Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative Study of The Effect of Botanical Extract Mouthwashes of Tea Tree Oil/Aloe vera and Chlorhexidine on Prevention of Ventilator-Associated Pneumonia in Admitted Patients in Intensive Care Unites

Protocol summary

Study aim

Determining and comparing the effect of mouthwash containing tea tree oil/aloe vera extract and chlorhexidine on prevention of early and late ventilator-associated pneumonia in intubated patients hospitalized in intensive care units

Design

A clinical double-blind trial, with parallel groups, randomized by simple randomization method, with the participation of 62 intubated patients

Settings and conduct

This study is conducted in hospitals affiliated to Arak University of Medical Sciences and in intensive care units. Oral care in the intervention group was performed using tea tree oil/aloe vera mouthwash and in the control group using chlorhexidine 0.2%. Patients Due to the lack of consciousness and awareness as well as nurses and caregivers are unaware of the placement of people in the intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: •The presence of a endotracheal tube • Age 16 to 65 years •Mechanical ventilation for at least 72 hours •Absence of pulmonary infection based on the modified clinical pulmonary infection score (scoring less than 5 at the time of entering the study) •Absence of allergy to herbal compounds of tea tree oil or aloe vera Criteria for not entering the study: •Traumatization during intubation •Transferring the patient from ICU or his death •Extubation of the patient for any reason • Unwillingness of the patient's companions to continue the study •Observing side effects caused by mouthwash •Sudden changes in the patient's clinical condition or breathing pattern

Intervention groups

Oral care in intervention group will be performed using mouthwash containing tea tree oil/aloe vera extract and in control group by using 0.2% chlorhexidine mouthwash. The method, time, frequency of mouthwash is done in the same way in both groups.

Main outcome variables

ventilator-associated pneumonia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210104049936N1**
Registration date: **2022-08-14, 1401/05/23**
Registration timing: **prospective**

Last update: **2022-08-14, 1401/05/23**
Update count: **0**

Registration date

2022-08-14, 1401/05/23

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-16, 1401/05/25

Expected recruitment end date

2022-11-16, 1401/08/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Study of The Effect of Botanical Extract Mouthwashes of Tea Tree Oil/Aloe vera and Chlorhexidine on Prevention of Ventilator-Associated Pneumonia in Admitted Patients in Intensive Care Unites

Public title

Comparative Study of The Effect of Botanical Extract Mouthwashes of Tea Tree Oil/Aloe vera and Chlorhexidine on Prevention of Ventilator-Associated Pneumonia in Admitted Patients in Intensive Care Unites

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

To have oral endotracheal tube Age between 16 to 65 Being at least 72 hours ventilated Absence of pulmonary infection based on the modified pulmonary infection clinical score (score less than 5 at the time of study entry) Absence of history of allergy to herbal compounds of tea tree oil or aloe vera (based on the history obtained from the legal guardian or the patient's companion) Absence of specific oral lesions or infections Absence of sepsis, pulmonary thromboembolism, absence of history and signs of aspiration, absence of orthodontics, atelectasis, inflammatory gastrointestinal or bile ducts diseases and severe liver diseases according to the diagnosis of a specialist doctor (based on physical examination and history obtained from the legal guardian or with the patient).

Exclusion criteria:

Traumatization during intubation Transferring patient from the ICU (for any reason) or death before completing the study Patient extubation for any reason Withdrawal or unwillingness of the legal guardian of the patient to continue the study Observing side effects caused by using mouthwash such as hives, itching and skin rashes Sudden changes in the patient's clinical condition or breathing pattern The presence of defects in the patient's immune system

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method. At first, preferably two hospitals or two general intensive care units with similar care protocols are divided into two groups: A and B. Then envelopes will assigned to each, another person randomly chooses the envelopes and according to the classification, one of the units (hospitals) will be the intervention group and the other will be the control group. Then, based on the inclusion criteria, the researcher will enter the patients in each group and the intervention will be carried out for that group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the lack of consciousness and awareness, the patients are not aware of being placed in the intervention or control group. Mouthwash bottles are also covered before distribution and coded by a person who does not participate in the study. The researcher, his colleagues (nurses or caregivers) and the doctor who determines the final result of the study will not know about the placement of people in the intervention or control group. Therefore the principle of double-blindness of the study is maintained.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

13th floor, Block A, Central Headquarters of the Ministry of Health, Treatment and Medical Education, Simai Iran St., between South Flamak and Zarafshan Ave,. Quds town (west), Tehran

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Approval date

2022-06-21, 1401/03/31

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.062

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
Ventilator-Associated Pneumonia
Timepoint
Assessing the presence or absence of ventilator-associated pneumonia upon entering the study (before the start of the intervention), day 3 (to diagnose early ventilator-associated pneumonia) and day 7 (to diagnose late ventilator-associated pneumonia) after the intervention
Method of measurement
The diagnosis of ventilator-associated pneumonia in this research will be done using the Modified Clinical Pulmonary Infection Score (MCPIS). This tool includes five laboratory and a score of 0-2 is considered for each criterion and the maximum score is 10. If the sum of scores is equal to or more than 6, pneumonia is diagnosed.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Before performing oral care, hands are washed according to the instructions and gloves are worn, and the oral cavity is evaluated. If there is a lesion, the doctor will be informed and if other treatments are needed, appropriate measures will be taken according to the doctor's order. Cuff pressure is adjusted to ensure proper fit using a special manometer (20-30 cm of water). The position of all patients in this study will be semi-sitting with an angle of 30-45 degrees if there are no contraindications. Then, twice a day (every 12 hours), all areas of the mouth, including the inner and outer surfaces of the teeth (with rotating movements), gums and tongue (with movements from back to front) are brushed with a soft toothbrush. Before and after brushing each part of the mouth, tea tree oil/aloe vera mouthwash is poured in the same part with a special syringe and suctioned in less than 30 seconds. Closed suctioning of subglottic secretions is also performed, and if the patient has an airway, it is removed, cleaned and put back in the mouth. At the end, the modified clinical pulmonary infection score is given to each patient 72 hours (to evaluate the incidence of early VAP) and 7 days (to evaluate the incidence of late VAP) after the intervention. Mouthwash containing tea tree oil extract/aloe vera is named Irsha and produced by Shafa Pharmaceutical and Health Laboratory. It is supplied in 250 ml bottles and are used twice a day in the amount of 15 ml each time.
Category
Prevention

2

Description
Control group: Before performing oral care, hands are washed according to the instructions and gloves are worn, and the oral cavity is evaluated. If there is a lesion, the doctor will be informed and if other treatments are needed, appropriate measures will be taken according to the doctor's order. Cuff pressure is adjusted to ensure proper fit using a special manometer (20-30 cm of water). The position of all patients in this study will be semi-sitting with an angle of 30-45 degrees if there are no contraindications. Then, twice a day (every 12 hours), all areas of the mouth, including the inner and outer surfaces of the teeth (with rotating movements), gums and tongue (with movements from back to front) are brushed with a soft toothbrush. Before and after brushing each part of the mouth, the 0/2% chlorhexidine mouthwash is poured in the same part with a special syringe and suctioned in less than 30 seconds. Closed suctioning of subglottic secretions is also performed, and if the patient has an airway, it is removed, cleaned and put back in the mouth. At the end, the modified clinical pulmonary infection score is given to each patient 72 hours (to evaluate the incidence of early VAP) and 7 days (to evaluate the incidence of late VAP) after the intervention. 0.2% chlorhexidine solution is manufactured by Shahr Daru Company, which is used in the control group.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

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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
Shahid Beheshti 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
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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