# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Design, Implementation and Evaluation of a care program on outcomes of post extubation in patients admitted to the critical care unit.

## Protocol summary

**Study aim**
Compilation, implementation and evaluation of a care program on the outcomes after endotracheal tube removal in patients hospitalized in the special care department of selected hospitals of Isfahan University of Medical Sciences in 1403

**Design**
Two group in randomized trial with control group in 60 patient

**Settings and conduct**
Before the rextubation , the patient will be seen at the bedside for 48 hours, 1, 6, 12, 24, 48 hours, and the degree of complications will be measured.

**Participants/Inclusion and exclusion criteria**
1-Patients aged 18 and above. 2-Patients who have been under mechanical ventilation for at least 48 hours.

**Intervention groups**
Investigating the patient's ability to cough and release secretions, dysphagia and stridor in patients after tracheal tube removal

**Main outcome variables**
out come: stridor, dysphagia, reintubation

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20241222064129N1**
Registration date: **2025-01-19, 1403/10/30**
Registration timing: **registered_while_recruiting**

Last update: **2025-01-19, 1403/10/30**
Update count: **0**

**Registration date**
2025-01-19, 1403/10/30

**Registrant information**

**Name**
Fatemeh sadat احمدی

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 935 990 8835

**Email address**
fat.sdt.ahmadi@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2025-01-04, 1403/10/15

**Expected recruitment end date**
2025-03-20, 1403/12/30

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Design, Implementation and Evaluation of a care program on outcomes of post extubation in patients admitted to the critical care unit.

**Public title**
Design, Implementation and Evaluation of a care program on outcomes of post extubation in patients admitted to the critical care unit.

**Purpose**
Prevention

**Inclusion/Exclusion criteria**
**Inclusion criteria:**
1-Patients are 18 years old or older. 2-Patients who have been under mechanical ventilation for at least 48 hours.3.Patient that intubated due to each reason expect respiratory problem.

**Exclusion criteria:**
1.Dont like to continue the study2.The patient died3.unplanned extubation4.sever complications such as cardiorespiratory arrest, shock.

**Age**
From **18 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**
The random allocation of samples between two test and control groups will be done by minimization software, In this software you enter intervening variables on the results, samples will be assigned to the control and test groups. It means that the least significant difference in terms of intervening changes is between the two test and control groups.

**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**
Isfahan university of medical science

**Street address**
Hezar Jerib Ave, isfahan university of medical science

**City**
Isfahan

**Province**
Isfehan

**Postal code**
8174673461

**Approval date**
2024-12-03, 1403/09/13

**Ethics committee reference number**
IR.MUI.NUREMA.REC.1403.142

## Health conditions studied

### 1

**Description of health condition studied**
Extubation, post extubation stridor and dysphagia, reintubation

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**
and Evaluation of a care program on outcomes of post extubation

**Timepoint**
1,6,12,24,48 hour after extubation

**Method of measurement**
scoring scale

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: nebulizer therapy, cough assist

**Category**
Prevention

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Alzahra and kashani hospital

**Full name of responsible person**
Fateme sadat Ahmadi

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hezarjerib Ave. Isfahan university of medial science,nursing and midwife fculity

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**
Somaye Ghafari

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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**
Esfahan 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**
Esfahan University of Medical Sciences

**Full name of responsible person**
fateme sadat ahmadi

**Position**
student

**Latest degree**
Bachelor

**Other areas of specialty/work**
Nursery

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## Person responsible for scientific inquiries

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**Position**
professor

**Latest degree**
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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**
Dont Enough information

**Study Protocol**
No - There is not 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**

No - There is not 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