Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Assessing the effect of an oral hygiene protocol on ventilator associated pneumonia among the intubated patients hospitalized in Intensive care units

Protocol summary

Study aim

To determine the effectiveness of an oral health care protocol in the prevention of ventilator-associated pneumonia

Design

A multicenter interventional study with a control group, double-blind, randomized, which is conducted in a parallel design on 200 patients (100 patients in each of the intervention and control groups). Patients are allocated to intervention and control groups using the permuted block randomization (Block size=4). Since the block size is four, we can make six possible sequences; these are AABB, ABAB, ABBA, BAAB, BABA, BBAA

Settings and conduct

This multicenter clinical trial is conducted in the intensive care units of three hospitals in western Iran. The hospitals include Besat Hospital in Sanandaj (Kurdistan Province) and Taleghani and Imam Reza Hospitals in Kermanshah (Kermanshah Province).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age >= 18 years No trauma in the mouth area Intubation during the first 24 hours of arrival Intubation period of at least one and maximum 12 weeks, No hospitalization in any other hospitals during the last 48 hours Exclusion criteria: Patients with oral trauma or any facial fractures Patients who have the possibility of endotracheal tube removal in less than 48 hours Sever patients (with the possibility of death within 48 hours),

Intervention groups

Intervention group: an evidence-based protocol for oral care Control group: routine oral health care

Main outcome variables

Incidence of ventilator-associated pneumonia (VAP)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220215054026N1**
Registration date: **2022-12-17, 1401/09/26**
Registration timing: **retrospective**

Last update: **2022-12-17, 1401/09/26**
Update count: **0**

Registration date

2022-12-17, 1401/09/26

Registrant information

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Sharare Karimi
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

2016-06-01, 1395/03/12

Expected recruitment end date

2017-06-01, 1396/03/11

Actual recruitment start date

2017-06-01, 1396/03/11

Actual recruitment end date

2017-06-01, 1396/03/11

Trial completion date

2017-06-01, 1396/03/11

Scientific title

Assessing the effect of an oral hygiene protocol on ventilator associated pneumonia among the intubated patients hospitalized in Intensive care units

Public title

Assessing the effect of an oral hygiene protocol on ventilator associated pneumonia among the intubated patients hospitalized in Intensive care units

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age >=18 years Patient with no oral trauma Patient with no fracture in the face The patient must be intubated within the first 24 hours of admission. The patient has not been admitted to any other hospital department in the last 48 hours. Patients who are intubated for at least 1 week and at most 3 months. Written informed consent of the patient's guardian or companion (father, brother, grandfather) to participate in the study

Exclusion criteria:

Observing any injuries in the oral during the study Observinng any facial fracture during the study Patients who can remove the tracheal tube in less than 48 hours. Critically ill patients with life expectancy less than 48 hours

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **200**

Actual sample size reached: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients into the intervention and control groups will be done by permuted block randomization (block size=4). Since the block size in our study is four, we can make six possible sequences as follows; AABB, ABAB, ABBA, BAAB, BABA, BBAA The allocator will hide the block size from the executer and will use randomly mixed block sizes to prevent the prediction of the next assignment by executer and outcome assessor.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind. In the other words, patients and outcome assessors will be blinded to the intended intervention. According to the condition of the patients (being intubated), written informed consent to enter the study is obtained from the companions or guardians of the patient (father, brother, grandfather, etc.). To ensure blinding by outcome assessors, the oral and dental hygiene protocol (intended intervention) is placed next to the bed of all patients. Also the allocator will hide the block size from the executer and will use randomly mixed block sizes to prevent the prediction of the next assignment by the executer and outcome assessor.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kurdistan University of Medical Sciences

Street address

Pasdaran St. after Qods hospital

City

Sanandaj

Province

Kurdistan

Postal code

6617713446

Approval date

2016-05-04, 1395/02/15

Ethics committee reference number

IR.MUK.REC.1395.59

Health conditions studied

1

Description of health condition studied

Ventilator associated pneumonia

ICD-10 code

J95.851

ICD-10 code description

Ventilator associated pneumonia

Primary outcomes

1

Description

The occurence of ventilator-associated pneumonia (VAP)

Timepoint

After 48 hours of intubation and doing intervention, each patient will be evaluated daily for the occurrence of ventilator-associated pneumonia.

Method of measurement

Clinical criteria, the clinical pulmonary infection score (CPIS), that described initially by Johanson et al. And

suggested by the Centers for Disease Control and Prevention (CDC), will be used to assess the VAP. This tool consists of clinical, microbiological, physiological and radiographic evidence and allow us a numerical value to predict the presence/absence of VAP .

Secondary outcomes

empty

Intervention groups

1

Description

For the intervention group, in addition to all standard oral care, a supervised implementation of oral health guideline, including seven items will be considered as follows: 1) Wash your hands and then wear gloves. 2) Open the mouth and divide it into 4 quarters so that the oral examination can be done more easily from the upper right quarter to the lower right quarter. Report any abnormal findings such as white or red lesions, abnormal lumps, and halitosis in the form. (If such lesions are observed, nystatin should be prescribed according to the instructions: ten vials of 150,000 units / ml for two weeks / four times a day / two full droppers each time that should stay in the mouth for two minutes). 3) Increase the cuff pressure of the endotracheal tube to more than 20 mmHg while the patient's body is raised to 25 degrees, and then suction the subglottic area. 4) Turn the patient's head laterally and start brushing teeth and tongue, hard palate and gums in toothless patients with a baby toothbrush and toothpaste containing fluoride (not antibacterial). Brushing should be repeated every 8-12 hours for at least 5 minutes in each time. 5) Use normal saline solution to rinse your mouth after brushing and then suction. (You can spray normal saline on the teeth using a syringe)6) Use chlorhexidine gluconate 0.2% to rinse the patient's mouth, throat thoroughly, and suction after 1 to 2 minutes.7) Every 4 hours, apply a moisturizing gel on all the tissues inside the mouth and then apply Vaseline on the lips with a finger.

Category

Prevention

2

Description

Control group: The control group will be received all standard oral care (rinsing the mouth with normal saline and mouth and lung suctioning, cleaning the tongue and teeth with gas, rinsing with chlorhexidine 0.2%, and suctioning the rinsing solution).

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital of Kermanshah

Full name of responsible person

Ensi Koliaei

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3

Recruitment center

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Sponsors / Funding sources

1

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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
Sanandaj 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

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Sharing plan

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

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to

make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Effect of oral health care protocol on Ventilator-associated pneumonia

When the data will become available and for how long

After publishing the related paper - no time limitation

To whom data/document is available

Researchers

Under which criteria data/document could be used

To use in the systematic review and meta analysis study

From where data/document is obtainable

By mailing to corresponding author

What processes are involved for a request to access data/document

No specific process is needed. It can be available through contacting to the corresponding author

Comments