

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of Matrica oral rinse on incidence of Ventilator-Associated Pneumonia in hospitalized patient in critical care unitpatients

Protocol summary

Summary

The aim of this study is to determine effect of Matrica versus chlorhexidine oral rinse on incidence of ventilator-associated pneumonia in hospitalized patient in critical care unit. Inclusion criteria include more than 18 years old, under mechanical ventilation for more than 48 hours, no pneumonia, lack of oral trauma, no immunosuppressive diseases. Exclusion criteria: if a patient separated from mechanical ventilation for less than 48 hours. Sample size: Study conducted on 30 subjects from each group using a significance level of 5% and the 90% formula, samples in each group calculated. Intervention in both groups is the same and randomize. Patients of experimental and control groups receive daily twice Matrica oral rinse and Chlorhexidine 0.2% oral rinse, respectively. Patients are mouthwash for 7 days and ventilator-associated pneumonia assessed in 7th days by Clinical Pulmonary Infection Score.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201303058288N3**

Registration date: **2013-07-27, 1392/05/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-07-27, 1392/05/05

Registrant information

Name

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Name of organization / entity

Shahed University

Country

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Recruitment status

Recruitment complete

Funding source

Shahed University

Expected recruitment start date

2013-04-18, 1392/01/29

Expected recruitment end date

2013-09-21, 1392/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Matrica oral rinse on incidence of Ventilator-Associated Pneumonia in hospitalized patient in critical care unitpatients

Public title

Effect of Matrica oral rinse on incidence of Ventilator-Associated Pneumonia in hospitalized patient in critical care unit

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: more than 18 years old, under mechanical ventilation for more than 48 hours, no pneumonia, lack of oral trauma, no immunosuppressive diseases. Exclusion criteria: if a patient separated from mechanical ventilation for less than 48 hours.

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: 60

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahed University

Street address

Valiasr Ave, Rahimzadeh alley, No. 6, Shahed Nursing and Midwifery School, Tehran

City

Tehran

Postal code

Approval date

2013-04-10, 1392/01/21

Ethics committee reference number

41/168154

Health conditions studied

1

Description of health condition studied

Pneumonia

ICD-10 code

J17

ICD-10 code description

Pneumonia in diseases classified elsewhere

Primary outcomes

1

Description

Ventilator Associated Pneumonia(VAP)

Timepoint

Before the study and one week after the study

Method of measurement

CPIs index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: While the head of the bed is elevated, Mouthwash is done by a long-handled brush and one tablespoon of Matrica in a glass of diluted solution serum. Mouthwash is done about 10 minutes twice a day for one week. Also pharyngeal suctioning is done before and after mouthwash. After one week, Occurrence or non-occurrence of Ventilator-associated pneumonia assess by CPIs score as the primary outcome variable.

Category

Other

2

Description

Control group: in this group, mouthwash is done by a long-handled brush and chlorhexidine 0.2%. Duration of mouth care is one week. After one week, the occurrence of Ventilator-associated pneumonia evaluate by CPIs.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Qom University of Medical Sciences

Full name of responsible person

Street address

City

Qom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Mohammad Reza Heidari

Street address

No. 6, Rahimzadeh alley, Valiasr Ave

City

Tehran

Grant name

Grant code / Reference number

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

Yes
Title of funding source
Shahed University
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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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