Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of 1 liter versus 1.5 liter therapeutic thoracocentesis, 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 thoracocentesis (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

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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 Desaturatlon

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
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Gharib Street, End of Keshavarz blvd.
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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
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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

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Name of organization / entity
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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