

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of two methods of oral care on oral health and the prevention of ventilator-associated pneumonia in mechanically ventilated patients in intensive care unit

Protocol summary

Summary

The aim of this study is to compare two methods of oral care on oral health and the prevention of ventilator-associated pneumonia in mechanically ventilated patients. This study is a randomized controlled clinical trial which will be done on 68 patients who will be admitted to ICUs Of Imam Khomeini hospital in Ahwaz and meet inclusion criteria of. The patients will be randomly assigned into 2 equal 34 persons. In group A, all surfaces of mouth, gingiva, tongue, throat and teeth will be brushed by 20 cc of Chlorhexidine. In Group B, the same intervention will be done with chlorhexidine and Swabs. Mouth washing will be repeated every 12 hours to 5 days . Each intervention will be taken about 20 minutes. In both groups A and B oral health status, will be recorded, the daily at 6 pm according to the BRUSHED form. At the end of the study (fifth day) both groups A and B will be examined, terms of infection with and without of ventilator-associated pneumonia based on the CPIS forms.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013050813278N1**

Registration date: **2013-05-25, 1392/03/04**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-05-25, 1392/03/04

Registrant information

Name

Maryam Razeh

Name of organization / entity

Nursing and Midwifery School, Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor of Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2013-07-06, 1392/04/15

Expected recruitment end date

2013-10-23, 1392/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two methods of oral care on oral health and the prevention of ventilator-associated pneumonia in mechanically ventilated patients in intensive care unit

Public title

The effect of oral care on pulmonary infection in intensive care unit

Purpose

Prevention

Inclusion/Exclusion criteria

The inclusion criteria: Age between 18 to 65 years, Having oral endotracheal tube, lake of pneumonia before

the start of the study according to recognize a physician, the absence of immunosuppressive diseases according to recognize a physician, Be permitted to perform oral care for patients according to doctor, Not having dentures, No history of allergy to chlorhexidine, The absence of wound, infection and oral trauma, Without underlying lung problems (chronic obstructive pulmonary disease, lung cancer, trauma to the chest). Exclusion criteria were: death at the time of the study, Separation from mechanical ventilation at the time of the study, Re-intubation at the time of the study, initiation of pneumonia 48 hours after the start of the study, according to medical study View apparent aspiration

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Ethical Human Subject Review Board of Hamadan
University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Shaheed
Fahmideh Ave

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Postal code

6517838695

Approval date

2013-06-12, 1392/03/22

Ethics committee reference number

D/P/16/35/9/756

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

Oral Health

ICD-10 code

K00-14

ICD-10 code description

Disorders of tooth development and eruption

2**Description of health condition studied**

ventilator-associated pneumonia

ICD-10 code

J95.8

ICD-10 code description

Other postprocedural respiratory disorders

Primary outcomes**1****Description**

Oral Health

Timepoint

Daily for 5 days

Method of measurement

BRUASHED Scale

2**Description**

Pneumonia

Timepoint

Fifth Day

Method of measurement

CPIS Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: chlorhexidine mouthwash 0/2%,
2times a day for 5 days, using Children toothbrush

Category

Prevention

2**Description**

Control group: chlorhexidine mouthwash 0/2%, 2times a
day for 5 days, using guaz

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Ghلام Hossein Falahinia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor of Research and Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr. Heidar Tavalani

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Vice-Chancellor of Research and Technology,
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-Chancellor of Research and Technology, Hamadan
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

Department of Medical Surgical Nursing

Full name of responsible person

Ghلام Hossein Falahinia

Position

Nursing Masters

Other areas of specialty/work

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Full name of responsible person

maryam razeh

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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