and sterilization by posterior inter-costal approach

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imamkhomeini hospital, Tehran University of Medical Sciences

##### Full name of responsible person

Dr. Soheil Peiman

##### Street address

Gharib Street, End of Keshavarz blvd.

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

##### Full name of responsible person

Dr Ali Javad Mousavi

##### Street address

6th Floor, Central organization of Tehran university of medical sciences, Ghods street, Keshavaez blv, Tehran Tehran

##### City

Tehran

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Vice chancellor for research, Tehran University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

*empty*

#### Domestic or foreign origin

*empty*

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Department of Internal medicine, Tehran university of medical sciences

##### Full name of responsible person

Dr. Soheil Peiman

##### Position

Assistant professor

##### Other areas of specialty/work

##### Street address

Dr Nafissi's Building, Imamkhomeini hospital complex, Keshavarz blvd.

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+98 21 6693 9922

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##### Web page address

<http://www.tums.ac.ir/faculties/s-peiman>

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*