

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

Name

Nasrin Hanifi

Name of organization / entity

Zanjan University of Medical Sciences

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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

Ethics committee

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Postal code

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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

Name of organization / entity

zanjan university of medical sciences

Full name of responsible person

Nasrin hanifi

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Azadi Square, Tehran 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

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Masome masomi

Position

nursing student of M.S in critical care nursing

Other areas of specialty/work

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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