Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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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Hamadan

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
Ghlam Hossein Falahinia

Street address
Ahvaz, Pasdaran Av, Ghlam Hossein Falahinia

City
Hamadan

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 Tavilani

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

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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
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Position
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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