

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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

Endotracheal 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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Hashtgerd

Province

Alborz

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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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Email

Esmaeiliem@yahoo.com

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