

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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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 committe 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 Desatratlon

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

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Position

Assistant professor

Other areas of specialty/work**Street address**

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Full name of responsible person

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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