

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

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MSC

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Position

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Web page address

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