

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

**determine and compare the effect of chamomile mouthwash with chlorhexidine and the incidence of oral lesion in ICU patients.**

### Protocol summary

#### Summary

The aim of this study is comparing and determining the effects of chamomile mouthwash (intervention) and Chlorhexidine solution (control) for preventing of oral lesions. In this study 70 intubated patients who are admitted in ICU ward of Shahid Hashemi-Nejad Hospital, will be randomly into two groups. Technique, timing and frequency of mouthwash application is similar in both groups. In the intervention group, Control group members wash their mouths with chamomile. This action is done every 8 hours during 4 days. Control group members wash their mouths with 0.2% ( Zero point two percent) chlorhexidine solution. This action is also done every 8 hours for 2 minutes during 4 days for control group. patients with age of 18-65 years old who are admitted in ICU Less than 6 hours will be eligible to the study Transferring from ICU or death before the completion of intervention; allergy to mouthwash; history or current chronic or immune system diseases are exclusion criteria. During the study the mouth is checked three times a day before mouth intervention for four days, the patient's mouth is checked with Mucoid plaque score(MPS) and those features are recorded in the checklist

### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2015123125774N1**

Registration date: **2016-06-12, 1395/03/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

#### Registration date

2016-06-12, 1395/03/23

#### Registrant information

##### Name

Shima Yazdanparast

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 4441 9566

##### Email address

yazdanparastsh1@mums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

Vice chancellor for research, Sabzevar University of Medical Sciences

#### Expected recruitment start date

2016-01-04, 1394/10/14

#### Expected recruitment end date

2016-03-18, 1394/12/28

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

determine and compare the effect of chamomile mouthwash with chlorhexidine and the incidence of oral lesion in ICU patients.

#### Public title

The effect of chlorhexidine, and chamomile are two types of oral lesions

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

The inclusion criteria: Having oral endotracheal tube; being 18-65 years old; The absence of wound; infection

and oral trauma; Not having any symptoms or antecedent of aspiration; serious problems; and artificial teeth. Exclusion criteria are: death at the time of the study; Separation from mechanical ventilation at the time of the study; View apparent aspiration; existence of allergic reactions; restrictions on procedures and aspiration risk.

**Age**

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

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **70**

**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**

Ethics Committee Sabzevar University of Medical Sciences

**Street address**

Asad Abadi, st.

**City**

Sabzevar

**Postal code****Approval date**

2016-01-04, 1394/10/14

**Ethics committee reference number**

IR.MEDSAB.REC.1394.116

**Health conditions studied****1****Description of health condition studied**

Gingivitis, other disorder of lip and oral mucosa

**ICD-10 code**

K05, K13

**ICD-10 code description**

Gingivitis and periodontal diseases, Other diseases of lip

and oral mucosa

**Primary outcomes****1****Description**

Oral Health

**Timepoint**

Three times a day for 4 days

**Method of measurement**

Mucous plaque score

**Secondary outcomes****1****Description**

Plaque

**Timepoint**

Three times a day for 4 days

**Method of measurement**

Mucous plaque score

**Intervention groups****1****Description**

Control group: 35 patients with a solution of 0.2% Chlorhexidine mouthwash every 8 hours for 4 days.

**Category**

Prevention

**2****Description**

Group Intervention: After receiving the code of ethics of Sabzevar University of Medical Sciences and the satisfaction of patients for the study were 35 patients in the intervention group and mouthwashes every 8 hours for 4 days by a swab soaked in chamomile was dissolved.

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Hashemi-Nejad Hospital

**Full name of responsible person**

Shima Yazdanparast

**Street address**

Abo Rayhan, Blvd.

**City**

Mashhad

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Sabzevar University of Medical Sciences

**Full name of responsible person**

Dr Mohamad Mohamadzade

**Street address**

Asad Abadi, st.

**City**

Sabzevar

**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, Sabzevar 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**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Shima Yazdanparast

**Position**

Clinical Nurse Spacialist student

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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Zahra Estaji

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MSC

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## Person responsible for updating data

### Contact

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**Other areas of specialty/work**

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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*