

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 3527 4561

##### Email address

Abedinim951@mums.ac.ir

##### 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

## 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.

**City**

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**Postal code**

9137913316

**Phone**

+98 51 3854 3031

**Email**

froutanr@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

Daneshgah Street, Ghoreishi building.

**City**

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ramresearch@mums.ac.ir

**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**

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Abedini

**Position**

Ms.C student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

School of nursing, Ibn-e-sina street, Mashhad

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## Person responsible for scientific inquiries

### Contact

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**Latest degree**

Bachelor

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## Person responsible for updating data

### Contact

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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