Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of oropharyngeal decontamination by topical antibiotics on incidence of ventilator-associated pneumonia in hospitalized traumatic patients in intensive care units

Protocol summary

Study aim

Determination of the effect of oropharyngeal decontamination with local antibiotics on the frequency of ventilator-associated pneumonia in trauma patients in intensive care unit

Design

The study is a double-blind, clinical trial that consists of two groups of intervention and control.Participants will be selected on a 100-person, based on the inclusion and exclusion criteria, and will be assigned to the groups in a simple random manner. participants are selected from hospitalized patients in the intensive care units of Khatam al-Anbia hospital in Zahedan.

Settings and conduct

In this study, 100 patients were selected from traumatic patients admitted to the intensive care unit of Khatam-ol-Anbia hospital in Zahedan who were eligible and randomly divided into two groups of 50, using colored cards. The person in charge of oral care, department staff, expert researcher and a laboratory associate are not aware of how to drive randomization , solution with volume as much as and looks similar to the drug solution used in the intervention group. The intervention starts from the first day after intubation and lasts for at least 3 and up to 5 days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 and 65 years ; Perform intubation in the first 24 hours and wait at least 72 hours ; Clinical pulmonary infection score less than 6 at the time of arrival; Oral hygiene assessment checklist score 10 or less ; GCS less than 9. Non-compliance criteria: Damage to the mouth, jaw and face; Lack of cancer and diabetes and chronic obstructive pulmonary disease; immunosuppression due to certain medications or diseases; history of broad-based antibiotic therapy in the past 3 months;perform a cardiopulmonary resuscitation process.

Intervention groups

The intervention group patients in addition to usual care, including oral care with normal saline four times a day, will be received a pre-compounded solution with 2% concentration of nystatin, poly-myxin and neomycin after washing with normal saline in the oral cavity. The control group is 50 patients. In addition to routine care, normal saline mouthwash four times a day, will be rinsed with a solution that is similar in size and appearance to the intervention, four times a day.

Main outcome variables

Ventilator associated pneumonia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180110038298N1**
Registration date: **2018-02-23, 1396/12/04**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-23, 1396/12/04**
Update count: **0**

Registration date

2018-02-23, 1396/12/04

Registrant information

Name

Morteza Barani

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
2018-02-04, 1396/11/15

Expected recruitment end date
2018-07-16, 1397/04/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of oropharyngeal decontamination by topical antibiotics on incidence of ventilator-associated pneumonia in hospitalized traumatic patients in intensive care units

Public title
Effect of oropharyngeal decontamination by topical antibiotics on the ventilator associated pneumonia

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
The age of the patient is between 18 and 65 years Perform intubation in the first 24 hours and stay at least 72 hours Clinical pulmonary infection score less than 6 at the time of arrival Oral hygiene assessment checklist score 10 or less GCS less than 9

Exclusion criteria:
damage to the mouth, jaw and face cancer and diabetes and chronic obstructive pulmonary disease immunosuppression due to certain medications or diseases history of broad-based antibiotic therapy in the past 3 months perform a cardiopulmonary resuscitation process

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**
More than 1 sample in each individual
Number of samples in each individual: **4**
Tracheal and pharyngeal secretions samples are collected and cultured before intervention in both groups. After the end of the intervention, in each group, the tracheal and throat secretions were collected and cultured in the groups.

Randomization (investigator's opinion)
Randomized

Randomization description
At first, patients will be selected from eligible people with valid entry criteria and then assigned to two groups of intervention and control in a simple random manner. The randomization will be as follows: 100 cards (corresponding to the estimated sample size) are colored with green and orange colors. Green cards are assigned to the control group and 50 red cards for the intervention group. Cards are arranged randomly. After referring to the department and examining the patient and determining his eligibility, depending on the color of card is assigned to each patient, the control group or intervention is determined.

Blinding (investigator's opinion)
Double blinded

Blinding description
Only researcher will be aware of the randomness. In order to blindness, a nurse familiar with critical care , after education about the method of mouthwash and the use of tools, recruitment as a partner who is not familiar with how to allocate patients in the intervention or control group. The solution is uniform and looks similar to the drug solution is provided and give to the nurse for the control group. Proficient collaborator and Samples analyzer lab will not be aware of the randomness.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of zahedan university of medical Sciences

Street address
NO. 1 , Daneshgah Ave., Hesabi Squ., Pardis complex , university of medical sciences

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Approval date
2017-12-24, 1396/10/03

Ethics committee reference number
IR. ZAUMS. REC.1396.290

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 incidence of ventilator-dependent pneumonia

Timepoint

At the beginning of the study, before the intervention, and daily until the end of the intervention

Method of measurement

Clinical pulmonary infection score

Secondary outcomes

1

Description

Microorganisms grown from pharyngeal and tracheal secretion samples

Timepoint

The first day of the study before the intervention and 5

Method of measurement

Perform culturing in the laboratory by a laboratory collaborator

Intervention groups

1

Description

Intervention group: On the first day of intubation, oral washing perform four times a day, with normal saline solution. On the second day of intubation, collect the initial sample of the pharyngeal and tracheal secretions and sent to the laboratory for culture, then with a 2% concentration of poly-myxin, nystatin and neomycin, prepared and combined by investigator administer with a syringe on the oral cavity and the lips are used in such a way that the mucus is impregnated with it. This action is repeated four times after normal oral saline mouthwash. The duration of the study is at least three days, and if the terms of exclusion are not established, it lasts for a maximum of five days. At the end of the fifth day, the throat and tracheal secretions are again sampled and the intervention is completed.

Category

Prevention

2

Description

Control group: On the first day of intubation, mouth washing is perform four times in day, with normal saline solution. On the second day, first sampled the tracheal and pharyngeal discharge, then, daily after each oral wash with normal saline, a solution with the appearance and volume of the same basic solution used by the researcher with a syringe in the mouth and lips, is applied in such a way that the mucosa is impregnated. This action is repeated four times. The duration of the study is at least three days, and if the terms of exclusion are not established, it lasts for a maximum of five days. At the end of the fifth day, the throat and tracheal secretions are again sampled and the intervention is completed.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam-ol-Anbia Hospital in Zahedan

Full name of responsible person

Azizollah Jahantigh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
Zahedan 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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available