

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the Effect of Hyssop Essence and Chlorhexidine Gluconate Mouthwashes on Oral Hygiene in Intubated Patients in Intensive Care Unit

Protocol summary

Summary

The aim of this study is to compare the effect of Hyssop essence and Chlorhexidine Gluconate mouthwashes on oral hygiene in intubated patients in the ICU of Imam Khomeini medical educational center, Sari, Iran. This study is a double-blind randomized clinical trial. Eligible patients, will be randomly assigned to three groups : 1) 20 patients in the Zufa group, 2) 20 patients in the Chlorhexidine Gluconate group and 3) 20 patients in the Normal Saline group. Randomization will be performed through block randomization method. The method, timing and frequency of mouth washes in all groups will be done in the same way. Mouthwash volume is 15 cc and duration of washing is 30 seconds and frequency is twice a day (8 am and 4 pm). Checklist of Beck Oral Assessment Scale "BOAS" will be completed by trained nurse at the admission day and then, every day for 4 days.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017060711399N5**

Registration date: **2017-06-26, 1396/04/05**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-06-26, 1396/04/05

Registrant information

Name

Abbasali Ebrahimian

Name of organization / entity

Country

Iran (Islamic Republic of)

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ebrahimian.aa@gmail.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Semnan University of Medical Sciences

Expected recruitment start date

2017-06-30, 1396/04/09

Expected recruitment end date

2018-06-30, 1397/04/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effect of Hyssop Essence and Chlorhexidine Gluconate Mouthwashes on Oral Hygiene in Intubated Patients in Intensive Care Unit

Public title

The Effect of Hyssop Essence and Chlorhexidine Gluconate on Oral Hygiene

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age over 18 years; The Glasgow Coma Scale less than 8; The patient is intubated and received mechanical ventilation during the study; Non-antibiotic therapy over two weeks before hospitalization; Admission to ICU is past less than 12 hours; No history of allergy to the plants of the mint family (based on

evidence of the statements of the patient's family);
Having natural teeth; No history of radiation therapy;
Having a Naso-Gastric Tube and no feeding by mouth.
Exclusion criteria: History of radiation therapy; Diabetes;
Jaw and facial injuries; Pregnant women; Using of
immunosuppressive drugs such as Corticosteroids;
History of seizures.

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Samples will be randomly selected among one unit of
intensive care units of Sari Emam Khomani hospital.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Semnan University Of Medical
Sciences

Street address

Vice chancellor for research, Semnan University of
Medical Sciences, Basij Blvd

City

Semnan

Postal code

Approval date

2017-05-21, 1396/02/31

Ethics committee reference number

IR.Semums.Rec.1394.69

Health conditions studied

1

Description of health condition studied

Oral Hygiene in Intubated Patients

ICD-10 code

K13.7

ICD-10 code description

Other and unspecified lesions of oral mucosa

Primary outcomes

1

Description

Oral Hygiene

Timepoint

Primery day, then daily until 4 day

Method of measurement

Check list of oral health assessment

Secondary outcomes

1

Description

Duration of stay in the intensive care unit

Timepoint

Daily

Method of measurement

Questionnaire

Intervention groups

1

Description

In the experimental group, after washing hands, the bed head is elevated 30-45 degree. After wearing sterile gloves, the pressure of cuff in the tracheal tube is regulated in the range of 20-25 cmh2o by the help of pressure manometer .Then half of Hyssop mouthwash solution 0.02% (7.5 cc) is sprinkled to different parts of the patient's mouth. Internal and external surface of the upper and lower teeth, sides and surface of tongue are cleaned with a soft pediatric toothbrush. After the brushing procedure, the other half mouthwash solution (7.5 cc) will be sprayed to different parts of the mouth. After that, the remained solution in the mouth will be suctioned using a sterile catheter in less than 30 seconds. Oral wash will be done for patients during 30 seconds, twice a day (8 am and 4 pm), for 4 days.

Category

Prevention

2

Description

In the control group, after washing hands, the bed head is elevated 30-45 degree. After wearing sterile gloves, the pressure of cuff in the tracheal tube is regulated in the range of 20-25cmH2O by the help of pressure manometer .Then half of Chlorhexidine Gluconate mouthwash solution 0.2% (7.5 cc) is sprinkled to different parts of the patient's mouth. Internal and external surface of the upper and lower teeth, sides and surface of tongue are cleaned with a soft pediatric toothbrush. After the brushing procedure, the other half

mouthwash solution (7.5 cc) will be sprayed to different parts of the mouth. After that, the remained solution in the mouth will be suctioned using a sterile catheter in less than 30 seconds. Oral wash will be done for patients during 30 seconds, twice a day (8 am and 4 pm), for 4 days.

Category

Prevention

3

Description

In the placebo group, after washing hands, the bed head is elevated 30-45 degree. After wearing sterile gloves, the pressure of cuff in the tracheal tube is regulated in the range of 20-25cmH2O by the help of pressure manometer .Then half of Normal Saline mouthwash solution 0.9% (7.5 cc) is sprinkled to different parts of the patient's mouth . Internal and external surface of the upper and lower teeth, sides and surface of tongue are cleaned with a soft pediatric toothbrush. After the brushing procedure, the other half mouthwash solution (7.5 cc) will be sprayed to different parts of the mouth. After that, the remained solution in the mouth will be suctioned using a sterile catheter in less than 30 seconds. Oral wash will be done for patients during 30 seconds, twice a day (8 am and 4 pm), for 4 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomaini Hospital

Full name of responsible person

Mehrvarz Alishah

Street address

Imam Khomaini Hospital, Amir-Mazandarani Blvd, Sari.

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Semnan University of Medical Sciences

Full name of responsible person

Dr Ali Rashidi-Pour

Street address

Vice chancellor for research, Semnan University of Medical Sciences, Basij Blvd

City

Semnan

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, Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Mehrooz Alishah

Position

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Other areas of specialty/work

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Position

Faculty member of Semnan University of Medical Sciences

Other areas of specialty/work

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Semnan University of Medical Sciences

Full name of responsible person

Abbasali Ebrahimian

Position

Faculty member of Semnan University of Medical Sciences

Other areas of specialty/work**Street address**

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City

Semnan

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