

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Effects of Botanical mouthwash of Aloe Vera on ventilator associated pneumonia of patients having Endotracheal tube hospitalized in the Intensive Care Unit

#### Protocol summary

##### Summary

This is a double blind clinical trial that will be performed to compare the effects of two mouthwashes (Aloe Vera and normal saline) on dental plaque index and pneumonia in shiraz namazi hospital. Patient or legal guardians and physician who diagnosed pneumonia are not aware of the type of the mouthwash. 79 patients having endotracheal tube will be chosen according to inclusion and exclusion criteria and will be divided in two groups randomly (Aloe Vera and normal saline). Oral care and mouth washing will be performed in intervention group by the use of 15 ml Aloe Vera mouthwash, every 12 hours and for 4 days and in control group by the use of 15 ml normal saline in the same way. Oral care in both groups will be done similarly. For collecting data (at first and 4 days later), dental plaque index (O'Leary) and modified clinical pulmonary infection score.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016052828134N1**

Registration date: **2016-06-21, 1395/04/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-06-21, 1395/04/01

##### Registrant information

##### Name

Nasrin mirbastegan

##### Name of organization / entity

shahid beheshti university of medical science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8865 5366

##### Email address

tannaz.saeidzadeh@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research deputy of SHahid Beheshti university of medical science

##### Expected recruitment start date

2016-01-30, 1394/11/10

##### Expected recruitment end date

2016-04-20, 1395/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of Botanical mouthwash of Aloe Vera on ventilator associated pneumonia of patients having Endotracheal tube hospitalized in the Intensive Care Unit

##### Public title

Effects of Botanical mouthwash of Aloe Vera on ventilator associated pneumonia of patients having Endotracheal tube hospitalized in the Intensive Care Unit

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion Criteria: 18-65 years old; having endotracheal tube through the mouth; admitted to ICU less than 12 hours; having natural teeth; don't have history of use antibiotic two weeks ago; don't have pregnancy and no history of allergy to herbal compounds; don't have HIV

and use of steroid drugs; not have an injury in the mouth and around it;not have pneumonia;don't have history of use antibiotic on two weeks ago;don't have leukopenia and neutropenia and serum albumin <2/5 mg/dl; Exclusion criteria: to discharge from the ICU or die before completing the study; inclination to continue the study;>6 score of clinical pulmonary infection score on 12 hours first time admission

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **79**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****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**

Side of Ayatollah Taleghani hospital, Shaheid Aarabi street, Yaman street, Shaheid Chamran highway, Tehran

**City**

Tehran

**Postal code****Approval date**

2015-12-14, 1394/09/23

**Ethics committee reference number**

ir.sbm.u.phnm.1394.216

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

Pneumonia

**ICD-10 code**

J15

**ICD-10 code description**

Influenza and pneumonia

**2****Description of health condition studied**

dental plaque

**ICD-10 code**

K03.6

**ICD-10 code description**

Deposits [accretions] on teeth

**3****Description of health condition studied**

dental plaque

**ICD-10 code**

K02.1

**ICD-10 code description**

Caries of dentine

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

Pneumonia

**Timepoint**

Immediately before intervention and four days later

**Method of measurement**

Modified clinical pulmonary infection score

**Secondary outcomes****1****Description**

Dental plaque index

**Timepoint**

Immediately before intervention and four days later

**Method of measurement**

O'Leary plaque index

**Intervention groups****1****Description**

intervention group: Using 15 ml of Aloe Vera mouthwash, every 12 hours, for 4 days.

**Category**

Treatment - Drugs

**2****Description**

Control group: Using 15 ml of normal saline, every 12 hours, for 4 days.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Shiraz Namazi hospital

**Full name of responsible person**

Mirbastegan Nasrin

**Street address**

Namazi hospital, Zand street, Namazi squer

**City**

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Research Deputy of Shahid Beheshti university of medical sciences

**Full name of responsible person**

Dr Zarghi

**Street address**

Side of Ayatollah Taleghani hospital. shaheid Aarbi street. Yaman street. Shahied CHamran highway

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research Deputy of Shahid Beheshti university of medical sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Shahid Beheshti university of medical sciences

**Full name of responsible person**

Nasrin Mirbastegan

**Position**

Master of critical care nursing

**Other areas of specialty/work****Street address**

Opposite to Rajae Heart Hospital, Cross of Valiasr and Neiaiesh Highway,Valiasr street

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**Postal code****Phone**

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mirbastegan.nasrin@gmail.com

**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

School of Nursing and Midwifery Shahid Beheshti university of medical sciences

**Full name of responsible person**

Mehryar Yoldashkhan

**Position**

Master of anesthesia

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## Person responsible for updating data

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**City**

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**Postal code****Phone****Fax****Email**

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**Web page address**

## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*