

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)

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+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

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Postal code

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Phone

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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

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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

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Position

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Person responsible for updating data

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City

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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