

# 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

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

#### 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,

#### 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**  
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

#### **City**

Yasuj

#### **Province**

Kohgilouyeh-va-Boyerahmad

#### **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.

##### **City**

Yasuj

##### **Province**

Kohgilouyeh-va-Boyerahmad

##### **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  
**Street address**  
Shahid Motahhari Blvd  
**City**  
Yasuj  
**Province**  
Kohgiluyeh-va-Boyr Ahmad  
**Postal code**  
74934-75918  
**Phone**  
+98 917 141 2552  
**Email**  
Dr.s.meh544@gmail.com

## Person responsible for scientific 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  
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**Email**  
Dr.s.meh544@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Yasouj University of Medical Sciences  
**Full name of responsible person**  
Saadat Mehrabi  
**Position**  
Associate professor  
**Latest degree**

Medical doctor  
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Dr.s.meh544@gmail.com

## 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