

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Email address

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

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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 scientific inquiries

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Sahiwal

Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

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Sahiwal

Full name of responsible person

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Position

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Latest degree

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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