# 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

**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**
prevention of Ventilator Associated Pneumonia

## 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**

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Iran (Islamic Republic of)

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**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**

Clinical Pulmonary Infection Scale

## 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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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
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## Person responsible for updating data

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student

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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**