Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

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

Protocol summary

Summary

The aim of this study is to determine effect of hydrogen peroxide oral rinse on incidence of ventilator-associated pneumonia in hospitalized patient in critical care unit. Inclusion criteria: more than 18 years old, under mechanical ventilation for more than 48 hours, no signs of aspiration, no pneumonia, no contraindications to oral care, lack of oral trauma, no contraindication to elevation of head of bed at least 30 degrees. Exclusion criteria: if a patient separated from mechanical ventilation for less than 48 hours. The society of under study: our samples include of patients, which hospitalized in ward of intensive care unit in Fatemiah and Amir-almomenin hospitals in Semnan that have inter criteria situation. Sample size: Study conducted on 15 subjects from each group using a significance level of 5% and the 80% formula, samples in each group calculated. Age, APACHE II score and type of intensive care unit are similar in the experimental and control group. Intervention in both groups is the same and randomize. Patients of experimental and control groups receive daily twice hydrogen peroxide 3% oral rinse and normal saline 0.9% oral rinse, respectively. Patients are mouthwash for 5 days and ventilator-associated pneumonia assessed in 1th and 5th days.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305236318N2**
Registration date: **2013-06-17, 1392/03/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-06-17, 1392/03/27

Registrant information

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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2013-06-05, 1392/03/15

Expected recruitment end date

2013-11-06, 1392/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

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

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: more than 18 years old, under mechanical ventilation for more than 48 hours, no signs

of aspiration, no pneumonia, no contraindications to oral care, lack of oral trauma, no contraindication to elevation of head of bed at least 30 degrees. Exclusion criteria: if a patient separated from mechanical ventilation for less than 48 hours.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **15**

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
Semnan University of Medical Sciences

Street address
Basij Bulvar, Semnan

City
Semnan

Postal code
3513138111

Approval date
2013-05-22, 1392/03/01

Ethics committee reference number
92/306537

Health conditions studied

1

Description of health condition studied
Ventilator-Associated Pneumonia

ICD-10 code
j69.0

ICD-10 code description
Pneumonitis due to food and vomit

Primary outcomes

1

Description
Ventilator-Associated Pneumonia

Timepoint
In 1th and 5th days

Method of measurement
The assessment tool of ventilator-associated pneumonia modified clinical pulmonary infection score, which according to the body temperature, the white blood cell count, tracheal secretions, Ratio of arterial oxygen pressure (Pao2) to inspired oxygen fraction (Fio2) and chest x ray diagnose pneumonia

Secondary outcomes

1

Description
Ventilator-Associated Pneumonia

Timepoint
In 1th and 5th days

Method of measurement
The assessment tool of ventilator-associated pneumonia modified clinical pulmonary infection score, which according to the body temperature, the white blood cell count, tracheal secretions, Ratio of arterial oxygen pressure (Pao2) to inspired oxygen fraction (Fio2) and chest x ray diagnose pneumonia.

Intervention groups

1

Description
In intervention group, after washing hands and elevation of bed's head and with wear of clear gloves, endo-tracheal tube cuff pressure reached to 25 centimeter of water and then by using of 4–6 swabs that soaked in 15 ml hydrogen peroxide solution 3% Mucous membrane of the mouth, tongue and gums is washed and then additional secretions is suctioned. Patients' mouthwashes are doing twice a day in 8 am and 4 pm for 5 days.

Category
Prevention

2

Description
In control group, after washing hands and elevation of bed's head and with wear of clear gloves, endo-tracheal tube cuff pressure reached to 25 centimeter of water and then by using of 4–6 swabs that soaked in 15 ml saline normal 0.9% Mucous membrane of the mouth, tongue and gums is washed and then additional secretions is suctioned. Patients' mouthwashes are doing twice a day in 8 am and 4 pm for 5 days.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Semnan University of Medical Sciences,Fatemiah Hospital and Amir-Almomenin Hospital
Full name of responsible person
Monir Nobahar
Street address
Semnan, University of Medical Sciences, Nursing and Paramedical University
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Dr. Raheb Ghorbani
Street address
Semnan, Boulvar Basij, University of Medical Sciences
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Semnan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan 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

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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