

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 2026

### Comparison of the effect of Thyme and Chlorhexidine glucosan mouthwash on oral health of ventilated patients in the intensive care unit

#### Protocol summary

##### Study aim

Comparison of the effect of thyme mouthwash and chlorhexidine gluconate on the oral health of ventilated patients in the intensive care unit

##### Design

A controlled, parallel-group, triple-blind, randomized, phase three clinical trial on 46 patients. Random allocation software will be used for randomization.

##### Settings and conduct

Patients will be divided into two groups receiving thyme mouthwash and chlorhexidine. Before each intervention, the position of the patient supine and if not prohibited, the patient's head will be raised 30 degrees. Before the intervention, the entire surface of the mouth, gums and teeth were brushed with a soft toothbrush for both groups, and then for the patients in the two groups, mouthwash with thyme and chlorhexidine three times a day and with 5 ml of mouthwash in the form of a swap or a wet brush. It will be done for 5 days. Before the intervention, two and five days after the intervention, the oral health will be evaluated with the oral health evaluation tool.

##### Participants/Inclusion and exclusion criteria

Intubated patients in intensive care unite 1) Require mechanical ventilation for at least 48 hours 2) No history of allergy to herbal compounds 3) Not using an endotracheal tube before hospitalization in intensive care unit 4) Having a nasogastric tube for feeding 5) Not getting pneumonia during hospitalization in intensive care unit 6) older than 18 years old 7) Consent to participate in the study by the patient or guardian 8) Not having obvious oral lesions in and around the mouth at the time of admission 9) The airway used for the patient is a tracheal tube 10) Not having an autoimmune disease or immune system deficiency

##### Intervention groups

The intervention groups: the group receiving thyme mouthwash and chlorhexidine.

##### Main outcome variables

oral health

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221119056537N1**

Registration date: **2023-08-10, 1402/05/19**

Registration timing: **prospective**

Last update: **2023-08-10, 1402/05/19**

Update count: **0**

##### Registration date

2023-08-10, 1402/05/19

##### Registrant information

##### Name

Haniyeh Samarghandi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 5722 5551

##### Email address

samarghandih992@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-05, 1402/06/14

##### Expected recruitment end date

2023-10-06, 1402/07/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparison of the effect of Thyme and Chlorhexidine glucosan mouthwash on oral health of ventilated patients in the intensive care unit

### Public title

Comparison of the effect of Thyme and Chlorhexidine glucosan mouthwash on oral health of ventilated patients in the intensive care unit

### Purpose

Other

### Inclusion/Exclusion criteria

#### Inclusion criteria:

1) Older than 18 years old 2) The patient needs mechanical ventilation at least for 48 hours 3) The airway used for the patient is a tracheal tube. 4) Not using an endotracheal tube before admission to the intensive care unit 5) Consent to participate in the study by the patient or guardian 6) Not having pneumonia during hospitalization in the intensive care unit 7) No history of allergy to herbal compounds 8) Not having an autoimmune disease or immune system deficiency 9) Absence of obvious lesions in and around the mouth upon admission Having a nasogastric tube for feeding

#### Exclusion criteria:

pregnancy extubation transfer from the intensive care unit to the ward or death of the patient

### Age

From **18 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **46**

### Randomization (investigator's opinion)

Randomized

### Randomization description

This method is used to avoid significant imbalances in the number of participants assigned to each group. Block randomization guarantees that there is no significant imbalance between the groups at any time during the randomization and at certain points the number of participants in each group is equal. Then the list of blocks is written and numbers are assigned to them (AABB(1)- ABAB(2)-ABBA(3)-BBAA(4)- BABA(5)- BAAB(6)) then choosing random numbers between 1 to 6 (for example 1 4 5 and...) and finally defining the treatment allocation list based on the previous random numbers (...AABB-BBAA-BABA-). In this design, the randomization unit is individual.

### Blinding (investigator's opinion)

Triple blinded

### Blinding description

1) The study participants are blind due to their low level of consciousness and being intubated. 2) The researcher will only apply chlorhexidine and thyme mouthwash by numbering them and will not know the identity of each mouthwash. 3) Statistical analysts will also analyze the data through coding.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences, School of Nursing and Midwifery

##### Street address

University St., Doctor's Road, Faculty of Nursing and Midwife

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

13944-91388

#### Approval date

2023-05-29, 1402/03/08

#### Ethics committee reference number

IR.MUMS.NURSE.REC.1402.038

## Health conditions studied

### 1

#### Description of health condition studied

Intubated patients hospitalized in intensive care unite

#### ICD-10 code

J39

#### ICD-10 code description

Other diseases of upper respiratory tract

## Primary outcomes

### 1

#### Description

Oral health score in oral health assessment questionnaire

#### Timepoint

Before the intervention, two and five days after using thyme and chlorhexidine mouthwash

#### Method of measurement

oral health assessment questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Before each intervention, the patient's position will be supine, and if not prohibited, the patient's head will be raised 30 degrees and turned to one side. Before using the mouthwash to prevent microaspiration, the tracheal tube cuff pressure will be measured once for both groups, and then the cuff stiffness method will be used for the next times to ensure the appropriate pressure of the cuff. Before the intervention, the entire surface of the mouth, gums and teeth will be brushed with a soft toothbrush. For patients in the intervention group, five milliliters of thyme mouthwash will be administered three times a day (every eight hours) as a wet swab for five days.

#### Category

Other

### 2

#### Description

Control group: Before each intervention, the patient's position will be supine, and if not prohibited, the patient's head will be raised 30 degrees and turned to one side. Before using the mouthwash to prevent microaspiration, the tracheal tube cuff pressure will be measured once for both groups, and then the cuff stiffness method will be used for the next times to ensure the appropriate pressure of the cuff. Before the intervention, the entire surface of the mouth, gums and teeth will be brushed with a soft toothbrush. For patients in the intervention group, five milliliters of Chlorhexidine mouthwash will be administered three times a day (every eight hours) as a wet swab for five days.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Qaem hospital

##### Full name of responsible person

Haniyeh Samarghandii

##### Street address

Ahmedabad Street, Ghaem Hospital

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

91766-99199

##### Phone

+98 51 3840 0001

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+98 51 3845 3239

##### Email

b.ghaem@mums.ac.ir

##### Web page address

<https://quaem.mums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Majid Ghayour Mobarhan

##### Street address

College of Nursing and Midwifery, University Street

##### City

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##### Province

Razavi Khorasan

##### Postal code

97165-91778

##### Phone

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##### Email

presidentoffice@mums.ac.ir

##### Web page address

<https://www.mums.ac.ir/>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

##### Full name of responsible person

Haniyeh Samarghandi

##### Position

Masters student

##### Latest degree

Bachelor

**Other areas of specialty/work**

Nursery

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Haniyeh Samarghandi

**Position**

Masters student

**Latest degree**

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**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Haniyeh Samarghandi

**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Email**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available