

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of Myrtus herbal mouthwash versus chlorhexidine mouthwash on the prevention of Ventilator Associated Pneumonia

Protocol summary

prevention of Ventilator Associated Pneumonia

Study aim

Comparison of the effect of Myrtus herbal mouthwash versus chlorhexidine mouthwash on the prevention of Ventilator Associated Pneumonia in ICU patients

Design

randomized, blinded, clinical trial with a parallel group design of 70 patients

Settings and conduct

70 patients with endotracheal tubes in the intensive care units of Ghaem Hospital in Mashhad, who have the criteria to enter the study, are evaluated and compared in the stages before the intervention and in the fifth day by using the Clinical Pulmonary Infection Scale.

Participants/Inclusion and exclusion criteria

The main caregiver of the patient should be consciously satisfied to participate in the research (due to the disorder in the patient's level of consciousness), The patient's age should be between 70-18 years, Immunosuppressive diseases and underlying lung disease are not recognized by the treating physician, Do not have a specific lesion in or around the mouth, Has no history of allergy to herbal ingredients (according to the history obtained from the patient's primary caregiver), Under mechanical ventilation through the endotracheal tube, At the time of hospitalization in the ICU and intubation, there is no evidence of pneumonia in chest radiography at the discretion of the treating physician, Must be mechanically ventilated for at least the next 48 hours (according to the definition of Ventilator Associated Pneumonia).

Intervention groups

The herbal mouthwash used in the intervention group and chlorhexidine mouthwash 0.2% in the control group for 5 days and three times a day by the same method are used by researcher. Other care will be the same in both groups.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200705048006N1**

Registration date: **2020-08-03, 1399/05/13**

Registration timing: **prospective**

Last update: **2020-08-03, 1399/05/13**

Update count: **0**

Registration date

2020-08-03, 1399/05/13

Registrant information

Name

Ali Farahmandnasab

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3859 1511

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farahmandna961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-21, 1399/06/31

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Myrtus herbal mouthwash versus chlorhexidine mouthwash on the prevention of Ventilator Associated Pneumonia

Public title

Comparison of the effect of Myrtus herbal mouthwash versus chlorhexidine mouthwash on the prevention of Ventilator Associated Pneumonia

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

The main caregiver of the patient should be consciously satisfied to participate in the research (due to the disorder in the patient's level of consciousness) The patient's age should be between 70-18 years Immunosuppressive diseases and underlying lung disease are not recognized by the treating physician Do not have a specific lesion in or around the mouth Has no history of allergy to herbal ingredients (according to the history obtained from the patient's primary caregiver) Under mechanical ventilation through the endotracheal tube At the time of hospitalization in the ICU and intubation, there is no evidence of pneumonia in chest radiography at the discretion of the treating physician Must be mechanically ventilated for at least the next 48 hours (according to the definition of Ventilator Associated Pneumonia)

Exclusion criteria:

Withdrawal of the patient's primary caregiver from continuing the study Transfer or death of the patient, removal of the endotracheal tube before 48 hours Allergic reaction to mouthwash Observation of obvious aspiration (observation of gastric material during endotracheal tube suction, change of position, cough, etc.) Do not have an upper airway infection (based on your doctor's diagnosis)

Age

From **18 years** old to **70 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Care provider
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a random sequence generated by SPSS software that is written on small cards and kept in an envelope in a package. After confirming the entry of each research unit into the study, the envelope is opened and based on the entered code, the patient enters one of the two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

- Participants in this study are unconscious patients and their primary caregiver is unaware of the type of mouthwash used for them. Therefore, the patient's primary caregiver is blind to the intervention. - After data collection by one researcher, statistical analysis will be performed by another person who does not know the type of intervention and data related to each group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Mashhad University of Medical Sciences

Street address

Ibn Sina Avenue, Faculty of Nursing and Midwifery

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2020-07-06, 1399/04/16

Ethics committee reference number

IR.MUMS.NURSE.REC.1399.015

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

Ventilator Associated Pneumonia

ICD-10 code

J00-J99

ICD-10 code description

Diseases of the respiratory system:pneumonia

Primary outcomes**1****Description**

prevention of Ventilator Associated Pneumonia

Timepoint

Before the intervention and the fifth day after the intervention

Method of measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group receives oral care with the herbal mouthwash for 5 days and three times a day by the same method by the researcher. Other care will be the same in both groups. This mouthwash is a leaf extract of the plant with a concentration of 5%, which will be prepared and calibrated by the Faculty of Traditional and Complementary Medicine.

Category

Treatment - Drugs

2

Description

Control group: Oral care with chlorhexidine mouthwash 0.2% of the construction of Iran Najo Pharmaceutical Factory, which will be poured in 30 cc, will be received by the researcher in the same way for 5 days and three times a day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان قائم (عج) مشهد

Full name of responsible person

علی فرهمند نسب

Street address

مشهد، میدان دکتر علی شریعتی، ابتدای خیابان احمدآباد

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

محسن تفقدی

Street address

خیابان دانشگاه، رو به روی خیابان دانشگاه 18، معاونت پژوهش و فناوری دانشگاه

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Razavi Khorasan

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+98 51 3841 2081

Email

tafaghodim@mums.ac.ir

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Ali Farahmand Nasab

Position

دانشجو

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Mashhad, Ibn Sina Street, School of Nursing and Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

علی فرهمند نسب

Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All potential data can be shared after people have not been identified

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

The data can be used for other human research and health centers

From where data/document is obtainable

Library of Mashhad School of Nursing and Midwifery

What processes are involved for a request to access data/document

By visiting the library of Mashhad School of Nursing and Midwifery in person or online

Comments

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ali Farahmand Nasab

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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