

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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Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Express way, Tehran
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Person responsible for updating data

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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