Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Infection Control Guidelines implementation on incidence of Ventilator-Associated Pneumonia in hospitalized patients in intensive care unit

Protocol summary

Study aim
determine the effect of infection control guidelines on the incidence of Ventilator Associated Pneumonia (VAP) in patients admitted to the Intensive Care Unit (ICU).

Design
this study is a clinical trial, and in this study non-randomized purposive sampling method was utilized and subjects were divided into two groups of control and intervention.That the VAP prevention guideline is being implemented in intervention group and those guidelines do not apply to them are considered as the control group.

Settings and conduct
This study was conducted to prevent ventilator-associated pneumonia in the form of evidence-based guideline for controlling infection in patients under mechanical ventilation admitted in Intensive Care Unit of Imam Khomeini and Golestan hospitals in Ahvaz city between June 2018 and September 2018 with a sample size of 130 patients and For 5 days, the intervention group includes 65 patients and the control group is 65 patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria: did not have pneumonia before admission, Tracheal intubation and attachment to ventilator. Exclusion criteria: Length of hospitalization is more than 20 days, below 18 years age

Intervention groups
semi recumbent position,use of standard bed in ICU, change of suction equipment, use of close suction system, oral intubation technique, use of (HME) filter, ventilator circuit change, use of chlorhexidine gluconate mouthwash, subglottic secretion suction, set of Cuff pressure in (ET) tubes in the range of 20–30 cm H2O, elevation the head of the bed at 30 to 45 degrees, during and after gavage. Routine care is performed in the control group and researcher does not intervene.

Main outcome variables
incidence of ventilator associated pneumonia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180709040402N1**
Registration date: **2018-09-28, 1397/07/06**
Registration timing: **retrospective**

Last update: **2018-09-28, 1397/07/06**
Update count: **0**

Registration date
2018-09-28, 1397/07/06

Registrant information

Name
Ali Safavi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-23, 1397/04/02

Expected recruitment end date
2018-09-20, 1397/06/29

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Infection Control Guidelines implementation on incidence of Ventilator-Associated Pneumonia in hospitalized patients in intensive care unit

Public title

The Effect of Infection Control Guidelines on Incidence of Ventilator-associated Pneumonia.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients admitted to the intensive care unit. Absence of pneumonia before entering the study. Non-Cystic Fibrosis Patients, Pleural Empyema, acquired pneumonia from the community and Neutropenia. did not have aspiration before admission Length of hospitalization is less than 20 days Endotracheal intubation and connected to ventilator

Exclusion criteria:

Extropulmonary infection Symptoms occur less than 48 hours after mechanical ventilation Patients with incomplete file and clinical information

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Jundishapur Ahvaz University of Medical Sciences

Street address

No.Golestan, Esfand St, Jundishapur University of Medical Sciences

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Province

Khouzestan

Postal code

15794-61357

Approval date

2018-06-08, 1397/03/18

Ethics committee reference number

IR.AJUMS.REC.1397.202

Health conditions studied

1

Description of health condition studied

Ventilator-associated Pneumonia (VAP)

ICD-10 code

J17

ICD-10 code description

Ventilator-associated Pneumonia (VAP)

Primary outcomes

1

Description

incidence of ventilator associated pneumonia

Timepoint

Before and after the intervention

Method of measurement

Use of modified Clinical Pulmonary Infection Score (mCPIS)

Secondary outcomes

1

Description

the amount of antibiotic use

Timepoint

before and after the intervention

Method of measurement

taking daily dose

Intervention groups

1

Description

1. semi recumbent position. 2. use of standard bed in ICU. 3. change of suction equipment (Catheter and tube). 4. use of close suction system. 5. oral intubation technique. 6. chest physiotherapy. 7. use of Heat and Moisture Exchanger (HME) filter. 8. ventilator circuit change. 9. hand washing. 10. Deep Venous Thrombosis prophylaxis. 11.peptic ulcer prophylaxis. 12. use of chlorhexidine gluconate (0.2 or 0.12 percent) mouthwash. 13. subglottic secretion suction. 14. set of Cuff pressure in endotracheal (ET) tubes in the range of

20–30 cm H2O. 15. elevation the head of the bed at 30 to 45 degrees, during and after gavage.

Category
Prevention

2

Description
Routine care is performed in the control group and researcher does not intervene.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Hospitals of Imam Khomeini and Golestan

Full name of responsible person
Safavi Ali

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Safavi Ali

Position
student Critical Care Nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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
No - There is not a plan to make this available

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

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Study data can be shared after coding

When the data will become available and for how long
Start accessing the data three months after the publication of the article

To whom data/document is available
Academic and academic institutions

Under which criteria data/document could be used
Citation to the results of the study, comparison with other studies is permitted. And any copying of results and data forms is impermissible.

From where data/document is obtainable
Nursing and Midwifery Library, Faculty of Nursing, Jondishapoor University of Medical Sciences, Ahvaz, Iran. Safavi Ali Project Executive. 09188415182 ،Safaviali999@yahoo.com

What processes are involved for a request to access data/document
Three months after the publication of the article, dated 2019/04/02, emails or telephone data files will be available.

Comments