# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

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

## Protocol summary

**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 .

## 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**

Iran (Islamic Republic of)

**Phone**

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**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

**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, Admision 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**
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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*