

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effect of Propolis mouthwash on incidence of Ventilator-Associated Pneumonia in hospitalized patient in critical care unit

Protocol summary

Study aim

Determine the effect of Propolis mouthwash on incidence of Ventilator Associated Pneumonia in hospitalized patient in critical care units.

Design

This is a double blind randomized controlled clinical trial with a parallel group design.

Settings and conduct

This study is done in ICU Imam Hussein (AS) and Bahar hospitals in Shahrud. Intervention in both groups is the same and randomize. Patients of experimental and control groups receive daily twice Propolis and Chlorhexidine mouthwash, respectively. Patients are mouthwash for 7 days and ventilator-associated pneumonia assessed in 1th; 3th; 5th and 7th days. Nurse and the data analyst are blinded to the allocation status.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients 18-75 years old; Under mechanical ventilation for more than 48 hours; Glasgow Coma scale between 6-11; Feeding with gastric tube; No contraindications to oral care; Propolis insensitivity. Exclusion criteria: Tracheotomy; Jaw and facial trauma; Weakness of the immune system.

Intervention groups

In the intervention group, mouthwash by using Propolis solution, each containing 3 mg of propolis in 1 ml, are doing twice a day in 8 am and 4 pm for 7 days. In the control group, mouthwash using Chlorhexidine 0.2% solution, twice a day in 8 am and 4 pm for 7 days.

Main outcome variables

Ventilator-Associated Pneumonia

General information

Reason for update

Student problems related to pregnancy and childbirth, having a baby, have led to delays in the sampling process.

Acronym

IRCT registration information

IRCT registration number: **IRCT20110427006318N12**

Registration date: **2019-04-02, 1398/01/13**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-18, 1401/01/29**

Update count: **1**

Registration date

2019-04-02, 1398/01/13

Registrant information

Name

Monir Nobahar

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 3365 4190

Email address

Nobahar43@Yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-04, 1397/11/15

Expected recruitment end date

2023-03-11, 1401/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Propolis mouthwash on incidence of Ventilator-Associated Pneumonia in hospitalized patient in critical care unit

Public title

Effect of Propolis mouthwash on incidence of Pneumonia in hospitalized patient in critical care unit

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients 18-75 years old Under mechanical ventilation for more than 48 hours Glasgow Coma scale between 6-11 Feeding with gastric tube No contraindications to oral care Propolis insensitivity

Exclusion criteria:

Tracheotomy Jaw and facial trauma Weakness of the immune system

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

The research sample assigned to the groups of the study by permuted blocks randomization. In order to establish the number of samples assigned to each group (intervention and control), a random method with 4 blocks is used, so that each block has an equal number of each group, and the research sample assigned to the groups of the study by blocks randomization. Also blocking is used within age, sex and mode of the mechanical ventilation device. According to the age, sex and mode of mechanical ventilation variables are influence factors to the ventilator associated pneumonia; patients are selected and blocked that they are similar to another age (± 5 years, maximum difference 10 years), sex and mode of mechanical ventilation.

Blinding (investigator's opinion)

Double blinded

Blinding description

The propolis mouthwash is used in intervention group and the chlorhexidine mouthwash is used in the control group. Propolis mouthwash (A) and chlorhexidine mouthwash (B) defined and blind available to the nurse. Also the data analyst is blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical sciences

Street address

Semnan University of Medical Sciences, Basij Boulevard, Semnan

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Semnan

Province

Semnan

Postal code

3513138111

Approval date

2018-12-18, 1397/09/27

Ethics committee reference number

IR.SEMUMS.REC.1397.208

Health conditions studied

1

Description of health condition studied

Ventilator-Associated Pneumonia

ICD-10 code

J95.851

ICD-10 code description

J95.851 Postprocedural respiratory disorders, not elsewhere classified

Primary outcomes

1

Description

Ventilator-Associated Pneumonia

Timepoint

1th; 3th; 5th and 7th 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

empty

Intervention groups

1

Description

Intervention group: In the intervention group, mouthwash by using Propolis solution, each containing 3 mg of propolis in 1 ml, are doing twice a day in 8 am and

4 pm for 7 days.

Category

Prevention

2

Description

Control group: In the control group, mouthwash using Chlorhexidine 0.2% solution, twice a day in 8 am and 4 pm for 7 days.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hussein (AS) and Bahar hospitals in Shahroud

Full name of responsible person

Monir Nobahar

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Semnan University of Medical Sciences, Basij Boulevard, Semnan.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parviz Kokhaei

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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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Monir Nobahar

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Data is confidential

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Data is confidential

When the data will become available and for how long

It was possible to publish the paper from the study.

To whom data/document is available

Research group

Under which criteria data/document could be used

After publishing the resulting paper, it can be made available to others in order to use the results of the study.

From where data/document is obtainable

An article published in an valid journal among available journals

What processes are involved for a request to access data/document

The process of publishing an article in the journal

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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