Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 Shahroud. 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)

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+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
City
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

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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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Position

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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