

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 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)

###### Phone

+98 25 3107 1082

###### Email address

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 20-25cmH<sub>2</sub>O 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

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**Full name of responsible person**

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**Position**

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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*