

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The Comparison of the effects of Botanical mouthwashes of Miswak/Aloe Vera and Chlorhexidine on dental plaque and gingivitis Index 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 (Miswak/Aloe Vera and Chlorhexidine) on dental plaque and gingival index in Yazd educational hospitals. 76 patients having endotracheal tube will be chosen according to inclusion and exclusion criteria and will be divided in two groups randomly (Miswak/Aloe Vera and Chlorhexidine). Oral care and mouth washing will be performed in intervention group by the use of 15 ml Miswak/Aloe Vera mouthwash, every 12 hours and for 4 days and in control group by the use of 15 ml Chlorhexidine 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 gingival index (Loe & Sillness) will be used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014062418212N1**
Registration date: **2014-10-05, 1393/07/13**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-10-05, 1393/07/13

Registrant information

Name

Sahra Rezaei

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2014-11-28, 1393/09/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of the effects of Botanical mouthwashes of Miswak/Aloe Vera and Chlorhexidine on dental plaque and gingivitis Index of patients having endotracheal tube hospitalized in the Intensive Care Unit.

Public title

The effects of botanical mouthwashes of Miswak/Aloe Vera and Chlorhexidine on healing of dental plaque and gingivitis of Patients having endotracheal tube

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: 18-65 years old; having endotracheal tube through the mouth; admitted to ICU less than 24 hours; no history of allergy to herbal compounds and chlorhexidine; having natural teeth; not have an injury in the mouth and around it; Exclusion criteria: to discharge from the ICU or die before completing the study;

inclination to continue the study; any damage caused by endotracheal tube, air way or any other factors.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

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

Research Deputy of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Alamoll Huda Street, Railroad Street, Arak, Iran

City

Arak

Postal code

3848176941

Approval date

2014-03-16, 1392/12/25

Ethics committee reference number

92-159-5

Health conditions studied

1

Description of health condition studied

Dental plaque

ICD-10 code

K03.6

ICD-10 code description

Deposits [accretions] on teeth

2

Description of health condition studied

Gingival index

ICD-10 code

K05.0

ICD-10 code description

Acute gingivitis

3

Description of health condition studied

Dental plaque

ICD-10 code

K02.1

ICD-10 code description

Caries of dentine

4

Description of health condition studied

Gingival index

ICD-10 code

K05.1

ICD-10 code description

Chronic gingivitis

5

Description of health condition studied

Gingival index

ICD-10 code

K05.4

ICD-10 code description

Periodontosis

Primary outcomes

1

Description

Dental Plaque Index

Timepoint

Immediately before intervention and four days later

Method of measurement

O'Leary Index

2

Description

Gingival Index

Timepoint

Immediately before intervention and four days later

Method of measurement

Loe & Sillness

Secondary outcomes

1

Description

Temperature

Timepoint

Immediately before intervention and four days later

Method of measurement

Thermometer

2

Description

Blood Pressure

Timepoint

Immediately before intervention and four days later

Method of measurement

Millimeters of Mercury, Using Manometer and Blood Pressure Cuff

3

Description

Pulse Rate

Timepoint

Immediately before intervention and four days later

Method of measurement

Pulse Counting

4

Description

Respiratory Rate

Timepoint

Immediately before intervention and four days later

Method of measurement

Respiratory Rate Counting

Intervention groups

1

Description

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

Category

Treatment - Drugs

2

Description

Control group: Using 15 ml of Chlorhexidin mouthwash every 12 hours, for 4 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadooghi Hospital of Yazd

Full name of responsible person

Dr. Mohammad Hossien Jarahzadeh, Anesthesiologist, and Intensive Care Fellowship Specialist

Street address

Shahid Sadooghi Hospital, Ebne Sina Blvd, Shahid

Ghandi Blvd., Safaieh, Yazd

City

Yazd

2

Recruitment center

Name of recruitment center

Shahid Rahnemon hospital of Yazd

Full name of responsible person

Dr. Mohammad Hossien Jarahzadeh, Anesthesiologist, and Intensive Care Fellowship Specialist

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Shahid Rahnemoon Hospital, Dadgostari Alley, Farokhi street, Azadi Square, Yazd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Arak University of Medical Sciences

Full name of responsible person

Mr.Babaie

Street address

Faculty of Nursing and Midwifery, Arak University of Medical Sciences, Sardasht, Arak, Iran

City

Arak

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Deputy of Arak 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

Arak University of Medical Sciences

Full name of responsible person

Sahra Rezaei

Position

Bachelor of Nursing

Other areas of specialty/work

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