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Study Identification

Unique Protocol ID:	ASHassaballaMD
Brief Title:	Pleural Manometry in Thoracocentesis
Official Title:	Pleural Manometry During Thoracocentesis in Patients With Malignant Pleural Effusion: How Much Fluid Should we Drain?
Secondary IDs:	

Study Status

Record Verification:	March 2022
Overall Status:	Completed
Study Start:	July 1, 2019 [Actual]
Primary Completion:	December 31, 2021 [Actual]
Study Completion:	December 31, 2021 [Actual]

Sponsor/Collaborators

Sponsor:	Aly Sherif Hassaballa
Responsible Party:	Sponsor-Investigator Investigator: Aly Sherif Hassaballa [ashassaballa] Official Title: Clinical Professor Affiliation: Ain Shams University
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: FWA00017585 Board Name: Research Ethics Committee Board Affiliation: Faculty of Medicine, Ain Shams University Phone: 01066789189 Email: research_ethical_committe@med.asu.edu.eg Address: Abbasia, Cairo

Data Monitoring:	No
FDA Regulated Intervention:	No

Study Description

Brief Summary:	The study aiming to measure the pleural pressure during thoracocentesis in patients with pleural effusion and the value of their measurement in both diagnostic and therapeutic decisions.
Detailed Description:	This prospective controlled trial study will be performed between July 2019 and December 2020. the investigators will enroll patients with large volume pleural effusion referred to our Cardiothoracic Department, Faculty of Medicine, Ain Shams University to perform therapeutic thoracentesis. All the patients will sign an informed consent for pleural pressure monitoring during and after therapeutic thoracentesis. The study aiming to measure the pleural pressure during thoracocentesis in patients with pleural effusion and the value of their measurement in both diagnostic and therapeutic decisions.

Conditions

Conditions:	Thoracocentesis of Pleural Effusion
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Diagnostic
Study Phase:	N/A
Interventional Study Model:	Parallel Assignment This prospective controlled trial study will be performed between August 2019 and August 2020. We will enroll patients with large volume pleural effusion referred to our Cardiothoracic Department, Faculty of Medicine, Ain Shams University to perform therapeutic thoracentesis. All the patients will sign an informed consent for pleural pressure monitoring during and after therapeutic thoracentesis.
Number of Arms:	2
Masking:	None (Open Label)
Allocation:	Randomized
Enrollment:	110 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Manometer Group Therapeutic thoracentesis will be performed in a sitting position. wide bore catheter as a pleural catheter will be inserted into the pleural cavity. simple water manometer will be connected to the pleural catheter via 3-way adapter.connected to the infusion lines with	Diagnostic Test: Pleural Manometry Recording pleural pressure during therapeutic thoracocentesis using a simple water manometer.

Arms	Assigned Interventions
one draining into the drainage collection bottle and the other pre-flushed with normal saline hanging down till 40 cm below the puncture site and then rising up (forming a “U”) with the ascending arm taped to the IV stand. baseline pleural pressure will be registered before the beginning of pleural fluid withdrawal. Pleural pressure curve will subsequently be registered after the withdrawal of each 200 ml of pleural fluid up to a total volume of 1000 ml.	
No Intervention: Conventional Group Therapeutic thoracentesis will be performed in a sitting position. The skin will be cleaned with betadine antiseptic solution. Pleural aspiration should take place in a clean area using full aseptic techniques. 5–10 cc Lidocaine 2% will be given as local anesthetic in the site of puncture. the IV cannula is advanced till fluid is aspirated. Then, the needle is withdrawn and the catheter is fixed to two 3-way adapters fixed in series placed in between. connected to the infusion lines with one draining into the drainage collection bottle.	

Outcome Measures

Primary Outcome Measure:

1. the pleural pressure
   To measure the pleural pressure(mmHg) during thoracocentesis in patients with pleural effusion using a simple water pleural manometer

   [Time Frame: Continous monitoring during the whole session of thoracocentesis]

Eligibility

Minimum Age:	18 Years
Maximum Age:	85 Years
Sex:	All
Gender Based:	No
Accepts Healthy Volunteers:	Yes
Criteria:	Inclusion Criteria:

1. age between 18 and 85 years,
2. pleural effusion occupying at least one-third of the ipsilateral hemithorax in P-A chest radiograph (CXR)
3. no contraindications for therapeutic thoracentesis
4. general health condition allowing prolonged procedure of therapeutic thoracentesis.

Exclusion Criteria:

- patients with very small amounts of pleural effusion
- patients on mechanical ventilation
- patients using anticoagulant therapy
- patients refusing to be subjected to thoracocentesis.

Contacts/Locations

Central Contact Person: Aly S Hassaballa, Ms.c
Telephone: +201066789189
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Central Contact Backup:

Study Officials: NOTE : Study Official is required by the WHO and ICMJE.

Locations: **Egypt**
Cardiothoracic Surgery Hospital, Faculty of Medicine, Ain Shams University
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IPDSharing

Plan to Share IPD: No

References

Citations:

Links:

Available IPD/Information: