Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the effect of distilled water and normal saline instillation during endotracheal suctioning on hemodynamic parameters and ventilator associated pneumonia among patients under mechanical ventilation

Protocol summary

Study aim

Comparison the effect of distilled water and normal saline instillation during endotracheal suctioning on hemodynamic parameters and ventilator associated pneumonia among patients under mechanical ventilation

Design

A parallel single blinded randomized controlled clinical trial

Settings and conduct

Selecting of 60 intubated patients admitted to the intensive care unit of Imam Jafar Sadegh Hospital affiliated to Alborz University of Medical Sciences, randomly, and instillation 3 to 5 cc of either distilled water or normal saline in the trachea before endotracheal suctioning for 5 continuous days by nurse in the intervention and control group, respectively, and after that, obtaining culture from trachea and send it to the laboratory to determine the ventilator-associated pneumonia by the laboratory staffs blinded to the allocation groups

Participants/Inclusion and exclusion criteria

Inclusion criteria: Negative culture of the trachea; Systolic blood pressure more than 90 mmHg; Normal level of electrolytes; Without cardiac arrhythmia; Urinary output more than 30 cc per hour; Without asthma, chronic obstructive pulmonary disease, or lung infections. Exclusion criteria: With previous asthma, chronic obstructive pulmonary disease, or lung infections.

Intervention groups

Intervention group: Instillation of 3 to 5 cc of distilled water (Samen company, Iran) in the trachea before endotracheal suctioning for 5 continuous days by nurse
Control group: Instillation of 3 to 5 cc of normal saline (Samen company, Iran) in the trachea before endotracheal suctioning for 5 continuous days by nurse

Main outcome variables

Ventilator associated pneumonia; Hemodynamic parameters such as blood pressure, heart rate, respiratory rate, and peripheral blood oxygen saturation (SpO2)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161124031068N2**
Registration date: **2018-10-20, 1397/07/28**
Registration timing: **retrospective**

Last update: **2018-10-20, 1397/07/28**
Update count: **0**

Registration date

2018-10-20, 1397/07/28

Registrant information

Name
Maryam Esmaeili
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

2017-12-22, 1396/10/01

Actual recruitment end date

2018-06-22, 1397/04/01

Trial completion date

2018-07-23, 1397/05/01

Scientific title

Comparison the effect of distilled water and normal saline instillation during endotracheal suctioning on hemodynamic parameters and ventilator associated pneumonia among patients under mechanical ventilation

Public title

Comparison the effect of distilled water and normal saline on hemodynamic parameters and ventilator associated pneumonia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Negative culture of the trachea at the beginning of intubation Systolic blood pressure more than 90 mmHg without administration of inotropic drugs Normal level of electrolytes Without cardiac arrhythmia Urinary output more than 30 cc per hour Without asthma Without chronic obstructive pulmonary disease Without lung infections

Exclusion criteria:

With previous asthma With previous chronic obstructive pulmonary disease With previous lung infections

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block balanced randomization method will be used. Randomization sequence will be generated by free website available from: www.randomization.com. In order to determine the randomization sequence in this website, 4 subjects in each block will be considered. Thus, by considering letter A for control group and letter B for intervention group, randomization sequence will be generated for 21 blocks. For random allocation concealment, cards containing blocks will be inserted in standard envelopes. In order to determine the allocation group, one envelope will be taken randomly by the researcher after shuffling.

Blinding (investigator's opinion)

Single blinded

Blinding description

All cultures related to the patients will be sent to laboratory. However, laboratory staffs prepared the culture would not be aware of the allocation groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

No. 123, School of Nursing and Midwifery, Tehran University of Medical Sciences, Nosrat St., Tohid Sq., Tehran Town,

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2017-12-16, 1396/09/25

Ethics committee reference number

IR.TUMS.FNM.REC.1396.4263

Health conditions studied

1

Description of health condition studied

Ventilator associated pneumonia (VAP)

ICD-10 code

J95.851

ICD-10 code description

Ventilator associated pneumonia

Primary outcomes

1

Description

Ventilatore associated pneumonia

Timepoint

Before intervention and 5 days after intervention

Method of measurement

Endoteracheal culture

Secondary outcomes

1

Description
Blood pressure
Timepoint
Before and 5 minutes after endotracheal suctioning
Method of measurement
Vital-signs monitoring device

2

Description
Heart rate
Timepoint
Before and 5 minutes after endotracheal suctioning
Method of measurement
Vital-signs monitoring device

3

Description
Respiratory rate
Timepoint
Before and 5 minutes after endotracheal suctioning
Method of measurement
Vital-signs monitoring device

4

Description
Peripheral blood oxygen saturation (SpO2)
Timepoint
Before and 5 minutes after endotracheal suctioning
Method of measurement
pulse oximeter

Intervention groups

1

Description
Intervention group: Instillation of 3 to 5 cc of distilled water (Samen company, Iran) in the trachea before endotracheal suctioning for 5 continuous days by nurse
Category
Prevention

2

Description
Control group: Instillation of 3 to 5 cc of normal saline (Samen company, Iran) in the trachea before endotracheal suctioning for 5 continuous days by nurse
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Jafar Sadegh Hospital
Full name of responsible person
Maryam Esmaeili
Street address
Imam Jafar Sadegh Hospital, Parastar Ave, Hashtgerd, Alborze state
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Email
EmamJafarsadegh@abzums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammadali Sahraian
Street address
Research deputy of Tehran University of Medical Sciences, No. 21, Qods St., Keshavarz Blvd., Tehran Town,
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msahrai@tuma.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Maryam Esmaeili

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Email
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
After making data unrecognizable, all data will be shared.

When the data will become available and for how long
Starting in January 2020

To whom data/document is available
It will be available for researchers working in academic institutions.

Under which criteria data/document could be used
For people that have academic education and these data can be useful for their research.

From where data/document is obtainable
Maryam Shafei; maryam_nursing@yahoo.com

What processes are involved for a request to access data/document
email to "maryam_nursing@yahoo.com" and comment that why he/she wants to access to these data

Comments