

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of combined mouthwash on the prevention of ventilator-acquired pneumonia in mechanically ventilated patients admitted to intensive care unit

#### Protocol summary

##### Study aim

The effect of combined mouthwash on the prevention of ventilator-acquired pneumonia in mechanically ventilated patients admitted to intensive care unit

##### Design

Single-blind randomized clinical trial study

##### Settings and conduct

This Single-blind randomized clinical trial study will conduct in mechanically ventilated patients admitted to the intensive care unit.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients under mechanical ventilation; over 18 years old; Patients admitted to intensive care units. Exclusion criteria: patients with brain death, patients with a GCS =3; mechanically ventilated patients less than 48 hours.

##### Intervention groups

Intervention group: patients in the intervention group will receive combination of gentamicin of 2%, colestin of 2% and vancomycin of 2% that it will be rubbed into the oral mucos for 4 times per day (every 6 hours). Control group: patients in the control group will receive chlorhexidine mouthwash of 0.2% that it will be rubbed into the oral mucos for 4 times per day (every 6 hours). Mouthwashes will be used until the creation of pneumonia symptoms, patient mortality, and endotracheal intubation in both groups.

##### Main outcome variables

microorganisms isolated from culture of endotracheal tube secretions; duration of mechanical ventilation; length of stay in intensive care unit and mortality in patients.

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20171221037983N5**

Registration date: **2019-09-30, 1398/07/08**

Registration timing: **retrospective**

Last update: **2019-09-30, 1398/07/08**

Update count: **0**

#### Registration date

2019-09-30, 1398/07/08

#### Registrant information

##### Name

Mohammad Amin Valizadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3346 9935

##### Email address

valizademohammadamin@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2017-04-21, 1396/02/01

#### Expected recruitment end date

2017-09-21, 1396/06/30

#### Actual recruitment start date

2017-04-21, 1396/02/01

#### Actual recruitment end date

2017-09-21, 1396/06/30

#### Trial completion date

2017-09-21, 1396/06/30

#### Scientific title

The effect of combined mouthwash on the prevention of ventilator-acquired pneumonia in mechanically

ventilated patients admitted to intensive care unit

#### Public title

The effect of mouthwash on the prevention of ventilator-acquired pneumonia

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

mechanically ventilated patients Age over 18 years  
Admitted patients in the intensive care unit

##### Exclusion criteria:

brain death patients Patients with GCS=3 Patients with  
mechanical ventilation less than 48 hours

#### Age

From **18 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant

#### Sample size

Target sample size: **124**

Actual sample size reached: **124**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Patients will randomly divided into two intervention and control groups. Individual numbers will be allocated to the intervention group and pair numbers to the control group.

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

The study will be a single-blind study and patients will be blind that they belonged to the intervention or control group.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

###### Street address

Resalat Street; Urmia University of Medical Sciences; Urmia; Iran

###### City

Urmia

#### Province

West Azarbaijan

#### Postal code

57147-83734

#### Approval date

2016-07-27, 1395/05/06

#### Ethics committee reference number

ir.umsu.rec.1395.205

### Health conditions studied

#### 1

##### Description of health condition studied

Mechanically ventilated patients

##### ICD-10 code

Y65.8

##### ICD-10 code description

Other specified misadventures during surgical and medical care

### Primary outcomes

#### 1

##### Description

microorganisms isolated from culture of endotracheal tube secretions

##### Timepoint

microorganism isolated from positive culture of endotracheal tube secretions from the onset of mouthwash till seven days after intervention or patient's death and discharge

##### Method of measurement

Culture of tracheal tube secretions

#### 2

##### Description

Duration of mechanical ventilation

##### Timepoint

The length of mechanically ventilation during hospitalization at the intensive care unit.

##### Method of measurement

Days of Mechanical Ventilation

#### 3

##### Description

mortality in patients

##### Timepoint

Patient's death during hospitalization at the intensive care unit

##### Method of measurement

Death or survival of the patient

### Secondary outcomes

#### 1

##### Description

Length of stay in hospital

## Timepoint

The number of hospitalization days

## Method of measurement

Number of days

## Intervention groups

### 1

#### Description

Intervention group: combined mouthwash of gentamycin of 2%, Cleistine of 2% and vancomycin of 2% that it will rubbed for 4 times per day (every 6 hours) into patients' oral mucosa with a finger.

#### Category

Treatment - Other

### 2

#### Description

Control group: Chlorhexidine mouthwash of 0.2% that it will rubbed for 4 times per day (every 6 hours) into patients' oral mucosa with a finger.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Urmia Imam Khomeini Hospital

##### Full name of responsible person

Dr.Mohammad Amin Valizade Hasanlouei

##### Street address

Imam Khomeini Hospital; Ershad Street; Modarres Blvd; Urmia; Iran

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

81351-57157

##### Phone

+98 44 3198 8293

##### Email

valizademohammadamin@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Oroumia University of Medical Sciences

##### Full name of responsible person

Dr.Iraj Mohebbi

##### Street address

Urmia University of Medical Sciences; Resalat Street; Urmia; Iran

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

57147-83734

##### Phone

+98 44 3223 1930

##### Email

irajmohebbi@umsu.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Amin Valizade Hasanlouei

##### Position

professor of University

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

Imam Khomeini Hospital; Ershad Street; Modarres Blvd; Urmia; Iran

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Oroumia University of Medical Sciences

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Dr.Mohammad Amin Valizade Hasanlouei

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professor of University

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**Contact**

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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**

Confidentiality of information

**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**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable