# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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**

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**Full name of responsible person**

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**Email**

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**Web page address**

http://www.zaums.ac.ir

**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**
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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