

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Comparison of the effect of 0.2% chlorhexidine solution and toothbrush in the prevention of oral lesions in intubated patients hospitalized in the intensive care unit

#### Protocol summary

##### Study aim

Comparison of the effect of 0.2% chlorhexidine solution and toothbrush in preventing oral lesions of intubated patients hospitalized in the intensive care unit.

##### Design

The present study is a randomized clinical trial with a sample size of 108 and permutation block method with a size of 6. Then the blocks are randomly numbered and selected, and the execution method based on the permutation within the block will be done.

##### Settings and conduct

The research population includes all patients admitted with a tracheal tube in the special care department of ICU A, ICU B, CCU A, CCU B, CCU C, CCU F, CCU G, CCU P of Shaheed Rajaie Cardiovascular Medical and Research Center .

##### Participants/Inclusion and exclusion criteria

Entry: Age above 18 years Having an oral tracheal tube for at least 3 days No wounds and severe injuries in the mouth Not having hepatitis B disease Not having HIV Not having coagulation problems, not allergic to chlorhexidine Not having artificial teeth Exit: Transfer of the patient from the intensive care unit during the study period Death of the patient during the study Allergic reaction Limitations in performing the technique Risk of aspiration Unwillingness to continue the study on the part of the legal guardians of the patients Perform tracheostomy during the study Endotracheal tube extubation during the study period

##### Intervention groups

Group A: use of 0.2% chlorhexidine solution Group B: Using a toothbrush Group C: combined use of toothbrush and chlorhexidine mouthwash

##### Main outcome variables

If the appropriate method of preventing oral lesions in intubated patients hospitalized in the intensive care unit is determined, which method can provide a more positive

result for the oral hygiene of the special unit patients, we can make our proposal for the oral hygiene of the intubated special unit patients.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230105057051N1**

Registration date: **2023-07-11, 1402/04/20**

Registration timing: **prospective**

Last update: **2023-07-11, 1402/04/20**

Update count: **0**

##### Registration date

2023-07-11, 1402/04/20

##### Registrant information

##### Name

mahnaz shamseh

##### Name of organization / entity

Shahid Rajaie Cardiovascular medical & Research Center

##### Country

Iran (Islamic Republic of)

##### Phone

+98 66 3343 5542

##### Email address

mashamceh@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-22, 1402/04/31

##### Expected recruitment end date

2023-09-22, 1402/06/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of 0.2% chlorhexidine solution and toothbrush in the prevention of oral lesions in intubated patients hospitalized in the intensive care unit

**Public title**

Comparison of the effect of 0.2% chlorhexidine solution and toothbrush in the prevention of oral lesions in intubated patients hospitalized in the intensive care unit

**Purpose**

Prevention

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

Age above 18 years Having an oral tracheal tube for at least 3 days No wounds and severe injuries in the mouth Not having hepatitis B disease Not having HIV Not having coagulation problems Insensitivity to chlorhexidine Not having artificial teeth

**Exclusion criteria:**

Transfer of the patient from the intensive care unit during the study period Death of the patient during the study Allergic reaction Limitations in performing the technique Risk of aspiration Unwillingness to continue the study on the part of the legal guardians of the patients Perform tracheostomy during the study Endotracheal tube extubation during the study period

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **108**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The research population includes all patients admitted to the special care department of ICU A, ICU B, CCU A, CCU B, CCU C, CCU F, CCU G, CCU P with a tracheal tube. The researcher will select the patients who meet the study entry criteria. For random allocation of people, permutation block method with size 6 will be used. Then the blocks are randomly numbered and selected and the execution method based on the permutation within the block will be done.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The research population includes all patients admitted to the special care department of ICU A, ICU B, CCU A, CCU B, CCU C, CCU F, CCU G, CCU P with a tracheal tube. The

researcher will select the patients who meet the study entry criteria. For random allocation of people, permutation block method with size 6 will be used. Then the blocks are randomly numbered and selected and the execution method based on the permutation within the block will be done. The participation of the patient will be voluntary and based on the informed consent of his legal guardian. In case of non-satisfaction, the transfer of the patient from the special care department, especially during the study period, the death of the patient during the study, the occurrence of an allergic reaction, the limitation in performing the technique, and the risk of aspiration will be excluded from the study.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics Committee of Shaheed Rajaie Cardiovascular Medical and Research Center

**Street address**

Vali Asr St. (AJ), next to Mellat Park, Niayesh corner

**City**

Tehran

**Province**

Tehran

**Postal code**

1995614331

**Approval date**

2023-07-09, 1402/04/18

**Ethics committee reference number**

IR.RHC.REC.1402.030

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

Oral lesions

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Oral hygiene method

**Timepoint**

It is done at 7:00 and 19:00 during 3 days (6 times in total)

### Method of measurement

It is checked using BOAS and MPS tools and recorded in the checklist.

## Secondary outcomes

### 1

#### Description

Oral health score

#### Timepoint

Intervention is done before each turn and recorded in the relevant checklist.

#### Method of measurement

It is checked using BOAS and MPS tools and recorded in the checklist.

## Intervention groups

### 1

#### Description

Control group: Mouthwash group (group A) is performed with 0.2% chlorhexidine solution according to the routine method of the department. In this way, 10 ml of chlorhexidine is poured into a sterile receiver and the balled cotton is dipped in the chlorhexidine solution with a tweezer and the oral cavity, tongue and teeth are washed with the chlorhexidine solution. This procedure is performed at 7:00 a.m. and at 7:00 p.m. during 3 days (6 times in total) and checking with the BOAS and MPS tools is done before each mouthwash and is recorded in the relevant checklist.

#### Category

Prevention

### 2

#### Description

Intervention group: In group B, using a soft toothbrush with half a centimeter of fluoride toothpaste on it, first all the internal and external surfaces of the teeth and gums with rotating movements, and then the surfaces of the tongue and palate with Back and forth movements are brushed. After brushing, the mouth is rinsed and cleaned with normal saline. This procedure is performed at 7 am and 7 pm during 3 days (6 times in total). Checking with BOAS and MPS tools is done before each brushing session and is recorded in the relevant checklist.

#### Category

Prevention

### 3

#### Description

Intervention group: In group C (combined use of toothbrush and chlorhexidine mouthwash), at 7:00 a.m. and at 7:00 p.m. during 3 days (6 times in total), using a soft toothbrush and toothpaste containing fluoride, first all internal and external surfaces of the teeth and gums It is brushed with circular movements and then the surfaces of the tongue and palate are brushed with back

and forth movements. After brushing, every part of the mouth is wet with normal saline, and the mouth is rinsed and cleaned with that. Then, 10 ml of chlorhexidine is poured into a sterile receiver and the balled cotton is soaked in the chlorhexidine solution with a tweezer and the mouth cavity, tongue and teeth are washed with the chlorhexidine solution. Checking with BOAS and MPS tools is done before each intervention with toothbrush and mouthwash and is recorded in the relevant checklist.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shaheed Rajaie Cardiovascular Medical & Research Center

##### Full name of responsible person

mahnaz shamseh

##### Street address

Vali Asr St. (AJ), next to Mellat Park, Niayesh corner

##### City

Tehran

##### Province

Tehran

##### Postal code

1995614331

##### Phone

+98 21 23921

##### Email

mashamceh@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shaheed Rajaie Cardiovascular Medical & Research Center

##### Full name of responsible person

Saeideh Mazloomzadeh

##### Street address

Vali Asr St. (AJ), next to Mellat Park, Niayesh corner

##### City

Tehran

##### Province

Tehran

##### Postal code

1995614331

##### Phone

+98 21 2392 3982

##### Email

sa.mazloom@gmail.com

#### Grant name

#### Grant code / Reference number

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

No

**Title of funding source**

Shaheed Rajaie Cardiovascular Medical & Research Center

**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**

Shaheed Rajaie Cardiovascular medical & Research Center

**Full name of responsible person**

Mahnaz Shamseh

**Position**

Master's student in special care nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Dorna 2 Alley; Mirdamad Street; Karim Khan Zand square

**City**

Khorramabad

**Province**

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**Postal code**

6818965398

**Phone**

+98 66 3343 5542

**Fax****Email**

mashamceh@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shaheed Rajaie Cardiovascular Medical & Research Center

**Full name of responsible person**

Mahnaz Shamseh

**Position**

Master's student in special care nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Shaheed Rajaie Cardiovascular Medical & Research Center

**Full name of responsible person**

Mahnaz Shamseh

**Position**

Master's student in special care nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

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**Phone**

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**Fax****Email**

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**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**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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