Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of botanical extract mouthwashes of meswak/aloe vera and chlorhexidine on prevention of ventilator-associated pneumonia in ventilated patient

Protocol summary

Study aim

The effect of mouthwash containing toothbrush / aloe vera wood extract and chlorhexidine solution on ventilator-induced pneumonia in patients with inpatient chip tubes in intensive care units is compared.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 70 patients. For randomization, the necessary software for permutation blocks is used

Settings and conduct

Intubated patients admitted to the intensive care units of Vali-e-Asr Teaching Hospital in Arak are randomly divided into two groups. Oral care and rinsing in patients in the intervention group using mouthwash containing toothbrush extract / aloe vera, and in patients in the control group using chlorhexidine mouthwash 0.2%.

Participants/Inclusion and exclusion criteria

Entry criteria: the presence of a chip tube through the mouth, age 16 to 65 years, artificial ventilation for at least 72 hours, the absence of pulmonary infection , lack of sensitivity to plant compounds, absence of sepsis, pulmonary embolism, Atherosclerosis, inflammatory diseases of the gastrointestinal tract, bile ducts and severe liver disease Criteria for leaving the study: Transfer of the patient from the ICU or his death before completing the study, the reluctance of the patient's companions to continue the study, observation of complications from using mouthwash such as urticaria, itching and skin rash, sudden changes in The patient's clinical condition or respiratory pattern, the presence of a defect in the patient's immune system

Intervention groups

Oral care and washing is performed in patients of the intervention group using mouthwash containing toothbrush / aloe vera wood extract, and in patients in the control group using chlorhexidine mouthwash 0.2%.

Main outcome variables

Comparison of ventilator-induced pneumonia in patients of the intervention and control group.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161014030294N4**
Registration date: **2020-09-09, 1399/06/19**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-09, 1399/06/19**
Update count: **0**

Registration date

2020-09-09, 1399/06/19

Registrant information

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Mansoreh Karimikia

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-20, 1399/03/31

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of botanical extract mouthwashes of meswak/aloe vera and chlorhexidine on prevention of ventilator-associated pneumonia in ventilated patient

Public title

Comparison of the effect of botanical extract mouthwashes of meswak/aloe vera and chlorhexidine on prevention of ventilator-associated pneumonia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Existence of endotracheal tube through the mouth Age 16 to 65 years Mechanical ventilation for at least 72 hours Absence of lung infection based on the clinical score of the modified lung infection Lack of sensitivity to plant compounds Absence of sepsis Absence of pulmonary thromboembolism Absence of atelectasis Absence of inflammatory diseases of the gastrointestinal tract Absence of severe liver and bile duct diseases

Exclusion criteria:

Transfer the patient from the ICU or die before completing the study Reluctance of the patient's companions to continue the study Observe the side effects of using mouthwash such as hives, itching and skin rashes Sudden changes in the patient's clinical condition or respiratory pattern occur Existence of defects in the patient's immune system

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling is done purposefully. We perform permutation block randomization method with statistical software. We considered four blocks for two mouthwashes. The possibility of predicting the type of treatment for the researcher is reduced.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are divided into two groups in the form of permutation blocks. Patients and caregivers and nurses responsible for collecting data are unaware of the type of mouthwash used. Mouthwashes are used in the same container and labeled A and B so that they are not identifiable in terms of the type of mouthwash.Patients do not notice the difference in the taste of mouthwash due to intubation and anesthesia

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province, Iran

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Postal code

۳۸۱۹۶۹۳۳۴۵

Approval date

2019-06-08, 1398/03/18

Ethics committee reference number

IR.ARAKMU.REC.1398.082

Health conditions studied

1

Description of health condition studied

Ventilator-associated pneumonia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The rate of ventilator-induced pneumonia

Timepoint

72 hours and 7 days after the intervention and when the patient is extubated.

Method of measurement

Microbiological tests of lung secretions

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Mouthwash containing toothbrush wood extract / Aloe vera produced by Barij Essential Oil Company is used. 5 ml of mouthwash is poured into different parts of the mouth using a syringe and immediately sucked. This operation is performed every 8 hours by the nurse for 14 days. The lung secretion culture test is performed on the third, seventh and fourteenth day.

Category
Prevention

2

Description
Control group: Mouthwash containing 0.2% chlorhexidine is used. 5 ml of mouthwash is poured into different parts of the mouth using a syringe and immediately sucked. This operation is performed every 8 hours by the nurse for 14 days. The lung secretion culture test is performed on the third, seventh and fourteenth day.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Vali Asr Hospital in Arak

Full name of responsible person
Behnam Mahmoudieh

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Sponsors / Funding sources

1

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Name of organization / entity
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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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Mansoreh Karimi Kia

Position
Lecturer

Latest degree
Master

Other areas of specialty/work
Nursery

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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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

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
Start the access period 2 months after printing the results

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Use documentation by citing the source

From where data/document is obtainable
Mansoreh Karimi Kia Arak University of Medical Sciences Phone 09181600717 Email karimikia93@gmail.com

What processes are involved for a request to access data/document
After receiving the request by phone or email, the data will be sent within 2 weeks.

Comments