

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effect of Clove extract mouthwash on incidence of Ventilator Associated Pneumonia in hospitalized patient in critical care unit

Protocol summary

Study aim

Effect of Clove extract mouthwash on incidence of Ventilator Associated Pneumonia in hospitalized patient in critical Care Unit

Design

Clinical trial, by using block randomization, the patients enter in intervention or control group, a pilot study including 10 patients from each group, will determine the size of the sample, parallel groups, triple blind.

Settings and conduct

This study is a triple blind randomized clinical trial that is done in the intensive care units of kosar hospital of Semnan. The nurse who performed the mouthwash, patients and the physician evaluating ventilator-associated pneumonia and statistician were blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: new patient admitted to the intensive care unit; age over 18 years; patients under mechanical ventilation for more than 48 hours; no aspiration symptoms or pneumonia; no infection with Covid-19; no contraindications to oral care; no contraindication to elevation of head of bed at least 30 degrees; insensitivity to chlorhexidine 0.2%. Exclusion criteria: fever 38.5 and above during the first 24 hours after intubation; positive PCR test (infection of Covid-19); re-intubation more than 3 times; apache II score above 30.

Intervention groups

In the intervention group, mouthwash by 15 ml of clove extract, with concentration 33% from 20% solution, are doing twice a day in 8 am and 4 pm for 5 days. In the control group, mouthwash by 15 ml of Chlorhexidine 0.2% solution, are doing twice a day in 8 am and 4 pm for 5 days.

Main outcome variables

Ventilator-Associated Pneumonia is evaluated with the assessment tool of ventilator-associated pneumonia modified.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110427006318N13**

Registration date: **2020-10-11, 1399/07/20**

Registration timing: **prospective**

Last update: **2020-10-11, 1399/07/20**

Update count: **0**

Registration date

2020-10-11, 1399/07/20

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

2020-10-26, 1399/08/05

Expected recruitment end date

2021-04-25, 1400/02/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Clove extract mouthwash on incidence of Ventilator Associated Pneumonia in hospitalized patient in critical care unit

Public title

Effect of Clove extract mouthwash on incidence of Ventilator-Associated Pneumonia

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

New patient admitted to the intensive care unit Age over 18 years Patients under mechanical ventilation for more than 48 hours No aspiration symptoms or pneumonia No infection with Covid-19 No contraindications to oral care No contraindication to elevation of head of bed at least 30 degrees Insensitivity to chlorhexidine 0.2%

Exclusion criteria:

Fever 38.5 and above during the first 24 hours after intubation Positive PCR test (infection of Covid-19) Re-intubation more than 3 times Apache II score above 30

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

The research sample assigned to the groups of the study by permuted blocks randomization. The blocks will be AB or BA. A is the intervention group, B is the control group. After randomly selecting one of the two possible blocks, two consecutive samples are randomly placed in intervention or control group. Blocking is used within gender and age. Regarding to the age, the first patient is randomly placed in the intervention or control group, the next patient with maximum age difference of five years is placed in another group. If the next patient's age difference is more than five years, the patient is randomly placed in another age block. Regarding to the gender, randomization is done separately for men and women. In other words, the first female patient is randomly placed in the intervention or control group and next female patient is placed in another group. For the male patients division is done in the same way.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, mouthwashes will be prepared by the investigator and given blindly to the critical care unit nurse, who performed the mouthwash. Patients are not

aware of the type of solution. The physician evaluating Ventilator-Associated Pneumonia and the statistician are blind to the study groups (intervention and control).

Placebo

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 science

Street address

Semnan University of Medical Sciences, Basij Boulevard, Semnan

City

Semnan

Province

Semnan

Postal code

3513138111

Approval date

2020-09-22, 1399/07/01

Ethics committee reference number

IR.SEMUMS.REC.1399.184

2**Ethics committee****Name of ethics committee**

Ethics committee of Semnan University of Medical science

Street address

Semnan University of Medical Sciences, Basij Boulevard, Semnan

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Postal code

3513138111

Approval date

2020-09-22, 1399/07/01

Ethics committee reference number

IR.SEMUMS.REC.1399.184

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

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 to inspired oxygen fraction and chest x ray diagnose pneumonia.

Secondary outcomes

1

Description

Ventilator-Associated Pneumonia

Timepoint

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 to inspired oxygen fraction and chest x ray diagnose pneumonia.

Intervention groups

1

Description

Intervention group: In the intervention group, mouthwash by 15 ml of clove extract, with concentration 33% from 20% solution, prepared from Dr. Jahangir company, are doing twice a day in 8 am and 4 pm for 5 days.

Category

Prevention

2

Description

Control group: In the control group, mouthwash by 15 ml of Chlorhexidine 0.2% solution, prepared from the donyaye behdasht company, are doing twice a day in 8 am and 4 pm for 5 days.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar hospital

Full name of responsible person

Monir Nobahar

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Faculty Nursing and Midwifery, Semnan University of Medical Sciences, Semnan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

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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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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

Ph.D.

Other areas of specialty/work

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

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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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

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not 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 a 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