Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparative study of the effectiveness of mouthwash containing either ozone water or chlorhexidine in the prevention of oral lesions and ventilation associated pneumonia in mechanically ventilated patients

Protocol summary

Summary

Introduction: Oral health is one of the most common measures for assessing personal well-being. Intubation of ICU inpatients endangers their oral health and increases their susceptibility to pneumonic diseases. This study was conducted to compare the effectiveness of two mouthwashes, containing either chlorhexidine or ozonized water, in preventing oral lesions and ventilator associated pneumonia (VAP). Materials and methods: Designed as a clinical trial, 74 patients were selected on the basis of accessibility and convenience, while considering the study criteria. The demographic information of all patients was gathered using a questionnaire. Patients were randomly assigned to either the control group (35 patients) or the test group (39 patients). Patients in the control or test group used a mouthwash containing either chlorhexidine (0.2% by wt.) or ozonized water (0.05 ppm by wt.) three times per day, respectively. To study oral lesions, the validated Beck oral assessment scale (BOAS) was used. The patients were also assessed using the clinical pulmonary infection score (CPIS) scale to evaluate them in terms of the VAP.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080523520N1**
Registration date: **2015-10-30, 1394/08/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-10-30, 1394/08/08

Registrant information

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Nasrin Hanifi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2013-10-17, 1392/07/25

Expected recruitment end date

2014-03-17, 1392/12/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effectiveness of mouthwash containing either ozone water or chlorhexidine in the prevention of oral lesions and ventilation associated pneumonia in mechanically ventilated patients

Public title

Comparative study of the effectiveness of mouthwash containing either ozone water or chlorhexidine in the prevention of oral lesions and ventilation associated pneumonia in mechanically ventilated patients

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: Patients who for 12 hours intubated and connect them mechanical ventilation and remained under mechanical ventilation during the study; patients aged 18-70 years; women who were not pregnant; no artificial teeth; had not severe anemia; had not alcohol poisoning; bleeding or sores in the mouth had not Exclusion criteria: Patients with mechanical ventilation ended in less than 48 hours; the patient died or for any reason or legal guardians of the patient and his doctor to participate in the study were withdrawn; despite the digestive tubes were vomiting during the study.
Age
From **18 years** old to **76 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
Had not

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Zanjan University of Medical Science
Street address
Azadi Square,Zanjan University of Medical Science
City
Zanjan
Postal code
13191-45156
Approval date
2013-09-21, 1392/06/30
Ethics committee reference number
ZUMS.REC.1392.106

2

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Approval date
2013-09-21, 1392/06/30
Ethics committee reference number
ZUMS.REC.1392.106

Health conditions studied

1

Description of health condition studied
Diseases of the respiratory system
ICD-10 code
10
ICD-10 code description
Chapter X Diseases of the respiratory system (J00-J99)

Primary outcomes

1

Description
Oral lesions
Timepoint
after intervention, the second, third and fourth day of hospitalization
Method of measurement
Beck

Secondary outcomes

1

Description
VAP
Timepoint
The first , third and fourth day of hospitalization
Method of measurement
CPIS

Intervention groups

1

Description
In intervention group mouthwash with 0.05 ppm ozone water
Category
Prevention

2

Description
In the control group mouthwash containing 0.2% chlorhexidine
Category

Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Zanjan University of Medical Science
Full name of responsible person
Mosavi Hospital
Street address
masome masomi
City
Gavazng road, Mousavi Hospital, part icu

Sponsors / Funding sources

1

Sponsor
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zanjan university of medical sciences
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Grant name
معاونت پژوهشی دانشگاه علوم پزشکی زنجان
Grant code / Reference number
414
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
zanjan university of medical sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty