

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of applying an ice pack to the trachea before extubation on post-extubation complications in ICU patients: A randomized controlled trial

Protocol summary

Study aim

The impact of tracheal ice pack application on post-extubation outcomes in ICU patients: A randomized controlled trial.

Design

A clinical trial with a control group, double-blind, randomized using a table of numbers will be conducted on 106 patients.

Settings and conduct

The study enrolled 106 patients who were intubated for more than 72 hours and admitted to the intensive care unit of Shahid Bahonar Hospital in Kerman in 2024. The outcome assessors and the investigator were blinded after the registration form was completed. The intervention group received standard care plus tracheal ice pack application for two hours before extubation, while the control group received only standard care. The patients were followed up at 2, 6, and 24 hours after discharge and assessed for level of consciousness, cough, hoarseness, sore throat, stridor, re-intubation, and non-invasive ventilation (NIV).

Participants/Inclusion and exclusion criteria

The inclusion criteria for the study are: willingness to participate in the research. The exclusion criteria also include: patient with cough or hoarseness before surgery, presence of airway anomaly, history of previous tracheal surgery, trauma or neck surgery, previous tracheostomy, history of asthma and COPD and respiratory diseases.

Intervention groups

The intervention group received standard care plus tracheal ice pack application for two hours before extubation, while the control group received only standard care.

Main outcome variables

Average voice severity score; Average cough score; M; Average sore throat score; Frequency of stridor;

Frequency of Non-invasive ventilation (NIV) use

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120922010900N6**

Registration date: **2024-04-29, 1403/02/10**

Registration timing: **registered_while_recruiting**

Last update: **2024-04-29, 1403/02/10**

Update count: **0**

Registration date

2024-04-29, 1403/02/10

Registrant information

Name

Hosein Sattari

Name of organization / entity

kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 34 1322 2250

Email address

sattari@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2025-02-19, 1403/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of applying an ice pack to the trachea before extubation on post-extubation complications in ICU patients: A randomized controlled trial

Public title
Applying an ice pack to the trachea before extubation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Intubated people hospitalized in the intensive care unit
Exclusion criteria:
Coughing or harshness of voice before surgery Airway anomaly Previous tracheal surgery history Trauma or neck surgery Previous tracheostomy History of asthma and COPD and respiratory diseases

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target sample size: **106**

Randomization (investigator's opinion)
Randomized

Randomization description
After selecting the patients, the block randomization method with 4, 6, and 8 block sizes (with SPSS software) will be used to assign people to two groups. will be. In this method, each person is assigned a unique code and it will help the blinding process. They will be placed in one of the intervention (53 patients) and control (53 patients) groups

Blinding (investigator's opinion)
Double blinded

Blinding description
The study was blinded for the outcome assessors and the investigator, but not for the patient caregivers who were aware of the group assignments.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Afzalipour Hospital- Kerman University of Medical Sciences
Street address
Afzalipour Hospital
City
Kerman
Province
Kerman
Postal code
7616913355
Approval date
2023-10-09, 1402/07/17
Ethics committee reference number
IR.KMU.AH.REC.1402.116

Health conditions studied

1

Description of health condition studied
Intubated patient in the intensive care unit
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Need or lack of non-invasive ventilation
Timepoint
At 2, 6, and 24 hours post-extubation
Method of measurement
observation

2

Description
Hoarseness
Timepoint
At 2, 6, and 24 hours post-extubation
Method of measurement
Based on the criterion of voice violence questionnaire

3

Description
Cough
Timepoint
At 2, 6, and 24 hours post-extubation
Method of measurement
Based on the criteria of the cough questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: In addition to common treatments, which include the use of a T-tube, Continuous Positive Airway Pressure (CPAP), Synchronized Intermittent Mandatory Ventilation (SIMV), and pressure support methods, a cold compress is applied using ice in a bag placed over the skin of the neck area. This extends from the distal mandible to the sternal notch for a duration of 2 hours by a trained nurse, 2 hours prior to the extubation of the tracheal tube for patient

Category

Treatment - Other

2

Description

Control Group: The standard treatments prior to the separation of the patient from the tracheal tube, depending on the clinical conditions of the patients, may involve one or more methods. These include the use of a T-tube, Continuous Positive Airway Pressure (CPAP), Synchronized Intermittent Mandatory Ventilation (SIMV), and pressure support methods.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar Hospital

Full name of responsible person

Hossein Sattari

Street address

Shahid Bahonar Hospital

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7613747181

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Sattari@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Hosien Sattari

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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

Not applicable

Title and more details about the data/document

Primary outcome information will be shared after de-identification.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Employees in public and private scientific institutions

Under which criteria data/document could be used

Analysis on the data is not allowed

From where data/document is obtainable

Hossein Sattari by email Sattari@kmu.ac.ir

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

Immediately after the request

Comments