

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of the Antibacterial Effects of Matrica and Chlorhexidine Mouthwashes in ICU patients

Protocol summary

Summary

The aim of this study is to compare the Antibacterial Effects of Matrica and Chlorhexidine 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 two equal (30 persons) groups: 1- Chlorhexidine group (control) 2- Matrica group (intervention). The patients will be matched by drug regimen, duration of ICU and hospital stay, and frequency of mouth washing with normal saline before study. In both group, 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 matrica 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 significant decrease of the total number of *S.aureus* and *pneumococcus* after using mouthwashes

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904244365N2**

Registration date: **2010-08-24, 1389/06/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-08-24, 1389/06/02

Registrant information

Name

Afshin Gholipour Baradari

Name of organization / entity

Mazandaran University of Medical Sciences

Country

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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

2010-08-22, 1389/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Antibacterial Effects of Matrica and Chlorhexidine Mouthwashes in ICU patients

Public title

Comparison of the Antibacterial Effects of Matrica and Chlorhexidine Mouthwashes in ICU patients

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 days, GCS < 8, More than 106 bacteria in salivary sample before mouthwash usage Exclusion Criteria: Re-intubation, History of antibiotic therapy before admission, Oral anticoagulation therapy, CHF and

Hypertension (BP > 140/90), 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, Negative cultures of S.aureus and pneumococcus before use of mouthwash, Occurrence of any reaction to Mouthwashes

Age

From **15 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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Moallem Square

City

sari

Postal code

46175866

Approval date

2010-08-04, 1389/05/13

Ethics committee reference number

89-55

Health conditions studied

1

Description of health condition studied

ventilator associated pneumonia

ICD-10 code

j13-j15.2

ICD-10 code description

Pneumonia due to Streptococcus pneumoniae-
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

Secondary outcomes

1

Description

any reaction to Mouthwashes

Timepoint

after using of mouthwashes

Method of measurement

inspection

Intervention groups

1

Description

All surfaces of mouth, gingiva, tongue, throat and teeth will be swapped carefully by 10 cc of Chlorhexidine 0.2 % mouthwash for 6 minutes

Category

Prevention

2

Description

All surfaces of mouth, gingiva, tongue, throat and teeth will be swapped carefully by 10 cc of matrica mouthwash for 6 minutes

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

ICUs of Imam Khomeini General Hospital

Full name of responsible person

Afshin Gholipour Baradari, MD, CCMF, Assistant professor

Street address

Imam Khomeini general Hospital, Amir St.

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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

Mazandaran University of Medical Sciences, Moallem Square

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Sari

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**Street address**

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Person responsible for scientific inquiries

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Position

CCMF, Assistant Professor, Chief of ICU

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Person responsible for updating data

Contact

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