

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Effect of thyme spray on oropharyngeal bacterial colonization in patients hospitalized in critical care units

#### Protocol summary

##### Study aim

Determine the effect of thyme spray on oropharyngeal bacterial colonization in hospitalized patients in critical care units

##### Design

This is a double blind randomized controlled clinical trial with a parallel group design.

##### Settings and conduct

This is a randomized controlled clinical trial study in which three groups of thyme spray in addition to routine oral care, water spray in addition to routine oral care, and only routine oral care will be done on 90 patients with Glasgow's coma scale between 3 to 15 who hospitalized at critical care units at Kowsar hospital affiliated to Semnan University of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient's level of consciousness is between 15-3 according to Glasgow's coma scale; the patient feed through the nasogastric tube. Exclusion criteria: Maxillofacial trauma so that oral care is difficult; confirmed hypersensitivity to thyme compounds.

##### Intervention groups

All study groups are including a routine oral care, which consists of 0.2% chlorhexidine mouth washing, manufactured by Behsa Pharmaceutical Company (Iran), three times a day. However, in addition to the abovementioned oral care, the intervention group will also receive four puffs Thyme spray (manufactured by: Zardband Company), four times a day, in the right and left buccal area for 48 hours; patients in the placebo group, will also receive four puffs distilled water spray (manufactured by: Samen Mashad Company) four times a day in the right and left buccal area for 48 hours; and the control group will not receive any additional care.

##### Main outcome variables

Oropharyngeal bacterial colonization

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180623040212N1**

Registration date: **2019-07-21, 1398/04/30**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-07-21, 1398/04/30**

Update count: **0**

##### Registration date

2019-07-21, 1398/04/30

##### Registrant information

##### Name

hesamedin Askari Majdabadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3365 4190

##### Email address

haskari68@sem.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-23, 1397/05/01

##### Expected recruitment end date

2019-08-23, 1398/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of thyme spray on oropharyngeal bacterial colonization in patients hospitalized in critical care units

**Public title**

Effect of thyme Spray on oropharyngeal bacterial colonization

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Hospitalization time is less than 24 hours. Patients' age between 15 to 75 years. The patient's level of consciousness is between 3-15 according to Glasgow's coma scale. The patient feed via nasogastric tube.

**Exclusion criteria:**

Immunodeficiency due to chemotherapy, radiotherapy and immunosuppressive diseases. Confirmed hypersensitivity to thyme compounds.

**Age**

From **15 years** old to **75 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Care provider
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Samples will be randomly allocated in three groups: A- thyme spray with routine care, B- routine care plus water spray and C-routine care by using a web-based software for generating random numbers (Kitset, available from: <https://kitset.ir/numbers/random>). According to this method, each block will contain three randomly generated numbers 1 to 3 representing the aforementioned interventions A to C respectively. The allocation of patients to the groups will follow the sequence of the randomly generated numbers in each block.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Once each intervention is completed, the samples of the pharynx will be taken for culture; so that to prevent of any bias, a nurse who is responsible for gathering the samples of throat secretions, as well as the laboratory expert who tests the samples, and also the statistician who is responsible for analyzing data will be blinded.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Semnan University of Medical Sciences and Health

**Street address**

Semnan University of Medical Sciences, Basidj boulevard

**City**

Semnan

**Province**

Semnan

**Postal code**

3514716989

**Approval date**

2018-05-20, 1397/02/30

**Ethics committee reference number**

IR.SEMUMS.REC.1397.078

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

Oropharyngeal bacterial colonization

**ICD-10 code**

J02.9

**ICD-10 code description**

Acute pharyngitis, unspecified

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

Oropharyngeal Bacterial colonization

**Timepoint**

Admission time at critical care unit (before intervention) and 48 hours later

**Method of measurement**

Evaluation of the number of bacterial colonies in the pharynx culture sample

**2****Description**

Beck Oral Assessment

**Timepoint**

Admission time at critical care unit (before intervention) and 48 hours later

**Method of measurement**

Beck Oral Assessment Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The first intervention group, in addition to routine oral care, which consists of 0.2% chlorhexidine mouth washing, manufactured by Behsa Pharmaceutical Company (Iran), three times a day, while in semi-sitting position with 45 ° angle received Thyme spray produced by Zardband Company every 6 hours for 48 hours, two puffs in the right buccal portion and two puff at the left.

#### Category

Prevention

### 2

#### Description

Placebo group in addition to routine oral care, which consists of 0.2% chlorhexidine mouth washing, manufactured by Behsa Pharmaceutical Company (Iran), three times a day, will receive distilled water spray manufactured by the Samen Mashad Company (Iran) in a similar container of Thyme spray every 6 hours for 48 hours, two puffs in the right buccal and 2 puffs in the left buccal area in semi-sitting position with a 45-degree bed angle.

#### Category

Placebo

### 3

#### Description

Control group receive only routine mouth care which consists of 0.2% chlorhexidine mouth washing, manufactured by Behsa Pharmaceutical Company (Iran), three times a day.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kosar Hospital

##### Full name of responsible person

Elham Zamani pour

##### Street address

Kowsar hospital, Amin Blv. Golestan Township

##### City

Semnan

##### Province

Semnan

##### Postal code

3519899951

##### Phone

+98 23 3142 2252

#### Email

aeein59@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Semnan University of Medical Sciences

##### Full name of responsible person

Dr. Parviz Kokhaei

##### Street address

Semnan University of Medical Sciences, Basij Blv.

##### City

Semnan

##### Province

Semnan

##### Postal code

3514716989

##### Phone

+98 23 3345 1336

##### Email

pz\_kokh@yahoo.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Semnan 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

Semnan University of Medical Sciences

##### Full name of responsible person

Mohsen Soleimani

##### Position

Associate Prof.

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nursery

##### Street address

Semnan University of Medical Sciences, 5 kilometer to Damghan road, Standard Sq., Semnan/Iran

##### City

Semnan

##### Province

Semnan  
**Postal code**  
3513138111  
**Phone**  
+98 23 3365 4190  
**Email**  
soli257@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Semnan University of Medical Sciences  
**Full name of responsible person**  
Dr. Hesamedin Askari Majdabadi  
**Position**  
assistant prof.  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Health Education and Health Promotion  
**Street address**  
Semnan University of Medical Sciences, 5 kilometer to  
Damghan road, Standard Sq., Semnan/Iran  
**City**  
Semnan  
**Province**  
Semnan  
**Postal code**  
3513138111  
**Phone**  
+98 23 3365 4190  
**Email**  
hesamaskari@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Semnan University of Medical Sciences  
**Full name of responsible person**  
Elham Zamanipoor  
**Position**  
Msc. Student in critical care nursing  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Semnan University of Medical Sciences, 5 kilometer to  
Damghan road, Standard Sq., Semnan/Iran  
**City**  
Semnan  
**Province**  
Semnan  
**Postal code**  
3513138111  
**Phone**  
+98 233336544192  
**Email**  
aeein1359@gmail.com

## 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

Not applicable

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Not applicable

### Analytic Code

Not applicable

### Data Dictionary

Not applicable