

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of the effect of echinacea and chlorhexidine mouthwashes on oral health of intubated patients in the Intensive Care Unit

Protocol summary

Summary

The aims of this study is comparison the effect of Echinacea and chlorhexidine mouthwash on microbial flora of oral cavity. In this study 70 intubated patients who admitted in ICU ward of Vali Asr Hospital, will be randomly divided into two groups. Technique, timing and frequency of mouthwash application is similar in both groups. patients with age of 18-65 years old who were admitted in ICU Less than 12 hours will eligible to the study. Transferring from ICU or death before the completion of intervention; allergy to herbal medications; history or current chronic or immune system diseases are exclusion criteria. culture of oral specimens will taken at 0, 4 days after intervention. oral hygiene check lists including BOAS and MPS will be completed at 0 and 4 days after intervention too.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012092610942N1**

Registration date: **2012-11-05, 1391/08/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-11-05, 1391/08/15

Registrant information

Name

Mahdi Safarabadi

Name of organization / entity

Arak University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 1226 8316

Email address

safarabadi.m@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Arak University of Medical Sciences.

Expected recruitment start date

2012-05-21, 1391/03/01

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of echinacea and chlorhexidine mouthwashes on oral health of intubated patients in the Intensive Care Unit

Public title

Comparison of the effect of echinacea and chlorhexidine mouthwashes on oral health of intubated patients in the Intensive Care Unit

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : endotracheal intubation; 18-65 years of old, admission in ICU less than 12 hours. Exclusion criteria : transferring from ICU or death before the completion of intervention; any physical damage caused by the endotracheal intubation or airway or any other physical factors; Artificial teeth; antibiotic consumption before ICU admission; history of admission in other hospital wards before ICU admission; pregnancy; allergy to herbal medications; history or current chronic or

immune system diseases.

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

Gender
Both

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single 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 Arak University of Medical Sciences

Street address

Arak.Arak university of medical sciences.

City

Arak

Postal code

Approval date

2012-05-16, 1391/02/27

Ethics committee reference number

91-126-5

Health conditions studied

1

Description of health condition studied

Gingivitis

ICD-10 code

K05

ICD-10 code description

Gingivitis and periodontal diseases

2

Description of health condition studied

Diseases of pulp and periapical tissues

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

3

Description of health condition studied

Other disorders of teeth and supporting structures

ICD-10 code

K08

ICD-10 code description

Other disorders of teeth and supporting structures

Primary outcomes

1

Description

Oral microbial flora

Timepoint

Day 0,4

Method of measurement

culture of oral specimens

2

Description

oral health

Timepoint

Day 0,4

Method of measurement

BOAS and MPS check lists

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Echinacea 2% mouthwash, 3 times / day for 4 days. using by Applicator Swab for 10 min each time.

Category

Treatment - Drugs

2

Description

control group: chlorhexidine 2% mouthwash, 3 times/ day for 4 days, using by Applicator Swab for 10 min each time.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital of Arak city
Full name of responsible person
Mahdi Safarabadi
Street address
Valiasr hospital, Valiasr street, Arak.
City
Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research of Arak University of
Medical Sciences
Full name of responsible person
Dr. Davod Hekmatpuo
Street address
Arak University of Medical Sciences, Arak.
City
Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research 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
Mahdi safarabadi
Position
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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