

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 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)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### 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

### 1

#### 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

### 1

#### 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

### 1

#### 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

### 1

#### 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

### 2

#### 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 Faghieh Lotfi

**Street address**

Beheshti Hospital, Eram Ave.

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reza\_lotfi\_65@yahoo.com

## 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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Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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info.research@umsha.ac.ir

**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 Faghieh Lotfi

**Position**

Nursing Student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

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Dr. Khodayar Oshvandi

**Position**

PhD in Nursery

**Latest degree**

Ph.D.

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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**

Epidemiology

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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