

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Comparison of The Effect of Two Methods Mouth Wash (Chlorhexidine and Chlorhexidine Combined with Hydrogen Peroxide Solution) on Frequency of Oral Plaques and Ventilator-Associated Pneumonia in Patients Undergoing Mechanical Ventilation in the Intensive Care Unit of Imam Khomeini Educational Center, Urmia. 2017-18

Protocol summary

Study aim

The aim of this study was to determine the effect of applying two Methods Mouth Wash (Chlorhexidine and Chlorhexidine Combined with Hydrogen Peroxide Solution) on Frequency of Oral Plaques and Ventilator-Associated Pneumonia in Patients Undergoing Mechanical Ventilation in the Intensive Care Unit.

Design

A randomized clinical trial, pre test-post-test, with control group.

Settings and conduct

The study is a randomized clinical trial with a parallel design on two groups of patients in the intensive care unit of Imam Khomeini Hospital in Urmia, where 98 patients with inclusion criteria were randomly assigned into two groups A and B. Intervention in group A was oral care with chlorhexidine mouthwash (0.2%) and in group B (0.2% chlorhexidine mouthwash with 1.5% hydrogen peroxide solution).

Participants/Inclusion and exclusion criteria

Inclusion criteria for the study: 1) Age 18 to 65 years 2) Less than 48 hours have passed since the patient was admitted to the intensive care unit 3) No use of antibiotics before admission 4) No chronic diseases 5) No immune system disorder 6) No damage by endotracheal intubation or airway

Intervention groups

In group A mouth washing was performed with oral chlorhexidine 0.2% by the researcher and his trained assistant. In Group B, in addition to doing the above, 10 min after completing the work, 10 mL of hydrogen peroxide solution was poured into the Steel kidney tray, and the cotton swab was immersed in a 1.5% oxygenate solution and The oral cavity, tongue, and teeth were

washed for 2 minutes, and at the end, a deep throat mouth suction was taken.

Main outcome variables

Number of oral Plaques; Ventilator-Associated Pneumonia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171225038053N1**

Registration date: **2018-09-09, 1397/06/18**

Registration timing: **retrospective**

Last update: **2018-09-09, 1397/06/18**

Update count: **0**

Registration date

2018-09-09, 1397/06/18

Registrant information

Name

Mohammad Jabbari ghanati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 9931

Email address

jabbari.m@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-11, 1396/08/20
Expected recruitment end date
2018-01-21, 1396/11/01
Actual recruitment start date
2017-12-16, 1396/09/25
Actual recruitment end date
2018-03-10, 1396/12/19
Trial completion date
2018-08-12, 1397/05/21

Scientific title

Comparison of The Effect of Two Methods Mouth Wash (Chlorhexidine and Chlorhexidine Combined with Hydrogen Peroxide Solution) on Frequency of Oral Plaques and Ventilator-Associated Pneumonia in Patients Undergoing Mechanical Ventilation in the Intensive Care Unit of Imam Khomeini Educational Center, Urmia. 2017-18

Public title

Effect of Two Methods Mouth Wash (Chlorhexidine and Chlorhexidine Combined with Hydrogen Peroxide Solution) on Frequency of Oral Plaques and Ventilator-Associated Pneumonia in Patients Undergoing Mechanical Ventilation

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Less than 48 hours have passed since the patient was admitted to the intensive care unit. The lack of a specific lesion of mouth and around it by using the Beck Criterion

Exclusion criteria:

Antibiotics use before admission

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **98**

Actual sample size reached: **98**

Randomization (investigator's opinion)

Randomized

Randomization description

The research samples were placed through coin tossing in one of the control and intervention groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

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

Vice-chancellor for research of Urmia University of Medical Sciences, Resalat Blvd

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2017-11-15, 1396/08/24

Ethics committee reference number

IR.UMSU.rec.1396.332

Health conditions studied

1

Description of health condition studied

Ventilator-Associated Pneumonia

ICD-10 code

J18.9

ICD-10 code description

Pneumonia, unspecified organism

Primary outcomes

1

Description

The frequency of Ventilator-Associated Pneumonia

Timepoint

Before and 4 weeks after the intervention

Method of measurement

Beck oral assessment scale, CPIS, Mucosal-Plaque Score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mouthwash was performed in group A with oral chlorhexidine 0.2% by the researcher and his trained assistant.

Category

Prevention

2

Description

Intervention group: In Group B, in addition to doing the above, 10 min after completing the work, 10 mL of hydrogen peroxide solution was poured into the Steel kidney tray, and the cotton swab was immersed in a 1.5% oxygenate solution and oral cavity, tongue, and teeth were washed for 2 minutes, and at the end of mouthwash, a deep throat mouth suction was taken.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital in Urmia

Full name of responsible person

Mohammad Jabbari Ghanati

Street address

No.13 , Kaboodan, boostan, Saadi 1Ave

City

Urmia

Province

West Azarbaijan

Postal code

27555899636

Phone

+98 44 3328 4619

Email

jabbari.m@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Mohammad Jabbari Ghanati

Street address

No.13 , Kaboodan, boostan, Saadi 1Ave

City

Urmia

Province

West Azarbaijan

Postal code

2755589774

Phone

+98 44 3368 4619

Email

jabbari.m@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

Mohammad Jabbari Ghanati

Position

clinical supervisor

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No.13 , Kaboodan, boostan, Saadi 1Ave

City

Urmia

Province

West Azarbaijan

Postal code

2755589696

Phone

+98 44 3368 4619

Email

jabbari.m@umsu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Mohammad Jabbari ghanati

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Emam Khomeini Hospital.,Ershad Blvd

City

Urmia

Province

West Azarbaijan

Postal code

2755599665

Phone

+98 44 3346 9931

Fax

+98 44 3346 9939

Email
m.jabbari647@gmail.com

+98 44 3346 9939

Email
m.jabbari647@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Mohammad Jabbari Ghanati

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Emam Khomeini Hospital., Ershad Blvd

City
Urmia

Province
West Azarbaijan

Postal code
2755599665

Phone
+98 44 3346 9931

Fax

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