Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The comparative effects of the mouthwash containing Zataria multiflora essence 2% and chlorhexidine 0.2% on the prevention of ventilator-associated pneumonia in patients admitted to intensive care units

Protocol summary

Study aim

To examine the effects of mouthwash containing Zataria multiflora essence 2% and chlorhexidin 0.2% on the prevention of ventilator associated pneumonia in patients admitted to intensive care units

Design

This is a single blind RCT. A total of 120 patients are selected based on convenience sampling and will be randomly allocated to either the experimental or control group.

Settings and conduct

120 patients to be admitted to ICUs are selected based on convenience sampling method and will be randomly allocated to either the experimental or control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18-65 years Having a tracheal tube <12 hours elapsed since ICU admission Having natural teeth Exclusion criteria: Patients with tracheostomy tube A history of taking antibiotics during the last two weeks A history of allergy to chlorhexidine and herbal mouthwashes Reintubation Severe maxillofacial trauma Cervical spine immobilization Pregnant and lactating women A history of malignancies A history of head and neck radiotherapy A history of oral mucositis and periodontal diseases Patients diagnosed with sepsis Immune system disorders Patients with lung diseases Simultaneously participating in other interventional studies Patients with COVID-19 in admission

Intervention groups

In the experimental group, the nurse will apply 10 CC of Zataria multiflora essence mouthwash 2% twice a day for five consecutive days. This group will also receive the routine mouth care with chlorhexidine 0.2% as the same as the control group. In the control group, the nurse will apply 10 CC of chlorhexidine 0.2% twice a day for five consecutive days.

Main outcome variables

Clinical Pulmonary Infection Score

General information

Reason for update

Patients will be recruited from two participating hospitals.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210523051370N6**
Registration date: **2022-05-21, 1401/02/31**
Registration timing: **prospective**

Last update: **2022-07-15, 1401/04/24**
Update count: **1**

Registration date

2022-05-21, 1401/02/31

Registrant information

Name

Seyed Afshin Shorofi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 7342

Email address

ashorofi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-05, 1401/03/15

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparative effects of the mouthwash containing Zataria multiflora essence 2% and chlorhexidine 0.2% on the prevention of ventilator-associated pneumonia in patients admitted to intensive care units

Public title

The effect of mouthwash containing Zataria multiflora essence 2% on the prevention of ventilator-associated pneumonia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 18-65 years Having a tracheal tube <12 hours elapsed since ICU admission Having natural teeth

Exclusion criteria:

Patients with tracheostomy tube A history of taking antibiotics during the last two weeks A history of allergy to chlorhexidine and herbal mouthwashes Reintubation Severe maxillofacial trauma Cervical spine immobilization Pregnant and lactating women A history of malignancy and cancer A history of head and neck radiotherapy A history of oral mucositis and periodontal diseases Patients diagnosed with sepsis Patients with immune system disorders Patients with lung diseases (including pneumonia, asthma, and allergic rhinitis) Simultaneously participating in other interventional studies Patients with COVID-19 in admission Withdrawal criteria: patient death; patients transferred to the ward or other hospitals; reintubation; side effects associated with the use of either mouthwash; oral mucositis and periodontal diseases; sepsis; unwillingness to continue participation in the study; eligibility criteria violated

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: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 120 eligible patients are selected based on convenience sampling and will then be randomly allocated to either the experimental (A) or control group (B) using permuted block randomization. When the block size is four, there are six possible sequences of letter placement (i.e., AABB1-ABBA2-BABA3-BBAA4-BABA5-ABAB6). Using Random Allocation Software 2.0, one of the numbers from one to six is randomly selected thirty times. Each number determines four modes of placement in a block. To ensure the concealment of the sequence of enrolment, we will use the sequentially numbered, opaque sealed envelopes (undertaken by a person unaware of the study objectives and group allocations). Each envelop will contain the group assignment for four patients. The assessor will be blind to treatment allocation.

Blinding (investigator's opinion)

Single blinded

Blinding description

To ensure the concealment of the sequence of enrolment, we will use the sequentially numbered, opaque sealed envelopes (undertaken by a person unaware of the study objectives and group allocations). The outcome assessor will also be blind to the random assignment of patients to the groups.

Placebo

Not used

Assignment

Parallel

Other design features

We will only take chest X-rays (CXR) for patients suspected of having pneumonia. An assessor with intensive care subspecialty will interpret the CXRs. Mouthwash (chlorhexidine 0.2% for the control group; chlorhexidine 0.2% + Zataria multiflora essence mouthwash 2% for the experimental group) will be administered twice a day (every 12 hours) for five consecutive days. The assessor will check and record the Clinical Pulmonary Infection Score (CPIS) of all patients on the first, third, and fifth days. The nurse who applies the mouthwash checks the patient's oral condition.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Bioethics Committee of Mazandaran University of Medical Sciences

Street address

Moalem Square, Sari, Mazandaran Province

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Sari

Postal code

4815733971

Approval date

2022-03-30, 1401/01/10

Ethics committee reference number

IR.MAZUMS..REC.1401.11695

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

Clinical Pulmonary Infection Score

Timepoint

Clinical Pulmonary Infection Score on first, third and fifth days of mouthwash use

Method of measurement

Pulmonary of Infection Survey Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patient is assessed for pneumonia using the Clinical Pulmonary Infection Score (CPIS) before the mouthwash is administered. All the tooth surfaces and gum are cleaned using a soft bristled toothbrush and toothpaste for 2 minutes. The teeth and mouth are then cleaned with 5 CC of 0.9% normal saline and oral suction is simultaneously performed for 30 seconds. Chlorhexidine 0.2 (10 cc) is then used to rinse the mouth for one minute twice a day. Thereafter oral suction is done for 30 seconds. Finally, the mouthwash containing Zataria multiflora essence 2% (10 cc) will be applied twice a day for one minute and oral suction is then performed for 30 seconds.

Category

Prevention

2

Description

Control group: The nurse will apply 10 CC of chlorhexidine 0.2% twice a day for five consecutive days.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr Seyed Afshin Shorofi

Street address

Imam Khomeini Hospital, Amir Mazandarani Street, Sari

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2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran 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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Seyed Afshin Shorofi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Complementary & Integrative Medicine

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Position

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Latest degree

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Person responsible for updating data

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Name of organization / entity

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Position

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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

All data will be kept confidential

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable