

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the immediate Antibacterial Effects of persica , Chlorhexidine and normal saline Mouthwash in ICU patients

Protocol summary

Summary

The aim of this study is to compare the Antibacterial Effects of Chlorhexidine, persica and normal saline Mouthwashes in ICU patients. This is a randomized double blind clinical trial which will be done on 60 patients who will be admitted to ICUs of Imam Khomeini General Hospital and meet inclusion criteria. Patients will be randomly assigned into three equal (20 persons) groups: 1. Chlorhexidine group 2. persica group 3. normal saline group. In three groups, all surfaces of mouth, gingiva, tongue, throat and teeth will be swabbed carefully by 10 cc of mouthwashes (Chlorhexidine 0.2 % in the first group and persica in second group) for 6 minutes. Immediately before and after using mouthwashes, salivary sample without any stimulation will be taken for culturing S.aureus and pneumococcus. The antibacterial effects of mouthwashes will be determined by the presence or absence of S. aureus and pneumococcus in samples after rinsing. To compare the number of bacterial colony ANOVA Test and for Comparison of S. aureus and pneumococcal in a group McNemar Test and between three groups Chi-Square Test were used.

General information

Acronym

persica

IRCT registration information

IRCT registration number: **IRCT138903254190N1**

Registration date: **2010-12-29, 1389/10/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-12-29, 1389/10/08

Registrant information

Name

Hadi Darvishi Khezri

Name of organization / entity

Islamic Azad University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2010-10-23, 1389/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the immediate Antibacterial Effects of persica , Chlorhexidine and normal saline Mouthwash in ICU patients

Public title

Antibacterial effects of chlorhexidine , persica and saline mouthwashes

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Age between 15-65 years, Third and fourth day of admission in ICU, Intubation and mechanical ventilation for 3 to 4 days, having NG tube

for 3 to 4 Exclusion Criteria: Re-intubation, History of antibiotic therapy before admission, Oral anticoagulation therapy, Respiratory and systemic infection, Autoimmune diseases and malignancies, History of allergy to mouthwash, asthma, allergic rhinitis and dermatitis, History of radiation therapy and immunosuppressive therapy including corticosteroid, Use of any kind of antimicrobial mouthwash within 2 months before admission, Diseases of oral mucosa and severe periodontitis, History of splenectomy and Tonsillectomy, Negative cultures of S.aureus and pneumococcus before use of mouthwash, Occurrence of any reaction to Mouthwashes

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

In this double blind randomized clinical trial samples in the three groups will be labeled by letters A, B and C and Laboratory staffs are unaware of the intervention groups. Patients are also blind as they are unconscious at the time of intervention.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Deputy of research of Mazandaran University of medical sciences

Street address

Moalem Square, Deputy of research of Mazandaran University of medical sciences

City

Sari

Postal code

48175-866

Approval date

2010-09-29, 1389/07/07

Ethics committee reference number

89-101

Health conditions studied**1****Description of health condition studied**

ventilator associated pneumonia

ICD-10 code

J13

ICD-10 code description

Pneumonia due to Streptococcus pneumoniae

2**Description of health condition studied**

ventilator associated pneumonia

ICD-10 code

J15.2

ICD-10 code description

Pneumonia due to staphylococcus

Primary outcomes**1****Description**

number of colony of S.aureus and pneumococcus

Timepoint

Immediately before and after using mouthwashes

Method of measurement

CFU(Colony-forming unit)

Secondary outcomes**1****Description**

any reaction to Mouthwashes

Timepoint

after using of mouthwashes

Method of measurement

inspection

Intervention groups**1****Description**

In first group, will used chlorhexidine gluconate 0.2% mouthwash, manufactured by pharmaceutical company of drug city (Tehran - Iran).all surfaces of mouth, gingiva, tongue, throat and teeth will be swapped carefully by 10 cc of mouthwashes (chlorhexidine gluconate 0.2%) for 6 minutes. Immediately before and after using of mouthwashes, salivary sample without any stimulation was taken for culturing S.aureus and pneumococcus.

Category

N/A

2

Description

In second group, will used persica 10% mouthwash, manufactured by pharmaceutical company of pursina. all surfaces of mouth, gingiva, tongue, throat and teeth will be swapped carefully by 10 cc of mouthwashes (persica 10%) for 6 minutes. Immediately before and after using of mouthwashes, salivary sample without any stimulation was taken for culturing S.aureus and pneumococcus.

Category

N/A

3

Description

In third group, will used normal salin mouthwash. all surfaces of mouth, gingiva, tongue, throat and teeth will be swapped carefully by 10 cc of mouthwashes (normal salin) for 6 minutes. Immediately before and after using of mouthwashes, salivary sample without any stimulation was taken for culturing S.aureus and pneumococcus.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

ICUs of Imam Khomeini General Hospital

Full name of responsible person

Hadi darvishi khezri-MSc of critical Care Nursing

Street address

Imam Khomeini general Hospital

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati MD

Street address

Deputy of research of Mazandaran University of medical sciences

City

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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

Mazandaran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University Of Medical Sciences

Full name of responsible person

Hadi Darvishi Khezri

Position

MSc of Critical care nursing-Nurse of ICU

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty