

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Effect of licorice mouthwash versus chlorhexidine mouthwash on oral health in intubated patients in intensive care unit: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of licorice mouthwash versus chlorhexidine mouthwash on oral health in intubated patients in intensive care unit

Design

This is a double-blind randomized clinical trial with control group, phase III, in which eligible patients will be randomly assigned through the drawing of lots to the intervention and control groups

Settings and conduct

This study will be performed in the Beheshti Hospital in Hamadan city on 120 eligible intubated patients in intensive care unit. The patients will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be double-blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 65 years Hospitalization in the intensive care unit Having an oral tracheal tube Having a gastric tube through the nose Exclusion criteria: Pregnancy Autoimmune diseases Pulmonary infection or sepsis Having artificial teeth Smoker

Intervention groups

Intervention group: Mouth washing with 15 ml of 2% licorice mouthwash solution for 30 seconds once a day for four days. Control group: Mouth washing with 15 ml of 2% chlorhexidine mouthwash solution for 30 seconds once a day for four days.

Main outcome variables

Primary outcome: Oral hygiene

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N461**
Registration date: **2023-02-07, 1401/11/18**

Registration timing: **prospective**

Last update: **2023-02-07, 1401/11/18**

Update count: **0**

Registration date

2023-02-07, 1401/11/18

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of licorice mouthwash versus chlorhexidine mouthwash on oral health in intubated patients in intensive care unit: a double-blind randomized clinical

trial	
Public title	Effect of licorice mouthwash versus chlorhexidine mouthwash on oral health in intubated patients in intensive care unit
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Age 18 to 65 years Hospitalization in the intensive care unit Having an oral tracheal tube Having a gastric tube through the nose
Exclusion criteria:	Pregnancy Autoimmune diseases Pulmonary infection or sepsis Having artificial teeth Smoker
Age	From 18 years old to 65 years old
Gender	Both
Phase	3
Groups that have been masked	- Participant - Outcome assessor
Sample size	Target sample size: 120
Randomization (investigator's opinion)	Randomized
Randomization description	Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.
Blinding (investigator's opinion)	Double blinded
Blinding description	Patients are unconscious, therefore, they will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics Committee of Hamadan University of Medical

Sciences	
Street address	Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City	Hamadan
Province	Hamadan
Postal code	6517838695
Approval date	2022-12-10, 1401/09/19
Ethics committee reference number	IR.UMSHA.REC.1401.780
Health conditions studied	
<u>1</u>	
Description of health condition studied	Oral health
ICD-10 code	Z01.20
ICD-10 code description	Encounter for dental examination and cleaning without abnormal findings
Primary outcomes	
<u>1</u>	
Description	Oral hygiene
Timepoint	On the fifth day after the intervention
Method of measurement	With clinical examination using abslang and flashlight
Secondary outcomes	empty
Intervention groups	
<u>1</u>	
Description	Intervention group: Mouth washing with 15 ml of 2% licorice mouthwash solution for 30 seconds once a day for four days.
Category	Treatment - Other
<u>2</u>	
Description	Control group: Mouth washing with 15 ml of 2% chlorhexidine mouthwash solution for 30 seconds once a day for four days.
Category	Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti Hospital in Hamadan city

Full name of responsible person

Reza Faghih Lotfi

Street address

Beheshti Hospital, Eram Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Reza Faghih Lotfi

Position

Nursing Student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

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

Undecided - It is not yet known if there will be 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

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

Clinical Study Report

Undecided - It is not yet known if there will be 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