

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The comparison between chlorhexidine solution and toothbrush in prevention of oral lesions in patients hospitalized in intensive care unit

#### Protocol summary

##### Summary

The aim of this study is comparing the effects of toothbrush (intervention) and Chlorhexidine solution (control) for preventing of oral lesions. In this study 30 intubated patients who are admitted in ICU ward of Shahid Beheshti Hospital, will be randomly divided into two groups. Technique, timing and frequency of mouthwash application is similar in both groups. In the intervention group, internal and external surfaces of the teeth and gums are rotationally brushed by using a soft kid's toothbrush and half a centimeter toothpaste. This action is done every 8 hours during 4 days. Control group members wash their mouths with 0.2 % ( Zero point two percent) chlorhexidine solution. This action is also done every 8 hours for 2 minutes during 4 days for control group. patients with age of 18-65 years old who are admitted in ICU Less than 6 hours will be eligible to the study. Transferring from ICU or death before the completion of intervention; allergy to mouthwash; history or current chronic or immune system diseases are exclusion criteria. During the study the mouth is checked three times a day before mouth intervention for four days, the patient's mouth is checked with Boas and Muroid plaque score(MPS) and those features are recorded in the checklist.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014012216309N1**

Registration date: **2014-04-18, 1393/01/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-04-18, 1393/01/29

#### Registrant information

##### Name

Mohammad Alinejad Moghadam

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 57 1444 5648

##### Email address

mohammadalinejad23@yahoo.com

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice-chancellor for Research of Sabzevar University of Medical Sciences

#### Expected recruitment start date

2013-11-15, 1392/08/24

#### Expected recruitment end date

2014-01-18, 1392/10/28

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The comparison between chlorhexidine solution and toothbrush in prevention of oral lesions in patients hospitalized in intensive care unit

#### Public title

Comparison the effect of chlorhexidine solution and toothbrush in the prevention of oral lesions

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

The inclusion criteria: Having oral endotracheal tube, being 18-65 years old ,The absence of wound, infection

and oral trauma, Not having diseases like hepatitis B and HIV; Not having any symptoms or antecedent of aspiration, serious problems, and artificial teeth. Exclusion criteria are: death at the time of the study, Separation from mechanical ventilation at the time of the study; View apparent aspiration, existence of allergic reactions; restrictions on procedures and aspiration risk.

#### Age

From **18 years** old to **65 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **30**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

In this double blind randomized clinical trial samples in the two groups will be labeled by letters A, B and The researcher who measures the Implications of the study is unaware of the intervention groups. Patients are also blind as they are unconscious at the time of intervention.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

##### Street address

School of Nursing and Midwifery; next to the police station to SHahroud road, Sabzevar

##### City

Sabzevar

##### Postal code

9613873136

#### Approval date

2013-11-12, 1392/08/21

#### Ethics committee reference number

medsab.Rec.92.3

## Health conditions studied

### 1

#### Description of health condition studied

Gingivitis

#### ICD-10 code

k05

#### ICD-10 code description

Gingivitis and periodontal diseases

### 2

#### Description of health condition studied

Other diseases of lip and oral mucosa

#### ICD-10 code

K13

#### ICD-10 code description

Other diseases of lip and oral mucosa

### 3

#### Description of health condition studied

Diseases of tongue

#### ICD-10 code

K14

#### ICD-10 code description

Diseases of tongue

## Primary outcomes

### 1

#### Description

oral health

#### Timepoint

Daily for 4 days

#### Method of measurement

Beck Oral Assessment Scale and Mucosal Plaque Score

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: After approving of the study by sciences vice chancellor of Sabzevar University of medical sciences and completing the written consent forms by all participants in the study, Patients are divided randomly into two equal groups: 15 patients in intervention and 15 in control group. In the intervention group, internal and external surfaces of the teeth and gums are rotationally brushed by using a soft kid's toothbrush and half a centimeter toothpaste .This action is done every 8 hours during 4 days.

#### Category

Prevention

### 2

#### Description

Control group: control group members wash their mouth with 0.2 % ( zero point two percent) chlorhexidine solution. This action is also done every 8 hours for 2 minutes during 4 days but for control group. Also, the observation of mouth is done by BOAS and MPS every 8 hours before utilizing a mouthwash (before washing mouth by chlorhexidine solution). Then, we record it in a checklist.

**Category**

Prevention

## Recruitment centers

1

**Recruitment center**

**Name of recruitment center**

Shaheed Beheshti Hospital

**Full name of responsible person**

Mohammad Alinejad Moghadam

**Street address**

Sabzevar University of Medical Sciences- SHaheed Beheshti Hospital

**City**

Sabzevar

## Sponsors / Funding sources

1

**Sponsor**

**Name of organization / entity**

Vice-chancellor for Research of Sabzevar University of Medical Sciences

**Full name of responsible person**

Moosa Reza Tadayonfar

**Street address**

School of Nursing and Midwifery; next to the police station to SHahroud road, Sabzevar

**City**

Sabzevar

**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 of Sabzevar 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**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Mohammad Alinejad Moghadam

**Position**

Student of MSc Nursing

**Other areas of specialty/work**

**Street address**

Faculty of nursing and midwifery , next to the police station at SHahroud road, Sabzevar

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## Person responsible for scientific inquiries

**Contact**

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Zahra Estaji

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MSc./Member of Faculty

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## Person responsible for updating data

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**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*