Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

SMALL BORE CATHETER VERSUS WIDE BORE CHEST TUBE IN THE MANAGEMENT OF MALIGNANT PLEURAL EFFUSION

Protocol summary

Study aim
To measure the effectiveness of small and large size chest drains on patient outcomes in malignant pleural effusion.

Design
Two intervention groups, eight patients to be randomly assigned to each group via Microsoft Excel, a single center, parallel, non-blinded randomized controlled trial.

Settings and conduct
The trial will be conducted in the pulmonology ward of a teaching hospital. Two groups of eight patients will be intubated with a small bore catheter and a large bore chest tube respectively. This trial is not blinded as the investigator and the patient both can see the size of the chest drain.

Participants/Inclusion and exclusion criteria
Only patients with malignant pleural effusion are included. Patients with hydropneumothorax, pneumothorax, and empyema thoracis are excluded.

Intervention groups
Two groups. The first group will be inserted with a small bore chest catheter. The second group will be inserted with a large bore chest tube.

Main outcome variables
Primary outcome: Duration of chest drain and hospitalization. Secondary outcome: Pain score during the course of intubation.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231105059962N1**
Registration date: **2023-11-09, 1402/08/18**
Registration timing: **prospective**

Last update: **2023-11-09, 1402/08/18**
Update count: **0**

Registration date
2023-11-09, 1402/08/18

Registrant information

Name
Ahmed Uzair

Name of organization / entity
Sahiwal medical college and allied teaching hospital Sahiwal

Country
Pakistan

Phone
+92 40 4502470

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rollno225@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-01, 1402/09/10

Expected recruitment end date
2024-03-01, 1402/12/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
SMALL BORE CATHETER VERSUS WIDE BORE CHEST TUBE IN THE MANAGEMENT OF MALIGNANT PLEURAL EFFUSION

Public title
Effect of different chest drain size in management of malignant pleural effusion

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Malignant pleural effusion

Exclusion criteria:

Hydropneumothorax Pneumothorax Empyema thoracis

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **16**

Randomization (investigator's opinion)

Randomized

Randomization description

- Simple method of randomization. - Unit of randomization is individual or patient. - A table of random numbers to be used for randomization. - Random sequence to be built by Microsoft Excel. - Allocation concealment was not carried out.

Blinding (investigator's opinion)

Not 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 Sahiwal medical college, STH and allied teaching hospitals, Sahiwal-57000, Pakis

Street address

Sahiwal medical college, college road, Sahiwal.

City

Sahiwal

Postal code

57000

Approval date

2023-11-01, 1402/08/10

Ethics committee reference number

81/IRB/SLMC/SWL

Health conditions studied

1

Description of health condition studied

Malignant pleural effusion

ICD-10 code

C78.2

ICD-10 code description

Secondary malignant neoplasm of pleura

Primary outcomes

1

Description

Duration of chest drain and hospitalization.

Timepoint

After the intervention until the improvement of clinical symptoms.

Method of measurement

Clinical assessment and radiology.

Secondary outcomes

1

Description

Pain during the course of intubation.

Timepoint

After the intervention until removal of chest drain.

Method of measurement

1-10 pain scoring by the patient.

Intervention groups

1

Description

Intervention group: Intervention group one will include eight patients with histology proved malignant pleural effusion. They will be intubated with a small bore chest catheter for symptomatic management and upon adequate drainage of pleural fluid for pleurodesis. Catheter will be kept in place until adequate drainage of the effusion. Aim is to define the patient outcomes in terms of duration of chest drain and hospitalization.

Category

Treatment - Devices

2

Description

Intervention group: Intervention group two will include eight patients with histology proved malignant pleural effusion. They will be intubated with large bore chest tubes for symptomatic management and upon adequate drainage of pleural fluid for pleurodesis. Chest tube will be kept in place until adequate drainage of the effusion. Aim is to define the patient outcomes in terms of duration of chest drain and hospitalization.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Sahiwal teaching hospital Sahiwal
Full name of responsible person
Ahmed Uzair
Street address
TB ward Sahiwal teaching hospital Sahiwal
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sahiwal medical college Sahiwal
Full name of responsible person
Muhammad Imran Hassan Khan
Street address
Sahiwal medical college, college road, Sahiwal
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slmcswl@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sahiwal medical college Sahiwal
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
Sahiwal medical college and allied teaching hospital Sahiwal
Full name of responsible person
Ahmed Uzair
Position
Medical Officer
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
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Person responsible for updating data

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available