

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

The comparative effects of mouthwash containing pomegranate peel extract (*Punica granatum*) and chlorhexidin 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 pomegranate peel extract (*punica granatum*) and chlorhexidin 0.2% on the prevention of ventilator associated pneumonia in patients admitted to intensive care units

Design

This is a single blind randomized controlled clinical trial. A total of 120 eligible patients will be selected based on convenience sampling. The researchers will allocate them to experimental and control groups using block randomization.

Settings and conduct

This is a single blind RCT (an assessor blind trial) in which a total of 120 patients to be admitted to ICUs will be selected based on convenience sampling method. The researchers will allocate them to experimental and control groups using block randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients aged 18-65 years having a tracheal tube up to 12 hours to elapse after ICU admission
Exclusion criteria: tracheostomy tube reintubation

Intervention groups

In the experimental group, the nurse will apply 20 CC of 5% pomegranate peel extract mouthwash twice a day using a syringe. Then, she cleanses the teeth, tongue, gum, and oral mucosa and simultaneously suctions the mouth and pharynx for 30 seconds. Finally, she moisturizes the lips with A+D moisturizing cream. If there is an airway, she will remove and clean it and put it back in the mouth. In the control group, the nurse will apply 10 CC of 0.2% chlorhexidine mouthwash solution twice a day on the teeth, tongue, gum, and oral mucosa and simultaneously suctions the mouth and pharynx for 30 minutes.

Main outcome variables

Pneumonia severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210523051370N4**

Registration date: **2021-10-12, 1400/07/20**

Registration timing: **prospective**

Last update: **2021-10-12, 1400/07/20**

Update count: **0**

Registration date

2021-10-12, 1400/07/20

Registrant information

Name

Seyed Afshin Shorofi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The comparative effects of mouthwash containing pomegranate peel extract (*Punica granatum*) and chlorhexidin 0.2% on the prevention of ventilator associated pneumonia in patients admitted to intensive care units

Public title
The effect of pomegranate peel extract on the prevention of ventilator-associated pneumonia

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 18-65 years Having a tracheal tube Up to 12 hours to elapse after ICU admission Not affected by immune system disorders or lung diseases, including pneumonia, asthma, and allergic rhinitis Having natural teeth Not simultaneously participating in other interventional studies
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 Pregnant and lactating patients A history of malignancy and cancer A history of head and neck radiotherapy A history of oral mucositis and periodontal diseases Patients with sepsis and COVID-19 in admission Patients with COVID-19 in admission

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 will be selected based on convenience sampling. The researchers will allocate them to experimental (A) and control groups (B) using block randomization. When the block size is four, there are six possible sequences of letter placement (i.e., AAB1-ABBA2-BABA3-BBAA4-BABA5-ABAB6). Then, 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. The blocks of four participants are randomly placed in 30 opaque envelopes and arranged based on their numbers. A person who is not a member of the research team and

is unaware of the research objectives and the participant's allocation in the study groups will seal the envelopes. The researcher will open the envelopes in order and assign the patients to the relevant groups. The assessor will also be blind to the random assignment of patients in the groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

The assessor will be blind to the random assignment of patients in 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. Oral care and using mouthwash (0.2% chlorhexidine for the control group and pomegranate peel extract mouthwash for the experimental group) will be performed 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. A dentist has adequately trained the nurse who applies the mouthwash and checks the patients' 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

City

sari

Province

Mazandaran

Postal code

4815733971

Approval date

2021-06-08, 1400/03/18

Ethics committee reference number

IR.MAZUMS.REC.1400.234

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. According to the CPIS, a score of 6 or higher indicates mechanical ventilator-associated pneumonia.

Timepoint

The assessor will check and record the Clinical Pulmonary Infection Score of all patients on first, third and fifth days.

Method of measurement

Pulmonary of Infection Survey Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Before using mouthwash, the pneumonia is assessed using the Clinical Pulmonary Infection Score (CPIS). To apply the mouthwash in the experimental and control groups, the researcher will prepare the required equipment at the patient's bedside. It includes suction, suction tip, Nelaton Catheter FG 14, toothpaste, toothbrush, moisturizing cream, 0.9% normal saline, 5 CC syringe, gloves, pomegranate peel extract mouthwash, scissors, bandage, and regular gauze. Then, the ICU nurse (someone other than the researchers) washes her hands, wears gloves, puts one centimeter of fluoride Signal toothpaste on a soft toothbrush, and brushes all the surfaces of the teeth (i.e., buccal, lingual/palatal, and the gum surfaces) with rotating along with up-down movements for 2 minutes. Then, she cleanses the surface of the teeth and mouth with 5 CC of 0.9% normal saline and simultaneously suctions it for 30 seconds. In the experimental group, the nurse, who is trained how to brush teeth and how to use chlorhexidine and pomegranate peel extract mouthwashes, will apply 20 CC of 5% pomegranate peel extract mouthwash twice a day using a syringe. Then, she cleanses the teeth, tongue, gum, and oral mucosa and simultaneously suctions the mouth and pharynx for 30 seconds.

Category

Prevention

2

Description

To apply the mouthwash in the control groups, the researchers will prepare the required equipment at the patient's bedside. It includes suction, suction tip, Nelaton Catheter FG 14, toothpaste, toothbrush, moisturizing cream, 0.9% normal saline, 5 CC syringe, gloves, 0.2%

chlorhexidine solution, scissors, bandage, and regular gauze. Then, the ICU nurse (someone other than the researchers) washes her hands, wears gloves, puts one centimeter of fluoride Signal toothpaste on a soft toothbrush, and brushes all the surfaces of the teeth (i.e., buccal, lingual/palatal, and the gum surfaces) with rotating along with up-down movements for 2 minutes. Then, she cleanses the surface of the teeth and mouth with 5 CC of 0.9% normal saline and simultaneously suctions it for 30 seconds. In the control group, the nurse will apply 10 CC of 0.2% chlorhexidine mouthwash solution twice a day on the teeth, tongue, gums, and oral mucosa and simultaneously suctions the mouth and pharynx for 30 minutes.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr Seyed Afshin Shorofi

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Imam Khomeini Hospital. Amir Mazandarani Street.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Prof. Majid Saeedi

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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
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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable