Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of intermittent subglottic secretions drainage combined with closed endotracheal suctioning in comparison with open endotracheal suctioning on incidence of ventilator associated pneumonia in intubated patients in Al-Zahra hospital intensive care units,Isfahan University of Medical Sciences.

Protocol summary

Summary

Objective: effect of intermittent subglottic secretions drainage combined with closed endotracheal suctioning on incidence of ventilator associated pneumonia in critical care units at Alzahra hospital, Isfahan, Iran in 2012. Study Design: randomized clinical trial. Study population: patients admitted to intensive care units of Alzahra hospital at Isfahan. Inclusion criteria: willingness to participate in the study; patients 18 to 60 years, intubation within 24 past hours, absence of pneumonia before intubation. Exclusion criteria: death before end of study, surgery in period of study. Intervention: in the intervention group subglottic secretions drainage, with use of inspiratory pause key that embedded in mechanical ventilator and endotracheal suctioning with closed endotracheal suctioning system was performed. Time of intervention: interventions were performed for 5 days after intubation. Ventilator-associated pneumonia-related variables, including body temperature, white blood cell count, assessment for purulent secretions, the ratio of arterial oxygen pressure to inspiratory oxygen fraction and infiltration on chest radiography of the patients, within 5 days in both groups were performed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013042913179N1**
Registration date: **2013-08-04, 1392/05/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-08-04, 1392/05/13

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2012-11-15, 1391/08/25

Expected recruitment end date

2013-02-13, 1391/11/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intermittent subglottic secretions drainage combined with closed endotracheal suctioning in comparison with open endotracheal suctioning on incidence of ventilator associated pneumonia in

intubated patients in Al-Zahra hospital intensive care units,Isfahan University of Medical Sciences.

Public title
prevention of ventilator associated pneumonia
Purpose
Prevention
Inclusion/Exclusion criteria
inclusion criteria: Patients 18 to 60 years, mechanical ventilation more than 48 hr,free of pneumonia before intubation, exclusion criteria:death before 48 hr, extubation before end of study, surgery during the study period.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Drainage of secretions around the endotracheal tube cuff was performed with inspiratory pause maneuver. The patient was blinded to intervention due to the anesthesia. Infectious disease specialist who was responsible for determining ventilator-associated pneumonia was blind to the grouping. the researcher were aware of the grouping.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Medical Ethics Committee of Isfahan university of medical science.
Street address
Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences, Azadi Square, Hezar-Jerib,Isfahan Isfahan Isfahan Iran, Islamic Republic Of 461-81746
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Approval date
2012-10-28, 1391/08/07
Ethics committee reference number
391295

Health conditions studied

1

Description of health condition studied
Ventilator Associated Pneumonia
ICD-10 code
J95.9
ICD-10 code description
Postprocedural respiratory disorder, unspecified

Primary outcomes

1

Description
Incidence of Ventilator Associated Pneumonia
Timepoint
Before intubation, day 1, day 2, day 3, day 4, day 5,
Method of measurement
Clinical Pulmonary Infection Score, CPIS.

Secondary outcomes

empty

Intervention groups

1

Description
Interventions in the Intervention group consist of closed suction system, 72-hour for endotracheal suctioning and subglottic secretions drainage. Every 3 hour, after oral full suction, the cuff of the endotracheal tube was connected to a cuff pressure gauge manometer. Inspiratory hold with use of inspiratory pause key that embedded in ventilator was performed. This key can hold breathing for 7 seconds and hyperinflated the lungs, in 3 seconds of holding the key, endotracheal tube cuff was depleted and pressure of air that trapping in the lungs, causing secretions to be pushed into the oral cavity. Tracheal tube cuff inflated in 6th second and the pressure was adjusted between 25 and 30 cm H2O. Oral cavity was cleaned with frequent suctioning. This maneuver was applied every three hours and immediately before the closed suction. For a closed suction, a suction catheter package that is used for 72hr was used. After identifying that the patient needs to be suctioned, Suction was attached to the suction connector and negative pressure was set to 200 cm H2O. Catheter sent into the patient's airway and after suction, catheter was removed.
Category
Prevention

2

Description
In the control group, open suctioning was performed in sterile method, and subglottic secretions drainage was not performed.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahras hospital
Full name of responsible person
Rahimeh Safdari
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Alzahra educational hospital. Shohadaye sofe avenue, Isfahan.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Isfahan University of Medical Sciences
Full name of responsible person
Dr Peiman Adibi
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Isfahan
Grant name
391295
Grant code / Reference number
391295
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Isfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty