# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Comparison of the Effectiveness of Ultrasound-Guided Versus Anatomical Landmark-Guided Percutaneous Dilatational Tracheostomy in Intensive Care Unit Patients

## Protocol summary


**Study aim**

compare the effectiveness and safety of ultrasound-guided percutaneous dilatational tracheostomy with the conventional landmark-based technique in ICU patients.

**Design**

This study was a randomized, open-label comparative study conducted in 70 ICU patients. The participants were allocated into two equal groups of 35 patients each: an ultrasound-guided percutaneous dilatational tracheostomy group and a conventional landmark-based tracheostomy group.

**Settings and conduct**

This study was conducted in the intensive care units of Qaem and Emam Reza educational, research, and treatment hospitals affiliated with Mashhad University of Medical Sciences. Eligible patients underwent percutaneous dilatational tracheostomy at the bedside under continuous monitoring of ECG, oxygen saturation, and blood pressure after informed consent was obtained.

**Participants/Inclusion and exclusion criteria**

Inclusion Criteria: • Critically ill patients requiring tracheostomy due to prolonged mechanical ventilation, airway obstruction, or other medical indications. • Age ≥18 years. • Patients with stable vital signs and acceptable laboratory values (e.g., normal platelet count, no active infection at the insertion site). • Patients who are expected to remain in the hospital for a minimum of 48 hours after the procedure. Exclusion Criteria: • Patients with coagulopathies (e.g., anticoagulation therapy that cannot be stopped before the procedure). • Patients with anatomical deformities of the neck (e.g., extensive scarring from prior surgeries, tumors, or trauma) that preclude either technique. • Pregnant women or patients who are unable to provide informed consent.

**Intervention groups**

The intervention group consisted of patients who underwent ultrasound-guided percutaneous dilatational tracheostomy.

**Main outcome variables**

Overall procedural success


## General information

**Reason for update**

**Acronym**

CEULPDT

**IRCT registration information**

IRCT registration number: **IRCT20260803070511N1**
Registration date: **2026-08-09, 1405/05/18**
Registration timing: **prospective**

Last update: **2026-08-09, 1405/05/18**
Update count: **0**

**Registration date**

2026-08-09, 1405/05/18

**Registrant information**


**Name**

Saeed Jamshidi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 915 315 5196

**Email address**

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**Recruitment status**

**Not yet recruiting**

**Funding source**

**Expected recruitment start date**

2027-09-05, 1406/06/14

**Expected recruitment end date**

2028-10-06, 1407/07/15

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparison of the Effectiveness of Ultrasound-Guided Versus Anatomical Landmark-Guided Percutaneous Dilatational Tracheostomy in Intensive Care Unit Patients

**Public title**
Comparison of the Effectiveness of Ultrasound-Guided Versus Anatomical Landmark-Guided Percutaneous Dilatational Tracheostomy
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
• Critically ill patients requiring tracheostomy due to prolonged mechanical ventilation, airway obstruction, or other medical indications. • Age ≥18 years. • Patients with stable vital signs and acceptable laboratory values (e.g., normal platelet count, no active infection at the insertion site). • Patients who are expected to remain in the hospital for a minimum of 48 hours after the procedure.
**Exclusion criteria:**
Patients with coagulopathies (e.g., anticoagulation therapy that cannot be stopped before the procedure).• Patients with anatomical deformities of the neck (e.g., extensive scarring from prior surgeries, tumors, or trauma) that preclude either technique.• Pregnant women or patients who are unable to provide informed consent.
**Age**
From **18 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **70**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
After assessment of the eligibility criteria and obtaining informed consent, eligible patients were randomly assigned in a 1:1 ratio to one of the two study groups: the intervention group, in which percutaneous dilatational tracheostomy was performed under ultrasound guidance, and the control group, in which the procedure was performed using the standard anatomical landmark-based technique. The unit of randomization was the individual patient, and no cluster randomization was applied. To maintain balance between the two groups, block randomization was used. The random allocation sequence was generated before patient enrollment using statistical software. No stratified randomization was performed; therefore, patients were not stratified according to variables such as age, sex, or disease severity. To ensure allocation concealment, the randomization sequence was placed in sequentially numbered, opaque, sealed envelopes. After confirming patient eligibility and obtaining informed consent, the next envelope in sequence was opened, and the assigned study group was revealed. This process prevented prediction of group assignment before final enrollment.
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**
The main objective of this study was to compare the effectiveness and safety of ultrasound-guided percutaneous dilatational tracheostomy with the conventional landmark-based technique in ICU patients.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Mashhad University of Medical Sciences
**Street address**
No 11 Honarestan 25
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
9178746936
**Approval date**
2026-08-03, 1405/05/12
**Ethics committee reference number**
IR.MUMS.MEDICAL.REC.1405.156

## Health conditions studied

### 1

**Description of health condition studied**
Percutaneous dilatational tracheostomy Ultrasound-guided tracheostomy Anatomical landmark-based tracheostomy Prolonged mechanical ventilationTracheostomy-related complications
**ICD-10 code**
Z93.0 J95.
**ICD-10 code description**
Z93.0 — Tracheostomy status Z99.1 — Dependence on respirator J96.0 — Acute respiratory failure J95.0 —

Tracheostomy complications

## Primary outcomes

### 1

**Description**
First Sucess rate
**Timepoint**
The procedure duration was measured in minutes, from the initiation of needle puncture until the appearance of the ventilator waveform (i.e., confirmation of effective ventilation
**Method of measurement**
Overall success was defined as successful completion of the tracheostomy procedure with correct placement of the tracheostomy tube in the appropriate position.

## Secondary outcomes

### 1

**Description**
Procedure time
**Timepoint**
The procedure duration was measured in minutes, from the initiation of needle puncture until the appearance of the ventilator waveform (i.e., confirmation of effective ventilation).
**Method of measurement**
confirmation of effective ventilation

## Intervention groups

### 1

**Description**
Intervention group: Patients underwent ultrasound-guided PDT, in which bedside ultrasound was used to identify tracheal rings, determine the optimal puncture site, measure skin-to-trachea distance, and avoid vascular or thyroid injury. Needle puncture was performed under static or real-time ultrasound guidance, followed by guidewire insertion.
**Category**
Treatment - Other

### 2

**Description**
Control group: Control group: Patients underwent conventional landmark-guided PDT based on palpation of anatomical landmarks without ultrasound assistance.
**Category**
Treatment - Other

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Ghaem Hospital Mashhad
**Full name of responsible person**
Dr Saeed Jamshidi
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Ahmad Abad Street
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Deputy of Research and Technology, Mashhad University of Medical Sciences
**Full name of responsible person**
Dr Zahra Meshkat
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**Grant name**
N/A
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Deputy of Research and Technology, Mashhad 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**
Mashhad University of Medical Sciences
**Full name of responsible person**
DR Saeed Jamshidi
**Position**
Resident
**Latest degree**
Specialist
**Other areas of specialty/work**
Anesthesiology
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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resident
**Latest degree**
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**Other areas of specialty/work**
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**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**
Yes - There is a plan to make this available
**Data Dictionary**
Yes - There is a plan to make this available
**Title and more details about the data/document**
Only part of the data, such as information related to the primary outcome or similar data, can be shared.
**When the data will become available and for how long**
from 2026
**To whom data/document is available**
Only for researchers affiliated with academic institutions.
**Under which criteria data/document could be used**
Only for researchers affiliated with academic institutions.
**From where data/document is obtainable**

Jamshidi_saeed@yahoo.com

**What processes are involved for a request to access data/document**

Via the provided email address.

**Comments**

None