

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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

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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**

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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master of critical care nursing

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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