

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of the effect of chlorhexidine and Persica mouthwash in the prevention of ventilator associated pneumonia in patients under ventilator admitted to the intensive care unit

Protocol summary

Study aim

Comparison of the effect of chlorhexidine and Persica mouthwash in preventing ventilator associated pneumonia in patients under ventilator

Design

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

Settings and conduct

This single-blind clinical trial study will be conducted to compare the effect of chlorhexidine and Persica mouthwash in the prevention of ventilator associated pneumonia in patients on ventilator admitted to the intensive care unit of Allameh Bahloul Gonabadi Hospital in 2023

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, 15 ml of 0.2% chlorhexidine solution and in the second intervention group, 15 drops of Persica solution will be Mouthwash twice 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: **IRCT20231122060135N1**

Registration date: **2024-01-22, 1402/11/02**

Registration timing: **registered_while_recruiting**

Last update: **2024-01-22, 1402/11/02**

Update count: **0**

Registration date

2024-01-22, 1402/11/02

Registrant information

Name

Mostafa Mirzaee fakhrrabad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-06-21, 1403/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of chlorhexidine and Persica mouthwash in the prevention of ventilator associated pneumonia in patients under ventilator admitted to the intensive care unit

Public title

Comparison of the effect of chlorhexidine and Persica mouthwash in the prevention of ventilator associated pneumonia in patients under ventilator

Purpose

Prevention

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 Undergo airway intubation on the first day The patient should remain intubated for at least 72 hours No immunosuppression due to certain drugs or diseases

Exclusion criteria:

Malignancy Diabetes Chronic obstructive pulmonary disease History of broad-spectrum antibiotic therapy in the last 3 months Dissatisfaction of patient or his/her companion to participate in the study

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Care provider

Sample size

Target sample size: **60**

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 two parts, and each part of the codes will be assigned to a group.

Blinding (investigator's opinion)

Single blinded

Blinding description

To blind the present study solutions will be prepared similarly in volume, shape, and smell and will be coded with labels A and B. Then these solutions will be given daily to a nurse who is completely unaware of the type of mouthwash.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zabol University of Medical Sciences

Street address

Zabol University of Medical Sciences, Shahid Rajaei Street, Zabol:Iran

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Sistan-va-Balouchestan

Postal code

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Approval date

2023-10-29, 1402/08/07

Ethics committee reference number

IR.ZBMU.REC.1402.091

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

Ventilator associated pneumonia

Timepoint

Ventilator associated pneumonia will be determined 5 days after the intervention.

Method of measurement

Clinical Pulmonary Infection Score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group will receive 15 ml of pre-prepared solution containing 0.2% chlorhexidine (Iran Najo Pharmaceutical Company) alone 2 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 15 drop of pre-prepared solution containing Persica (pur sina Pharmaceutical Company) alone 2 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

Allameh Bohloul Gonabadi Hospital

Full name of responsible person

Mostafa Mirzaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zabol University of Medical Sciences

Full name of responsible person

Khadijeh Rezaie Keikhaie

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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

Zabol 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

Zabol University of Medical Sciences

Full name of responsible person

Mostafa Mirzaei

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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 ProtocolUndecided - 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