

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of humidifier therapy on postextubation complications in older people after coronary artery bypass surgery

#### Protocol summary

##### Study aim

The aim of this study is to evaluate the effect of humidifier therapy on postextubation complications in older people after coronary artery bypass surgery.

##### Design

Samples will be chosen from the patients admitted to Shaheed Rajaei hospital affiliated with Iran University of Medical Sciences. In this randomized controlled clinical trial, 80 patients will be randomly assigned to the experiment and control groups. The outcome assessor will be blinded to assigned the patients to groups.

##### Settings and conduct

This study will be done in intensive care unit of Shaheed Rajaei hospital affiliated with Iran University of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria included: age above of 60 years; the absence of any cognitive impairment; patients with first undergoing surgery coronary artery bypass; history of having respiratory disease or sore throat during the preceding week; lack of drug addiction; conscious patients; anesthesia duration between 4 and 6 hours; four to five hours operation time, having endotracheal tube between 6 to 8 hours after the end surgery. Exclusion criteria included: patient with no cooperation ; physician disagreement; re-intubation tracheal tube after extubation; intubation more than 30 seconds; attempt for intubation more than once, traumatizing trachea, report of difficult intubation, death of patient during the study, delay of extubation process.

##### Intervention groups

The intervening group, receive ward routine care and also cool mist using nebulizer . The intervention group receive cool mist for 45 minutes before extubation and 45 minutes after extubation (90 min. overall).In control group, the 45 elderly patients receive only ward routine care .

##### Main outcome variables

Nausea, hoarseness, sore throat, and cough are

measured immediately, 6,12,18, and 24 hrs. after extubation.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110912007529N18**

Registration date: **2018-10-19, 1397/07/27**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-10-19, 1397/07/27**

Update count: **0**

##### Registration date

2018-10-19, 1397/07/27

##### Registrant information

##### Name

Nahid Rejeh

##### Name of organization / entity

Shahed University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5121 3071

##### Email address

reje@shahed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

##### Expected recruitment end date

2019-05-22, 1398/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
The effect of humidifier therapy on postextubation complications in older people after coronary artery bypass surgery

**Public title**  
The effect of humidifier therapy on postextubation complications in older people

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
age above of 60 years, the absence of any cognitive impairment, patients with first undergoing surgery coronary artery bypass, history of having respiratory disease or sore throat during the preceding week, lack of drug addiction, conscious patients, Anesthesia duration between 4 to 6 hours, four to five hours operation time, having endotracheal tube between 6 to 8 hours after the end surgery,

**Exclusion criteria:**  
Patient with no cooperation to end of study, physician disagreement, Re-intubation tracheal tube after extubation for any reason, intubation more than 30 seconds, attempt for intubation more than once, traumatizing trachea (during intubation), report of difficult intubation (mallampati intubation score of higher than class ii ), Death of patient during the study, Daley of extubation process

**Age**  
From **60 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**  
Target sample size: **80**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Eligible patients will be randomly assigned into two groups using permuted block randomization , Random numbers table will be used, Random allocation sequence will be determined using a computerized program.Opaque sealed sequentially numbered envelopes from number 1 to 80 will be used for allocation concealment

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Outcome assessor, staff nurses in the ICU and the statistical analyzer will be blind to patients' allocation of

the groups.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  
Eligible patients will be selected through convenience sampling and will be randomly assigned into 2 groups using permuted block randomization with allocation ratio of 1:1. Random allocation sequence will be determined using a computerized program. Opaque sealed sequentially numbered envelopes from number 1 to 80 will be used for allocation concealment.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shad University

##### Street address

Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

3319118651

#### Approval date

2018-09-03, 1397/06/12

#### Ethics committee reference number

IR.SHAHED.REC.1397.043

## Health conditions studied

### 1

#### Description of health condition studied

Nausea

#### ICD-10 code

R11.0

#### ICD-10 code description

Nausea

### 2

#### Description of health condition studied

Hoarseness

#### ICD-10 code

R49.0

#### ICD-10 code description

Dysphonia

### 3

#### Description of health condition studied

Cough  
**ICD-10 code**  
R05  
**ICD-10 code description**  
psychogenic cough

#### 4

##### **Description of health condition studied**

Sore Throat  
**ICD-10 code**  
J02  
**ICD-10 code description**  
acute sore throat

### **Primary outcomes**

#### 1

##### **Description**

hoarseness

##### **Timepoint**

immediately after , 6,12,18, and 24 hrs. after extubation

##### **Method of measurement**

four-point scale

#### 2

##### **Description**

nausea

##### **Timepoint**

immediately after , 6,12,18, and 24 hrs. after extubation

##### **Method of measurement**

four-point scale

#### 3

##### **Description**

Cough

##### **Timepoint**

immediately after , 6,12,18, and 24 hrs. after extubation

##### **Method of measurement**

four-point scale

#### 4

##### **Description**

sore throat

##### **Timepoint**

immediately after , 6,12,18, and 24 hrs. after extubation

##### **Method of measurement**

four-point scale

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

##### **Description**

Intervention group: The 45 elderly patients receive ward

routine care and also cool mist using nebulizer. The intervention group receive cool mist for 45 minutes before extubation and 45 minutes after extubation (90 min. overall).

##### **Category**

Prevention

#### 2

##### **Description**

Control group: The 45 elderly patients in control group receive only ward routine care.

##### **Category**

Prevention

### **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Shaheed Rajaei Hospital

###### **Full name of responsible person**

Maryam Nasrollahi

###### **Street address**

Shaheed Rajaei Hospital, Valiasr Ave Niayesh Intersection

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1995614331

###### **Phone**

+98 21 2204 2026

###### **Email**

rajaeehospital@sums.ac.ir

###### **Web page address**

### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Shahed University

###### **Full name of responsible person**

Vice chancellor for research, Shahed University, Dr. Zahra Kiasalari

###### **Street address**

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Express way, Tehran.

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###### **Postal code**

3319118651

###### **Phone**

+98 21 5121 3071

###### **Email**

Kiasalari@shahed.ac.ir

**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Shahed University  
**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**  
Shahed University  
**Full name of responsible person**  
Nahid Rejeh  
**Position**  
Associate Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nursery  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available