

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

A survey of the effect of ozonated water mouthwash on oral health and incidence of ventilator-associated pneumonia in patients connected to mechanical ventilation in intensive care units - A randomized clinical trial

Protocol summary

Study aim

Evaluation and Comparison of the Effects of Chlorhexidine and Ozonated Water Mouthwashes on the Mouth Health and Incidence of VAP in Patients Connected to Mechanical Ventilator in ICU

Design

In this study, using the quadruple-block random allocation method, the eligible subjects will be grouped into two groups administered by chlorhexidine and ozonated water mouthwashes (39 subjects in each group)

Settings and conduct

The present study will be performed at an ICU of Baghiyyatollah Hospital. the patients will be grouped into either intervention or control group. The intervention will be applied for 5 days, with the mouth health inspection performed every other day, the VAP will be examined without a knowledge of the group to which each subject belongs.

Participants/Inclusion and exclusion criteria

Inclusions criteria: Availability of tracheal tube and connecting to the mechanical ventilator within no more than 24 hours from the intubation of the patient and connection to the machine, No oral wounds or injuries, No immunosuppressive diseases, No symptoms of aspiration, No coagulation abnormalities, No dentures, No asthma, No allergy and nose/mouth inflammation, No radiotherapy treatment, No use of antibiotic mouthwash during the past two month, No pregnancy and exclusions criteria: any allergic response or reaction to brushing or any of the mouthwashes is observed, any of the symptoms of the aspiration is observed, symptoms of lung infection are observed, the patient is re-intubated , the patient's first-order relative(s) refuse to have the study continue, the patient is transferred to another hospital.

Intervention groups

The effects of chlorhexidine and 0.2% ozonated water mouthwashes on the mouth health and incidence of VAP will be investigated in intervention and control groups.

Main outcome variables

survey of oral health and incidence of ventilator-associated pneumonia

General information

Reason for update

Changing the age range of the research participant

Acronym

IRCT registration information

IRCT registration number: **IRCT20180213038720N2**

Registration date: **2019-12-18, 1398/09/27**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-13, 1399/02/24**

Update count: **1**

Registration date

2019-12-18, 1398/09/27

Registrant information

Name

Mostafa Soodmand

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A survey of the effect of ozonated water mouthwash on oral health and incidence of ventilator-associated pneumonia in patients connected to mechanical ventilation in intensive care units - A randomized clinical trial

Public title

A survey of the effect of ozonated water mouthwash on oral health and incidence of ventilator-associated pneumonia in patients connected to mechanical ventilation

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Availability of tracheal tube and connecting to the mechanical ventilation machine within no more than 24 hours from the intubation of the patient and connection to the machine. No oral wounds or injuries No engagement with immunosuppressive diseases No record or symptoms of aspiration No coagulation abnormalities No dentures No engagement with the asthma No allergy and nose/mouth inflammation No record of radiotherapy treatment No use of antibiotic mouthwash during the past two months No pregnancy NO symptoms of pulmonary infection

Exclusion criteria:

any allergic response to brushing, Toothpaste and any of the mouthwashes the patient's first-order relative(s) dissatisfaction with the study.

AgeFrom **15 years** old to **85 years** old**Gender**

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample sizeTarget sample size: **78****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization is planned to be performed using quadruple-block random allocation method to conduct experiments in two groups using chlorhexidine and ozonated water as mouthwash. The patients will be included in the study and grouped under either of the

two groups using SNOSE (Sequentially numbered, sealed, opaque envelopes) allocation concealment and the designed quadruple blocks by a statistics expert.

Blinding (investigator's opinion)

Double blinded

Blinding description

For the purpose of this study, the blinding will be performed as follows. Firstly, the resident at the ICU will group each patient under either of the two groups (chlorhexidine and ozonated water) using the designed quadruple blocks by a statistics expert. Next, trained nurses will administer, according to the respective protocol, the patients with the respective mouthwash without even knowing the type of the mouthwash. In the next stage, the researcher will undertake the mouth and teeth health inspection to see whether the ventilator-associated pneumonia (VAP) has occurred without no information on the grouping of the patients. Finally, once collected, the data will be analyzed by the statistics expert with no information about the group to which each patient belongs.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

(کمیته اخلاق دانشگاه علوم پزشکی بقیه الله (عج)

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Approval date

2019-09-02, 1398/06/11

Ethics committee reference number

IR.BMSU.REC.1398.146

Health conditions studied**1****Description of health condition studied**

ventilator-associated pneumonia

ICD-10 code

J67.7

ICD-10 code description

Air conditioner and humidifier lung

2

Description of health condition studied

oral health

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

oral health

Timepoint

Every other day

Method of measurement

Beck Oral Assessment Scale (BOAS), Mucosal Plaque Score (MPS)

2

Description

incidence of ventilator-associated pneumonia

Timepoint

Before the intervention and after the intervention

Method of measurement

Clinical Pulmonary Infection Score (CPIS), Cultivation of pharynx

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Firstly, inner surface of the mouth is thoroughly washed using a soft brush (for kids) on which 0.5 cm of fluoride-rich toothpaste is applied followed by a suction stage. Next, 15 mL of the ozonated water solution is used to wash all the surfaces across the entire mouth, tongue, and teeth using a sterilized syringe. After 30 seconds, the patient's mouth is subjected to suction at a pressure of -100 mmHg for a maximum of 10 seconds followed by hyper-oxygenating the patient with 100% oxygen for 2 minutes.

Category

Prevention

2

Description

Control group: Firstly, inner surface of the mouth is thoroughly washed using a soft brush (for kids) on which 0.5 cm of fluoride-rich toothpaste is applied followed by a suction stage. Next, 15 mL of the chlorhexidine 0.2 solution is used to wash all the surfaces across the entire mouth, tongue, and teeth using a sterilized syringe. After 30 seconds, the patient's mouth is subjected to suction at a pressure of -100 mmHg for a maximum of 10 seconds followed by hyper-oxygenating the patient with

100% oxygen for 2 minutes.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

(بیمارستان تخصصی و فوق تخصصی بقیه الله الاعظم (عج)

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

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Web page address

<https://research.bmsu.ac.ir/Portal/Home/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Collected data will be given to the individuals or organizations -a raw information- that will be provided with the consent of the participants without any name, address or telephone number, and other items.
When the data will become available and for how long
After we have finished the study if data crashed or disposed it will be reachable in a raw information.
To whom data/document is available
Just those have a Written request from authoritative research organizations.
Under which criteria data/document could be used
If there was need to be called in analysis field you can call 09116470641.
From where data/document is obtainable
Mostafa Soodmand, phone number: 09116470641
What processes are involved for a request to access data/document
After confirmation the requeste, only raw and

unidentifiable information from the mail will be delivered within one week.

Comments

If you have any question about this study call these numbers. 09116470641- 09155328439