

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Recruitment complete

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

Kohgiluyeh-va-Boyerahmad

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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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

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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

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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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

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