Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison between the cough peak expiratory flow measurement and the cough strength measurement with white paper test on the success of extubation in ICU patients.

Protocol summary

Study aim
Comparison between the cough peak expiratory flow measurement and the cough strength measurement with white paper test on the success of extubation.

Design
Clinical trial with control and parallel group, without blinding, random assignment to groups is based on random sequence generated by SPSS software.

Settings and conduct
Intubated patients in the ICU of Imam Reza Hospital, are divided into two groups: control (routine) and intervention. In the control group, the cough strength of the patient is measured by observing the piece of white paper which is moistened after 3 coughs through the tracheal tube. In the intervention group, cough strength is measured quantitatively using the Bellavista 1000 ventilator. In both groups, 24 and 48 hours after extubation, patients are examined for re-intubation criteria.

Participants/Inclusion and exclusion criteria
Inclusion: Be alert based on RASS scale (0 or 1). between 18-60 years. Spontaneous breathing more than 30 minutes. Suctioning is required every two hours or more. Mechanical ventilation longer than 24 hours. Exclusion: Lack of co-operation or inability to cough, Symptoms of tracheal stenosis, Aspiration within 24 hours before extubation, Hearing or visual problems, Start sedative drugs for patient.

Intervention groups
In the intervention group, the cough strength will be quantitatively measured by the Ventilator Bellavista 1000/e. In the control, the cough strength is assessed by white paper test.

Main outcome variables
extubation success

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171224038028N1**
Registration date: **2018-07-07, 1397/04/16**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-07, 1397/04/16**
Update count: **0**

Registration date
2018-07-07, 1397/04/16

Registrant information

Name
Mohsen Abedini

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-14, 1397/02/24

Expected recruitment end date
2018-11-15, 1397/08/24

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison between the cough peak expiratory flow measurement and the cough strength measurement with white paper test on the success of extubation in ICU patients.

Public title
Comparison between the cough peak expiratory flow measurement and the cough strength measurement with white paper test on the success of extubation

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Be alert based on RASS scale (0 or 1) Be admitted in ICU with diagnosis of internal disease. Age between 18-60 years. Spontaneous breathing more than 30 minutes. Suctioning is required every two hours or more. Mechanical ventilation longer than 24 hours.

Exclusion criteria:
Lack of co-operation or inability to cough Exacerbation of the disease before extubation Mental disorders and delirium Tracheal stenosis Having a tracheostomy Aspiration within 24 hours before extubation Hearing problems (deaf, despite the use of auxiliary equipment) and visual problems. Start sedative drugs for patient.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment using random sequence generated by SPSS software is implemented to select patients for intervention and control group.

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 Mashhad University of Medical Sciences

Street address
Daneshgah Street

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Approval date
2018-05-05, 1397/02/15

Ethics committee reference number
IR.MUMS.REC.1397.041

Health conditions studied

1

Description of health condition studied
Respiratory failure, unspecified

ICD-10 code
J96.9

ICD-10 code description
Respiratory failure, unspecified

Primary outcomes

1

Description
Extubation success

Timepoint
24 and 48 hours after weaning

Method of measurement
Measuring blood oxygen saturation

Secondary outcomes

empty

Intervention groups

1

Description
The patient which is ready for extubation, is connected to the ventilator with supportive mode. Then he is asked to cough three times. In this case, the peek expiratory flow rate of these coughs is calculated by the Bellavista 1000 ventilator.

Category
Diagnosis

2

Description
Control group: Based on the routine method, for the patient which is ready for extubation, a piece of white paper is kept at a distance of 1-2 cm from the endotracheal tube. The patient is then asked to cough three times.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Razieh Froutan
Street address
Ebn-e-Sina Street, Imam Reza square.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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
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Position
Ms.C student
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Person responsible for updating data

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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
There is not a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available