Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the efficacy and complications of chest tube removal in trauma patients ventilated and isolated from mechanical ventilation admitted to the Shahid Jalil Yasuj Intensive Care Unit: An interventional study - randomized clinical trial

Protocol summary

Study aim

Investigating the efficacy and complications of chest tube removal in trauma patients ventilated and isolated from mechanical ventilation admitted to the ICU

Design

This is a single-center interventional clinical study conducted at Jalil Hospital in Yasuj, including a total of 64 patients. Participants will be randomly assigned to two groups: an intervention group (Group A) and a control group (Group B). Randomization will be performed using a block randomization method with varying block sizes to ensure balanced allocation between the groups.

Settings and conduct

This trial will be conducted in the ICU setting where eligible trauma patients requiring both mechanical ventilation and thoracostomy will be enrolled. Participants will be randomly allocated to either the intervention group or the control group through block randomization with variable block sizes to ensure balanced distribution. The study will not use any form of blinding. All trial procedures will follow standardized clinical protocols to ensure consistency in conduct and data collection.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Traumatic patients of all ages admitted to the ICU of Jalil Hospital who are simultaneously undergoing mechanical ventilation and thoracostomy. Exclusion criteria: Non-traumatic patients; patients with underlying pulmonary diseases; patients with a history of thoracotomy surgery for any reason prior to the trauma; pregnant women.

Intervention groups

removing chest tube while patients are under mechanical ventilation.

Main outcome variables

Occurrence of pneumothorax, hemothorax, hemopneumothorax, air leak, pleural effusion, and empyema after removal of the chest tube.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250627066277N2**
Registration date: **2026-04-30, 1405/02/10**
Registration timing: **prospective**

Last update: **2026-04-30, 1405/02/10**
Update count: **0**

Registration date

2026-04-30, 1405/02/10

Registrant information

Name

Saadat Mehrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3333 7001

Email address

dr.s.meh544@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-05-31, 1405/03/10

Expected recruitment end date

2026-08-01, 1405/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy and complications of chest tube removal in trauma patients ventilated and isolated from mechanical ventilation admitted to the Shahid Jalil Yasuj Intensive Care Unit: An interventional study - randomized clinical trial

Public title

chest tube removal in trauma patients ventilated and isolated from mechanical ventilation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Traumatic patients of all ages admitted to the ICU of Jalil Hospital patients simultaneously undergoing mechanical ventilation and thoracostomy

Exclusion criteria:

Non-traumatic patients Patients with underlying pulmonary conditions Patients who had a history of thoracotomy surgery prior to the trauma for any reason. Pregnant women

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation of participants to the study groups will be performed using the block randomization method. The advantage of blocked randomization is that it ensures balance in the number of patients in each group. The groups will be defined using the codes A and B, with group A considered the intervention group and group B the control group. Before assigning individuals to one of the groups, a list of letters (A, B), representing the blocks, will be generated. This random allocation list will be created using the reputable website https://www.sealedenvelope.com. Each eligible and enrolled participant will be assigned to one of the groups according to the generated list. To prevent the risk of predictability of group assignments, blocks of varying sizes (2, 4, 6, and 8) will be created. Examples of blocks include: Two-unit block: AB Four-unit block: ABAB Six-unit block: AABABB Eight-unit block: ABBABABA

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 Yasuj University of Medical Sciences

Street address

Shahid Motahhari Blvd

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

74934-75918

Approval date

2025-06-19, 1404/03/29

Ethics committee reference number

IR.YUMS.REC.1404.063

Health conditions studied

1

Description of health condition studied

Traumatic Pneumothorax

ICD-10 code

S27.0

ICD-10 code description

Traumatic pneumothorax

2

Description of health condition studied

Traumatic hemothorax

ICD-10 code

S27.1

ICD-10 code description

Traumatic hemothorax

Primary outcomes

1

Description

pneumothorax

Timepoint

after intervention

Method of measurement

chest xray

2

Description
hemothorax
Timepoint
after intervention
Method of measurement
chest xray

3

Description
Pleural Effusion
Timepoint
after intervention
Method of measurement
chest xray

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, before the patient is extubated, if the necessary criteria for removing the chest tube are met, the chest tube will be clamped for 6 hours, during which the patient will be closely monitored. A second radiograph will be taken after 6 hours, and if no clinical or radiographic complications are present, the chest tube will be removed, taking all technical and ethical considerations into account.
Category
Treatment - Devices

2

Description
In the control group, after the patient is extubated, if the necessary criteria for removing the chest tube are met, the chest tube will be clamped for 6 hours, during which the patient will be closely monitored. A second radiograph will be taken after 6 hours, and if no clinical or radiographic complications are present, the chest tube will be removed, taking all technical and ethical considerations into account.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Jalil Hospital
Full name of responsible person
Saadat Mehrabi
Street address
Shahid Gharani Blvd
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Postal code
74934-75918
Phone
+98 74 3333 7001
Email
shahidjalil@yums.ac.ir
Web page address
https://shahidjalil.yums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Sirous Saleh Nasab
Street address
Shahid Motahhari Blvd.
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Kohgilouyeh-va-Boyrahmad
Postal code
94799-75919
Phone
+98 74 3334 6078
Email
research@yums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasouj 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
Yasouj University of Medical Sciences
Full name of responsible person
Saadat Mehrabi
Position
Associate professor

Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
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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
Our study data will be available upon reasonable request.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Our study data will be available upon reasonable request.
When the data will become available and for how long
Our data will be available after September 2026.
To whom data/document is available
Data will be available for people working in academic institutions.
Under which criteria data/document could be used
Researchers can use the data to perform meta-analysis.
From where data/document is obtainable
Data will be available via the Corresponding author's email.
What processes are involved for a request to access data/document
Researchers must send their institution's information and the reason they need the data.
Comments