Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)
Phone
+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
City
Kerman
Province
Kerman
Postal code
7613747181
Phone
+98 34 3223 5011
Email
Sattari@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Hossein Sattari
Street address
Shahid Bahonar Hospital
City
Kerman
Province
Kerman
Postal code
7613747181
Phone
+98 34 3223 5011
Email
Sattari@kmu.ac.ir
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
Street address
Afzalipoor Hospital
City
Kerman
Province
Kerman
Postal code
7613747181
Phone
+98 34 1322 2250
Fax
Email
hosattatri@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Hoseyn Sattari
Position
Anesthesiologist
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Afzalipoor Hospital
City
Kerman
Province
Kerman
Postal code
7613747181
Phone
+98 34 1322 2250
Fax
Email
hosattatri@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Hoseyn Sattari
Position
Anesthesiologist
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Afzalipoor Hospital
City
Kerman
Province
Kerman
Postal code
7613747181
Phone
+98 34 1322 2250
Fax
Email
hosattatri@gmail.com
Web page address

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