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)

Phone

+98 51 5697 3303

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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.
Age
From **15 years** old to **85 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target 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
Street address
Mullasadra Street,Vanak Square
City
Tehran
Province
Tehran
Postal code
1435916471
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, lounge, 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, lounge, 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
مرتضی ایزدی
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
غلامحسین علیشیری
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third floor, Baqiyatallah University of Medical Sciences ,Sheikh bahayi Ave,Mullasadra Ave,Vanak Square
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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

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mostafa Soodmand

Position

MSc Medical-Surgical of Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Professor

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Subspecialist

Other areas of specialty/work

Infectious diseases

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Position

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Latest degree

Master

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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.

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

Comments