Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effectiveness of Echinacea, Listerine, and chlorhexidine mouthwashes on oral microbial flora and oral health status of patients in Intensive Care Unit.

Protocol summary

Study aim

Comparing the effectiveness of Echinacea,Listerine, and chlorhexidine mouthwashes on oral microbial flora and oral health status of unconscious patients in Intensive Care Unit.

Design

A randomized clinical trial using blocking method with sealed envelopes with control group with parallel groups, three blinded with a sample size of 180, (three 60-person randomized groups).

Settings and conduct

Sampling will perform among hospitalized patients in the intensive care unit of Imam Hossein Hospital and Shohadaye Tajrish Hospital in Tehran. Patients will be divided into 3 groups (2 intervention and control). Individuals in each group received 15 cc of echinacea mouthwash, Listerine or Chlorhexidine. The outcome assessor, the research sample who anesthetized and the data analyst will be unaware of allocating the intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria:15-65 years old, consciousness level should be lower than 8. utilizing endotracheal tube and hospitalized less than 12 hours in intensive care unit. Exclusion criteria: Active periodontal disease, traumatic and oral anatomic lesions, using antibiotic two weeks before admission, systemic infections, autoimmune and malignant diseases, radiation therapy precedent. using immunosuppressive drugs, allergy to mouthwashes, patients with tracheostomy and pregnant women

Intervention groups

Group 1: 15 cc Echinacea mouthwash Group 2: 15 cc Listerine mouthwash Group 3 (control): 15 cc chlorhexidine mouthwash

Main outcome variables

To review the growth of microorganisms and their colonial characteristics, samples will grow in blood agar medium and then will grow for 48 hours at 37 ° C in the presence of 5-10% CO2. The laboratory will deliver the results as a printed report with patient code, and the data will use for analysis. Beck Oral Assessment Scale, will use to assess oral health in these patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191009045034N1**
Registration date: **2019-12-18, 1398/09/27**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-18, 1398/09/27**
Update count: **0**

Registration date

2019-12-18, 1398/09/27

Registrant information

Name

Simin Kakavandaraghi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effectiveness of Echinacea, Listerine, and chlorhexidine mouthwashes on oral microbial flora and oral health status of patients in Intensive Care Unit.

Public title
The Effectiveness of Echinacea, Listerine and Chlorhewidine mouthwashes on oral health and microbial flora.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
15 to 65 years old The level of consciousness lower than 8, based on the Glasgow scale Utilizing endotracheal tube for patients' breathing Lapsing maximum 12 hours after admitting the patient in intensive care unit
Exclusion criteria:
Having active periodontal disease Having oral Traumatic or anatomic lesions in mouth Having antibiotics two weeks before hospitalization Having systemic infections Having autoimmune or malignant diseases Radio therapy prescription Utilizing immunosuppressive drugs Allergy to mouthwashes (inflation and redness in gums and oral tissue) Patients with tracheotomy Pregnancy
Age
From **15 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **180**
Randomization (investigator's opinion)
Randomized
Randomization description
The method of randomization is hexagonal blocking and the randomization tool is the sealed envelope. An statistic expert will accomplish the randomization sequence by using the suitable software. Sampling will be done sequentially. In order to concealment, mouthwashes are poured into same bottles and given a code, which the main researcher will not be aware.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The outcome assessor, participants, and data analyst will not be aware of the assigned groups Participants will be unconscious Mouthwashes are poured into same bottles with different codes; which the outcome assessor will not see them. The data analyzer will also not be present in the research environment
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahroud of Medical Sciences
Street address
Shahroud University of Medical Sciences, 7th Tir Square, Shahroud, Iran
City
Shahroud
Province
Semnan
Postal code
36147-73947
Approval date
2019-10-06, 1398/07/14
Ethics committee reference number
IR.SHMU.REC.1398.085

Health conditions studied

1

Description of health condition studied
Microbial flora and oral hygiene of ICU patients
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The rate of oral microbial flora in unconscious patients
Timepoint
Prevalence of oral microbial flora in unconscious patients at baseline (before intervention) and one week after intervention
Method of measurement
Beck Oral Assessment Scale and Laboratory published reports of cultured and grown colonies

2

Description
Oral health status in unconscious patients
Timepoint

Oral hygiene status in unconscious patients at baseline (before intervention) and one week after intervention

Method of measurement

Beck Oral Assessment Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For group A, the entire oral surface is examined with BOAS Scale and then the patient's mouth is washed with 15 cc Echinacea solution for one week and then re-examined for hygiene and colonization and then the data will be analyzed

Category

Treatment - Drugs

2

Description

Intervention group: For group B, the entire oral surface is examined with BOAS Scale and then the patient's mouth is washed with 15 cc Listerin solution for one week and then re-examined for hygiene and colonization and then the data will be analyzed

Category

Treatment - Drugs

3

Description

the entire oral surface is examined with BOAS Scale and then the patient's mouth is washed with 15 cc Chlorhexidine solution for one week and then re-examined for hygiene and colonization and then the data will be analyzed

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein hospital and Shohadaye tajrish hospital

Full name of responsible person

Simin Kakavand Araghi

Street address

Chamran hospital, end of Sayyad Shirazi highway, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Simin Kakavand Araghi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
The obtained data after testing on 180 participants in Shohada Tajrish and Imam Hossein hospitals can be shared after unidentifiable individuals.

When the data will become available and for how long
Data will be accessible, 6 months after printing the results

To whom data/document is available
Researchers working in academies and scientific institutions, could access to data and documentation .

Under which criteria data/document could be used
To promote and extend the subject under study from other aspects and to compare the results with other relevant scientific results, it is permissible to use documentation and data to improve the level of health.

From where data/document is obtainable
simin_online.1988@yahoo.com

What processes are involved for a request to access data/document
After reviewing the reason of requesting to access documentation and data by the researcher, the data and documentation file will be sent to the researcher (one month after submitting the request).

Comments