Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 swapped 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 pneumoccocus. The antibacterial effects of mouthwashes will be determined by significant decrease of the total number of S.aureus and pneumoccocus 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 pneumoccocus 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 pneumoccocus

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.

City

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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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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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Web page address
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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