

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Evaluation and comparison of the effects of three oral care programs on oropharyngeal complications and the Occurrence of ventilator associated pneumonia in patients undergoing mechanical ventilation

Protocol summary

Study aim

Determination and comparison of the effects of three oral care programs on oropharyngeal complications and the Occurrence of ventilator associated pneumonia in patients undergoing mechanical ventilation

Design

All hospitalized patients with inclusion criteria will be selected and then divided into one of three groups using the statistical software; the study will have two intervention groups and one quasi-intervention group with parallel groups.

Settings and conduct

A clinical trial study on prophylaxis is conducted in Isfahan University of Medical Sciences Hospital without blinding

Participants/Inclusion and exclusion criteria

patient will have an endotracheal tube; Do not have mucosal inflammation or severe trauma to the mouth; Do not have Chronic Disease and Immune Deficiency; Have teeth; Do not have reentubation; Be the first day of patient intubation; No tracheostomy during the study; no apparent aspiration; at least platelet 40,000; at least INR 2; no transfer or discharge prior to day 7; no pneumonia within 48 hours of study

Intervention groups

The three intervention groups included: the first group taking oral care with chlorhexidine solution 0.2% and swab every 12 hours; the second group brushing with chlorhexidine 0.2% every 12 hours; the third group brushing every 6 hours, twice with chlorhexidine 0.2% and twice with normal saline; 12 hours interval; in all three groups oral suctioning, oral cavity moisturizing and lipsticking will be performed every 4 hours

Main outcome variables

pneumonia; oropharyngeal complications; oral care

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191012045066N1**

Registration date: **2019-11-07, 1398/08/16**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-25, 1398/09/04**

Update count: **1**

Registration date

2019-11-07, 1398/08/16

Registrant information

Name

Samira Ghasemi Gavarti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

samghasemi68@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

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

Evaluation and comparison of the effects of three oral care programs on oropharyngeal complications and the Occurrence of ventilator associated pneumonia in patients undergoing mechanical ventilation

Public title

The effects of oral care program on oropharyngeal complications and the Occurrence of ventilator associated pneumonia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patient will have an endotracheal tube Do not have mucosal inflammation or severe trauma to the mouth Do not have Chronic Disease and Immune Deficiency Have teeth Do not have reentubation Be the first day of patient intubation

Exclusion criteria:

Insertion a tracheostomy for the patient during the study The obvious aspiration Reduce platelet count to less than 40000 Increase INR to more than 2 Transfer or discharge the patient to another ward before the seventh day Diagnose pneumonia within the first 48 hours after mechanical ventilation is started

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: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Initially, patients with inclusion criteria will be selected one by one. Then, the variables defined for the software, including their age, sex, diagnosis, and chip tube number, are entered into the online minimap software. Software randomly divides patients into one of three groups. Sampling will continue this way until the required number of samples is completed.

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

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar jarib Ave

City

isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-08-26, 1398/06/04

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.333

Health conditions studied

1

Description of health condition studied

ventilator associated pneumonia

ICD-10 code

J95.851

ICD-10 code description

Ventilator associated pneumonia

2

Description of health condition studied

oropharyngeal complications

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Clinical pneumonia infection score

Timepoint

Before the intervention, on the fourth and seventh days of the intervention

Method of measurement

Modified clinical pneumonia infection score

2

Description

Oral Health Score

Timepoint

On the second, fourth and seventh days of the intervention

Method of measurement

Beck Oral Assessment Scale

3

Description

Oral Health Score

Timepoint

On the second, fourth and seventh days of the intervention

Method of measurement

Mucosal Plaque Score

Secondary outcomes

empty

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

Intervention group: Oral care with swab and chlorhexidine solution 0.2% every 12 hours and equal care between groups (oral cavity moistening and lipsticking every 4 hours and oral suctioning if needed)...

Category

Prevention

2**Description**

Intervention group: Oral care with toothbrush and chlorhexidine solution 0.2% every 12 hours and equal care between groups

Category

Prevention

3**Description**

Intervention group: Oral care every 6 hours, twice with toothbrush and 0.2% chlorhexidine solution every 12 hours, twice with toothbrush and normal saline every 12 hours and equal care between groups

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amin Hospital

Full name of responsible person

Dr. Hamid Melali

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2**Recruitment center****Name of recruitment center**

Alzahra hospital

Full name of responsible person

Dr. Majid Rezvani

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Alzahra Medical and Educational Center., Sofeh Boulevard., Shahid Keshvari Highway

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3**Recruitment center****Name of recruitment center**

Khorshid hospital

Full name of responsible person

Dr. Ramin Sami

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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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
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Somayeh Haghighat

Position
Senior lecturer- Faculty member of nursing and midwifery college

Latest degree
Master

Other areas of specialty/work
Nursery

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Position
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available