

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 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

Country

Iran (Islamic Republic of)

Phone

+98 84 3362 9012

Email address

safavi.a@ajums.ac.ir

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
City
Ahvaz
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

Street address

Golestan Hospital, Golestan- the 24-meter stree and between the beach boulevard, Martyrdom Square

City

Ahvaz

Province

Khuzestan

Postal code

-61357-15794

Phone

+98 61 3333 2368

Fax

+98 61 3336 1544

Email

Safavi.a@ajums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad badavi

Street address

Ground floor, University of Jundishapur University of Medical Sciences, Assistant Professor of Research and Technology Development, University City

City

Ahvaz

Province

Khuzestan

Postal code

15794- 61357

Phone

+98 61 3333 2368

Fax

+98 61 3336 1544

Email

Safavi.a@ajums.ac.ir

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

Street address

Safavi Karim home, 3Shahed Alley ,15 South Khordad

City

Abdanan

Province

Ilam

Postal code

6971664145

Phone

+98 84 3362 3105

Email

Safavi.a@ajums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Asadi Zakir Marzieh

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Ahvaz, Jundishapur University of Medical

Sciences, University of Ahvaz, School of Nursing and Midwifery

City

Ahvaz

Province

Khuzestan

Postal code

15794 - 61357

Phone

+98 61 3333 2368

Fax

+98 61 3336 1544

Email

marziyehasadizaker@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Safavi Ali

Position

intensive care Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, University of Ahvaz,
Jondishapur University of Medical Sciences

City

Ahvaz

Province

Khuzestan

Postal code

15794 - 61357

Phone

+98 61 3333 2368

Fax

+98 61 3336 1544

Email

Safavi.a@ajums.ac.ir

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