

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of systematic oral care on the preventing ventilator associated pneumonia in critically ill patients

Protocol summary

Summary

The aim of this study is to determine the effects of systematic oral care 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 100 admitted patients of Imam Khomeyni and Imam Reza hospitals in Sari and Amol 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, systematic oral care will be implemented in such a way that patients will be scored with Beck tool to determine the times of oral care. In each event of oral care, teeth will be brushed and chlorhexidine solution is sprayed on teeth and the lips moisture. Using Beck tool, oral condition of the patient will be examined on a daily basis. At first, third and fifth days of study condition of Mucosal-Plaque Score will be investigated in both groups. Both groups will be examined in terms of pneumonia incidence based on the CPIS forms.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015100424342N1**

Registration date: **2015-11-04, 1394/08/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-04, 1394/08/13

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor of Research and Technology ,
Mazandaran University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of systematic oral care on the preventing ventilator associated pneumonia in critically ill patients

Public title

The effect of systematic oral care 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: **100**

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

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

Street address

Moalem Square

City

Sari

Postal code

Approval date

2015-09-12, 1394/06/21

Ethics committee reference number

IR.Mazums.REC.94-1672

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

2

Description

Oral Health

Timepoint

Daily for 5 days

Method of measurement

BRUASHED Scale

3

Description

Mucosal-Plaque Position

Timepoint

First, third, Fifth Day

Method of measurement

Mucosal-Plaque Score

Secondary outcomes

empty

Intervention groups

1

Description

In intervention group, at first, oral condition of the patient will be scored by Beck form to determine the times of oral care. During each oral care, Endotracheal tube cuff pressure will be set in the range of 20 cm H2O. Teeth will be brushed by children soft toothbrush and toothpaste and washed with normal saline serum with suction in the same time. the amount of Mouthwash solution include 5 ml of % 12 Chlorhexidin will be sprayed on teeth. So the oral cavity' s suction will be done in mouth and throat simultaneous . Finally, lips get wet using moisturizing cream.

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

Imam Khomeini Hospital

Full name of responsible person

Street address

City

Sari

2

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Street address

City

Amol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Full name of responsible person

Hosin Enayati

Street address

Moalem Square

City

Sari

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,
Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Abdollah Haghighi

Position

Master Critical Care Nursing Student

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