

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

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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.

AgeFrom **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

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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 ventilation Tracheostomy-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 —

Primary outcomes

1

Description

First Success 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 updating data**Contact****Name of organization / entity**

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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