

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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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Name of organization / entity

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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, Fatemeh 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, Bouvar Basij, University of Medical Sciences

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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

Contact

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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