

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Comparison of the effect of chlorhexidine mouthwash with irsha mouthwash drop on probable ventilator-associated pneumonia in intensive care unit

#### Protocol summary

##### Study aim

Comparison of the effect of Chlorhexidine mouthwash with Irsha Mouth-Wash Drop on probable ventilator-associated pneumonia in intensive care unit

##### Design

This study is a double-blind randomized clinical trial study with parallel groups. 80 intubated patients undergoing mechanical ventilation will be divided into two groups using Random Allocation Software. Intervention group 1 includes (washing of mouth and teeth with 10 cc chlorhexidine 0.2% three times of day until 5 days) and intervention group 2 (washing of mouth and teeth with 20-25 drops irsha 0.2% three times of day until 5 days).

##### Settings and conduct

This study was carried out in Al-Zahra hospital in Isfahan during 2019 to 2020. A total of 80 patients undergoing mechanical ventilation are enrolled in the study according to inclusion and exclusion criteria and are divided into two groups of chlorhexidine and irsha by random allocation software. Patients, drug prescriber, data collector, and data analyzer were not aware of the groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years, requires mechanical ventilation for at least 48 hours, satisfaction to participate in the study and patients with natural teeth. Exclusion criteria: Specify any damage caused by endotracheal intubation, extubation before 5 days and patient death within 5 days of follow-up.

##### Intervention groups

Intervention group 1: Washing of mouth and teeth with 10 cc chlorhexidine 0.2% three times of day until 5 days. Intervention group 2: Washing of mouth and teeth with 20-25 drops irsha 0.2% three times of day until 5 days.

##### Main outcome variables

Incidence of pneumonia

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150613022681N2**

Registration date: **2020-04-30, 1399/02/11**

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

Last update: **2020-04-30, 1399/02/11**

Update count: **0**

##### Registration date

2020-04-30, 1399/02/11

##### Registrant information

##### Name

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 911 195 1374

##### Email address

alikiaib@med.mui.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2019-03-21, 1398/01/01

##### Expected recruitment end date

2020-05-20, 1399/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of the effect of chlorhexidine mouthwash with irsha mouthwash drop on probable ventilator-associated pneumonia in intensive care unit

## Public title

Comparison of the effect of chlorhexidine mouthwash and irsha mouthwash drop in the prevention of pulmonary infection in hospitalized patients in the intensive care unit

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age over 18 years Requires mechanical ventilation for at least 48 hours Satisfaction to participate in the study Patients with natural teeth

### Exclusion criteria:

Specify any damage caused by endotracheal intubation. Extubation before 5 days Patient death within 5 days of follow-up

## Age

From **18 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

A total of 80 intubated patients in intensive care unit are enrolled in the study according to inclusion and exclusion criteria and are divided into two groups with blocking method and by Random Allocation Software.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Patients are blinded by the type of medication used in the intensive care unit due to their intubation and relaxation, the drugs are also prepared in separate containers with numbers, and the nurse who used the medication for the patients does not know the type of drugs. After collecting the information, it enters the software by numbering, and after performing statistical analysis and completion of the work, the codes are determined.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

##### Street address

Hezar Jerib Street

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2019-11-12, 1398/08/21

#### Ethics committee reference number

IR.MUI.MED.REC.1398.414

## Health conditions studied

### 1

#### Description of health condition studied

Ventilator associated pneumonia

#### ICD-10 code

J95.851

#### ICD-10 code description

Ventilator associated pneumonia

## Primary outcomes

### 1

#### Description

Ventilator associated pneumonia incidence

#### Timepoint

After using the drug on a daily basis up to 5 days

#### Method of measurement

Clinical pulmonary infection score

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: washing of mouth and teeth with 10 cc chlorhexidine 0.2% three times of day until 5 days.

#### Category

Prevention

**2**

**Description**

Intervention group: washing of mouth and teeth with 20-25 drops irsha 0.2% three times of day until 5 days.

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Al-Zahra Hospital

**Full name of responsible person**

Babak Alikiai

**Street address**

Shohadaye Sofe St.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3620 2020

**Email**

alzahra@mui.ac.ir

**Web page address**

http://alzahra.mui.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayesh Haghjoo

**Street address**

Hezar Jarib Street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3792 3060

**Email**

haghjoo@med.mui.ac.ir

**Web page address**

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Babak Alikiai

**Position**

Assistant Professor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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**Contact**

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**Email**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

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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

Information belongs to government agency

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

Yes - There is 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

### Title and more details about the data/document

Because the information belongs to a government agency, it cannot be shared.

### When the data will become available and for how long

Any time

### To whom data/document is available

Any person

### Under which criteria data/document could be used

Under any circumstances

### From where data/document is obtainable

Any person, any time

### What processes are involved for a request to access data/document

Any procedure

### Comments