

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparative study of the effect of three types of mouthwash "Colistin and Chlorhexidine", "Tobramycin and Chlorhexidine" and "Chlorhexidine alone" in the prevention of ventilator-associated pneumonia in ICU patients

Protocol summary

Study aim

Determining and comparing the effect of three types of mouthwash "Colistin and Chlorhexidine", "Tobramycin and Chlorhexidine" and "Chlorhexidine alone" in the prevention of ventilator-associated pneumonia

Design

The present study is a randomized double-blind clinical trial.

Settings and conduct

This study is a double-blind clinical trial; in order to evaluate the effect of three types of mouthwash "colistin and chlorhexidine", "tobramycin and chlorhexidine" and "chlorhexidine alone" in the prevention of ventilator-associated pneumonia on 96 patients admitted to the intensive care unit of Alzahra Hospital in Isfahan will be performed in 2020-2021.

Participants/Inclusion and exclusion criteria

Inclusion criteria include age over 18 years and under 65 years, no damage to the mouth, jaw, and face, no immunosuppression due to certain drugs or diseases, the patient should be in the first 24 hours of intubation and should wait at least 72 hours for intubation, a clinical score of lung infection less than 6 on arrival, oral health assessment checklist score 10 and less. Exclusion criteria include having cancer and diabetes and chronic obstructive pulmonary disease, have a history of broad-spectrum antibiotic therapy in the last 3 months, performing the cardiopulmonary resuscitation process, and dissatisfaction of him or his companion to participate in the study.

Intervention groups

In the first intervention group, 5 cc of the solution containing colistin with chlorhexidine, in the second intervention group 5 cc of the solution of tobramycin with chlorhexidine, and in the control group 5 cc of the chlorhexidine solution alone will be prescribed 3 times a

day for 5 days.

Main outcome variables

Positive culture of the endotracheal tube; positive oral culture; type of microorganisms grown

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N1**

Registration date: **2020-09-11, 1399/06/21**

Registration timing: **prospective**

Last update: **2020-09-11, 1399/06/21**

Update count: **0**

Registration date

2020-09-11, 1399/06/21

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study of the effect of three types of mouthwash "Colistin and Chlorhexidine", "Tobramycin and Chlorhexidine" and "Chlorhexidine alone" in the prevention of ventilator-associated pneumonia in ICU patients

Public title
The effect of three types of mouthwash "Colistin and Chlorhexidine", "Tobramycin and Chlorhexidine" and "Chlorhexidine alone" in the prevention of ventilator-associated pneumonia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
No damage to the mouth, jaw and face Oral health assessment checklist score 10 and less Clinical score of lung infection less than 6 on arrival The patient should be in the first 24 hours of intubation and should wait at least 72 hours for intubation No immunosuppression due to certain drugs or diseases
Exclusion criteria:
Having cancer and diabetes and chronic obstructive pulmonary disease Have a history of broad-spectrum antibiotic therapy in the last 3 months Performing the cardiopulmonary resuscitation process Dissatisfaction of him or his companion to participate in the study

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
First, eligible patients will be selected non-randomized, sequential. Then these patients are coded using computer random allocation software, and then the codes are divided into three parts, and each part of the codes will be assigned to a group.

Blinding (investigator's opinion)
Double blinded

Blinding description
To blind the present study, a sample of mouthwash used in three types of "Colistin and Chlorhexidine",

"Tobramycin and Chlorhexidine" and "Chlorhexidine alone" was prepared by a pharmacist. These solutions will be prepared similarly in volume, shape, and smell and will be coded with labels A, B and C. Then these solutions will be given daily to a nurse who is completely unaware of the type of mouthwash. In addition, the partner specialist as well as the Laboratory Analyzer will not be aware of how randomization is performed.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfahan

Postal code

8179964167

Approval date

2020-05-31, 1399/03/11

Ethics committee reference number

IR.MUI.MED.REC.1399.118

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

Positive culture of endotracheal tube

Timepoint

Before and 5 days after starting treatment

Method of measurement

Laboratory

2

Description

Positive oral culture

Timepoint

Before and 5 days after starting treatment

Method of measurement

Laboratory

3

Description

Type of microorganisms grown

Timepoint

Before and 5 days after starting treatment

Method of measurement

Laboratory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group will receive 5 cc of a pre-prepared solution containing colistin 20 µg/mL (Darupakhsh company) along with chlorhexidine 0.2% (Darupakhsh company) 3 times a day for 5 days. This solution is applied to the mouth and lips, gums, and inside the cheeks using a swab.

Category

Treatment - Drugs

2

Description

Intervention group: Patients in this group will receive 5 cc of a pre-prepared solution containing tobramycin 10 µg/mL (Darupakhsh company) along with chlorhexidine 0.2% (Darupakhsh company) 3 times a day for 5 days. This solution is applied to the mouth and lips, gums, and inside the cheeks using a swab.

Category

Treatment - Drugs

3

Description

Control group: Patients in this group will receive 5 cc of pre-prepared solution containing 0.2% chlorhexidine (Darupakhsh company) alone 3 times a day for 5 days. This solution is applied to the mouth and lips, gums and inside the cheeks using a swab.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Mohammadreza Nazer

Street address

Shahid Sharifat Alley, Chaharbagh Bala Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

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Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Saeed Abbasi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

Saeed Abbasi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

Specialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available