

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the effect of comprehensive oral care program and combination of toothbrush and mouthwash with chlorhexidine 0.2% on the incidence of ventilator-associated pneumonia and oral health status in patients undergoing mechanical ventilation

Protocol summary

Study aim

Comparison of the effect of comprehensive oral care program and combined toothbrush and mouthwash program with 0.2% chlorhexidine on the incidence of ventilator-associated pneumonia and oral health status

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 90 patients, with permutation blocks were assigned to three groups

Settings and conduct

Intensive care unit of Khatam Al-Anbia Hospital in Zahedan. The anesthesiologist interpreting the chest photograph will not know about the patients in the three groups, the person performing the oral health assessment know about the groups.

Participants/Inclusion and exclusion criteria

Hospitalized patients with mechanically ventilated endotracheal tube

Intervention groups

Comprehensive oral care program: wash hands and wear gloves, control endotracheal tube cuff pressure, raise the head of the bed by 30 to 45 degrees, brush the inner and outer surfaces of teeth, gums and tongue for 2 minutes using a baby toothbrush and Toothpaste with rotational movements, deep throat and mouth suction for 30 seconds while 0.9% normal saline is poured into the patient's mouth and teeth, mouthwash with 0.2% chlorhexidine antibacterial solution with a swab, moisturizing all mucosal surfaces The patient's mouth, gums and tongue are swabbed and vitamin A + D is used to lubricate the lips. Combined program of toothbrush and mouthwash with chlorhexidine 0.2%: The intervention is performed during 5 days of study for 5 minutes each time of oral care. With a baby toothbrush and antimicrobial toothpaste containing half a centimeter of fluoride, all the outer and inner surfaces of

the teeth and gums are gently brushed with a circular motion. The teeth, tongue and palate surfaces are then brushed back and forth.

Main outcome variables

Ventilator-associated pneumonia, oral health status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201121049455N1**

Registration date: **2020-12-10, 1399/09/20**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-10, 1399/09/20**

Update count: **0**

Registration date

2020-12-10, 1399/09/20

Registrant information

Name

Fatemeh Kordsalarzahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 54 3343 0059

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-07, 1399/06/17

Expected recruitment end date

2021-09-08, 1400/06/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of comprehensive oral care program and combination of toothbrush and mouthwash with chlorhexidine 0.2% on the incidence of ventilator-associated pneumonia and oral health status in patients undergoing mechanical ventilation

Public title

Study of the effect of comprehensive oral care program and combination of toothbrush and mouthwash with chlorhexidine 0.2% on the incidence of ventilator-associated pneumonia and oral health status in patients undergoing mechanical ventilation.

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range 65-18 years On the second day of the patient's hospitalization Achieve a score less than or equal to 5 of the MCPIS criteria No severe damage to face and mouth No chronic disease and defective immune system No movable dentures The patient is not pregnant Normal coagulation status

Exclusion criteria:

Performing a tracheostomy procedure during the study Removal or replacement of endotracheal tube during the study Detach from mechanical ventilation before 96 hours Clearance from the ward Allergy to chlorhexidine Reluctance to continue the study by the legal guardian Patient death Evidence of signs and symptoms of aspiration after the start of the study according to the patient file

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Using permutation blocks, patients were assigned to three groups: comprehensive oral care program, combined toothbrush and mouthwash program, and control. Considering that three groups were considered in the study, patients were divided into fifteen cases of six blocks, A group of comprehensive oral care program and B group of toothbrush and mouthwash and C control

group (for example: (AABBCC, ABABCC, BBAACC,...)).

There were two people in each block from each group. The order of the blocks was determined randomly using a random number table and then the patients entered the comprehensive care, toothbrush, mouthwash and control group based on the blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

The ambiguity of the study was that the anesthesiologist interpreting the chest X-ray, which is part of the MCPIS instrument, did not know the patients in the three groups and confirmed the presence or absence of infiltration without knowing which group the patient was in. . Also, the person conducting the oral health assessment has no information about the patients' inclusion in the study groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Zahedan University of Medical Sciences

Street address

Zahedan University of Medical Sciences, Dr. Hesabi Square

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2020-09-07, 1399/06/17

Ethics committee reference number

IR.ZAUMS.REC.1399.220

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

Ventilator associated pneumonia

ICD-10 code

J15.6

ICD-10 code description

Pneumonia due to other Gram-negative bacteria

Primary outcomes

1

Description

Ventilator-dependent pneumonia score

Timepoint

Ventilator-dependent pneumonia score before intervention and end of fifth day

Method of measurement

Clinically modified pneumonia scale

2

Description

Oral health status

Timepoint

Beck oral assessment scale score during five days of study

Method of measurement

Beck Oral Assessment Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Comprehensive Oral Care Plan: The Comprehensive Oral Care Plan was designed based on previous studies and included performing the following 5 minutes of oral care each time: Washing hands and wearing gloves, controlling cuff tube pressure in Less than 25 mm Hg, raising the head of the bed by 30 to 45 degrees, brushing the inner and outer surfaces of the teeth, gums and tongue for 2 minutes using a baby toothbrush and toothpaste with rotating movements, deep throat and mouth suction. For 30 seconds while 0.9% normal saline is poured into the patient's mouth and on the teeth, rinse the mouth with 0.2% chlorhexidine antibacterial solution with a swab, moisten all surfaces of the patient's oral mucosa, gums and tongue using a swab. And use vitamin A + D to lubricate the lips. If there was an oral pharyngeal airway, it was removed, cleaned and repositioned in the patient's mouth.

Category

Prevention

2

Description

Intervention group: Combined program of toothbrush and mouthwash with chlorhexidine 0.2%: The intervention was performed during 5 days of study for 5 minutes each time of oral care. With a baby toothbrush and antimicrobial toothpaste containing half a centimeter of fluoride, all the outer and inner surfaces of the teeth and gums were gently brushed with rotating movements. The teeth, tongue surfaces, and palate were then brushed

back and forth. After brushing, each part of the mouth was cleaned with sterile distilled water, so that the applicator was soaked with sterile distilled water and rinsed and cleaned with that mouth. The mouth, tongue, and teeth were then flushed with a swab soaked in chlorhexidine solution. The control group received routine oral care.

Category

Prevention

3

Description

Control group: Mouthwash with chlorhexidine

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam Al-Anbia Hospital

Full name of responsible person

Fariba Yaghobinia

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

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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
Zahedan 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
Zahedan University of Medical Sciences

Full name of responsible person
Fariba Yaghoubinia

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - 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