Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of two different methods of pleural space catheter insertion on its consequences in critical care patients with and without ultrasound guidance: A clinical trial

Protocol summary

Study aim

Determining the effect of two different catheterization methods on outcomes with and without ultrasound guidance in critically ill intensive care patients

Design

Randomized controlled clinical trial, 68 patients

Settings and conduct

After receiving the code of ethics, the researcher will first be trained for one month under the supervision of a specialist so that he can independently insert a catheter into the patient. Initially, eighty patients will be selected, and after the researcher's training period, their number will increase to sixty-eight. During this period, the number of patients will not be included in the study. The patients' medical history will be reviewed, and all patients will undergo examinations including coagulation status and chest x-ray before and after the operation. The patient in the control group will undergo catheterization without ultrasound guidance and the patient in the experimental group will undergo catheterization with ultrasound guidance. After the catheter is inserted, its location will be confirmed with ultrasound and a chest x-ray will also be taken. Then, patients are monitored for complications and, according to the established goals, primary and secondary outcomes in patients are examined.

Participants/Inclusion and exclusion criteria

• Inclusion criteria: 1. Admission to the intensive care unit 2. Presence of pleural effusion • Exclusion criteria: 1. Patients with clinical instability 2. Presence of coagulopathy 3. Infection at the catheter site 4. Patient dissatisfaction

Intervention groups

Control group: Pleural catheter insertion without ultrasound guidance Intervention group: Pleural catheter insertion with ultrasound guidance

Main outcome variables

Fluid drainage rate, bleeding, infection, number of attempts, pneumothorax, length of ICU stay, length of ventilator dependency

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240925063165N1**
Registration date: **2025-01-23, 1403/11/04**
Registration timing: **registered_while_recruiting**

Last update: **2025-01-23, 1403/11/04**
Update count: **0**

Registration date

2025-01-23, 1403/11/04

Registrant information

Name

Zahra Fakhra

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 81261

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-21, 1403/10/01

Expected recruitment end date

2025-05-22, 1404/03/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of two different methods of pleural space catheter insertion on its consequences in critical care patients with and without ultrasound guidance: A clinical trial

Public title
The effect of ultrasound on pleural catheter placement
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Intensive care unit admission Presence of pleural effusion Adult
Exclusion criteria:
Patient with clinical instability Presence of coagulopathy Infection of catheterization site Patient's unconsent
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
After obtaining ethical approval and coordination with the head nurse and the intensive care unit officials, patients will be selected according to the inclusion criteria. Then, if they are conscious, the patient or their legal guardian will be spoken to and with informed written consent, the patients will be separated based on the random allocation method. In order to randomly allocate to the two experimental and control groups, a block randomization method with blocks of four was used. In this way, the experimental group was assigned to B and the control group to A, and in blocks of four with the letters A and B, six cases ABBA, AABB, ABAB, BABA,BBAA, BAAB were written on separate sheets of paper and dropped into a container. One of these sheets was randomly taken out of the container and the combination written on it was written down and that sheet was dropped into the container again. Since the sample size in this study is 68 patients, this operation was repeated seventeen times and each time the combination written on each sheet was recorded in the sequence of the combination written on the previous sheet. Then, each letter was assigned a number from one to sixty-eight in the order of the letters written down in a row, and each letter was placed in an envelope and its number was written on the envelope. Each time a patient was selected, one of these envelopes was opened in the order of the number written on the envelope, and it was determined whether the patient should be placed in the experimental or control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, patient blinding was implemented. This means that the patients were unaware of the treatment method (whether ultrasound-guided or non-ultrasound guided) they received. The anesthesiologist performing the catheter insertion was aware of the treatment assigned to each patient, but no bias influenced the execution of the procedure. Additionally, to avoid potential researcher bias, all clinical assessments and data collection were performed without knowledge of the treatment group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Baqiyatallah University of Medical Sciences
Street address
Baqiyatallah Al'Azam Hospital, after Sheikh Bahayi, Mulla Sadra Street, Vanak Squareanak Square
City
Tehran
Province
Tehran
Postal code
1435916471
Approval date
2024-02-03, 1402/11/14
Ethics committee reference number
IR.BMSU.BAQ.REC.1402.093

Health conditions studied

1

Description of health condition studied
Pleural effusion
ICD-10 code
J91
ICD-10 code description
Pleural effusion in conditions classified elsewhere

Primary outcomes

1

Description
The rate of fluid drainage from the pleural catheter
Timepoint
After catheter insertion
Method of measurement
The amount of fluid removed from the catheter

2

Description
Bleeding
Timepoint
One day
Method of measurement
Number of sterile gauzes

3

Description
Infection
Timepoint
One day after catheter insertion
Method of measurement
Positive pleural fluid culture after catheter insertion

4

Description
Number of attempts
Timepoint
During catheter insertion
Method of measurement
Counting times

5

Description
Pneumothorax
Timepoint
After catheter insertion
Method of measurement
Chest X ray

6

Description
Length of stay in the ICU
Timepoint
From admission to discharge from ICU
Method of measurement
Counting the number of days

7

Description
Duration of ventilator dependency
Timepoint
Time to wean from ventilator
Method of measurement
Counting days

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Without ultrasound guide
Category
Treatment - Devices

2

Description
Intervention group: With ultrasound guidance
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah hospital
Full name of responsible person
Zahra Fakhra
Street address
Baqiyatallah Al'Azam Hospital, after Sheikh Bahayi, Mulla Sadra Street, Vanak Squareanak Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Ali Bahramifar
Street address
South Sheikh Bahai Street, Mulla Sadra Street, Vanak Square, Tehran
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Bagheiat-allah University of Medical Sciences

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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Zahra Fakhra

Position

Anesthesiology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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General operation room, 2th floor, Baqiyatallah Al'Azam Hospital, after Sheikh Bahayi, Mulla Sadra Street, Vanak Square, Tehran

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information available.Protecting patient privacy and ensuring the security of their medical information are among our primary priorities. Furthermore, in accordance with data protection laws and ethical guidelines, the release of these data could lead to breaches of patient privacy. Additionally, not sharing IPD is a practical decision due to the technical complexities and high costs associated with data processing and anonymization, as well as security considerations.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available