

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

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

#### Protocol summary

##### Study aim

The effect of mouthwash containing toothbrush / aloë 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 / aloë 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 / aloë 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

##### Name

Mansoreh Karimikia

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3367 4702

##### Email address

m.karimikia@arakmu.ac.ir

##### 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/aloë vera and chlorhexidine on prevention of ventilator-associated pneumonia in ventilated patient

**Public title**  
Comparison of the effect of botanical extract mouthwashes of meswak/aloë 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

**City**

Arak

**Province**

Markazi

**Postal code**

۳۸۱۹۶۹۳۳۴۰

**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

##### Street address

Vali Asr Square

##### City

Arak

##### Province

Markazi

##### Postal code

3814957558

##### Phone

+98 86 3222 2004

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##### Email

Behnammahmoudye@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Alireza Kamali

##### Street address

A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak,  
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##### Email

a.kamali@arakmu.ac.ir

#### 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

##### Street address

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##### City

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##### Province

Markazi

##### Postal code

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##### Phone

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##### Email

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Behnam Mahmoudieh

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

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**Position**

Lecturer

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

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**Postal code**

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**Phone**

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**Fax**

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**Email**

karimikia93@gmail.com

## 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**