

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of oral care program on prevention of ventilator-associated pneumonia in intensive care unit patients

Protocol summary

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Summary

The aim of this study is to determine the effects of oral care program on pneumonia incidence for mechanically ventilated patients at Intensive Care Unit. This study is a randomized controlled clinical trial which will be carried out on 80 admitted patients of Amin hospital in Isfahan respectively. The patients will be randomly assigned in to two control and intervention groups. In control group, Routine oral care will be done and in intervention group, oral care will be implemented. every 12 hours , teeth will be brushed with chlorhexidine solution and every 4 hours the lips moisture.Both groups will be examined in terms of pneumonia incidence based on the CPIS forms at the first, third, and fifth days of the study .

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017101631200N2**

Registration date: **2017-10-23, 1396/08/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-23, 1396/08/01

Registrant information

Name

Vajihe Atashi

Name of organization / entity

Nursing Faculty of Isfahan University

Country

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Email address

Scientific title

Effect of oral care program on prevention of ventilator-associated pneumonia in intensive care unit patients

Public title

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

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Having intubation during study, Age between 18 to 65 years, Admission on ICU less than 12 hours, No further intubation, No extreme trauma of the face and mouth, No current hospitalization in other parts of the hospital, No pregnancy, Not having chronic disease and immune disorder, Patient with natural teeth, Lack of lung disease, Pneumonia and Sepsis according to CPIS tools. Exclusion Criteria: Transferring the patient from ICU or his/her death, Unwillingness to continue the study from the patient's legal guardian, Less than 48 hours under mechanical ventilation, Removing intubation before end of study, Allergic to chlorhexidine

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: **80**

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**

Isfahan University of Medical Science

Street address

Hezar-Jerib Ave., Isfahan

City

Isfahan

Postal code

81746 73461

Approval date

2016-07-27, 1395/05/06

Ethics committee reference number

IR.MUI.REC.1395.3.361

Health conditions studied**1****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**

Ventilator-Associated Pneumonia

Timepoint

First, Third, Fifth Day

Method of measurement

CPIS

Secondary outcomes**1****Description**

Oral Health

Timepoint

Daily for 5 days

Method of measurement

BOAS

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

Adjusting the pressure of the cuff of the endotracheal tube 20 using a special manometer.Brushing all internal and external surfaces of the teeth, gums and tongue for 2 min using a baby toothbrush and antimicrobial chlorhexidine0.12% every 12 hours.Moisturizing all surfaces of the oral mucosa, gums, and tongue of the patient using swabs and moisturizing gel every 4 hours. Thin layer of petroleum jelly was applied to the lip

Category

Prevention

2**Description**

In the control group, oral care will be performed by staff based on the daily routine.

Category

Prevention

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

Amin Hospital

Full name of responsible person**Street address****City**

Isfahan

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

Isfahan University of Medical Science

Full name of responsible person

Vajihe Atashi

Street address

Hezar-Jerib Ave., Isfahan

City
Isfahan

Grant name

Grant code / Reference number

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

Title of funding source
Isfahan University of Medical Science

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
Isfahan University of Medical Science

Full name of responsible person
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Nursing Phd Student

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Person responsible for updating data

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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