

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of nebulized eucalyptus on ventilator associated pneumonia in ventilated patients

Protocol summary

Study aim

Determine the effect of nebulized eucalyptus on ventilator associated pneumonia in ventilated patients

Design

Double blind clinical trial with randomized control group with Phase 3

Settings and conduct

This is a double blind clinical trial to evaluate effect of nebulized eucalyptus on ventilator associated pneumonia in ventilated patients in Isfahan Alzahra Hospital. 70 intubated patients are selected according to inclusion and exclusion criteria and randomly with Flip the coin method are assigned to intervention (eucalyptus inhalation) and control groups (normal saline inhalation). Once patients intubated, receive aerosolized eucalyptus or normal saline (as placebo) every 8 hours until removal the endotracheal tube. pneumonia are measured ,by MCPIS checklist. diagnosis of VAP is in association with anesthesiologist. The demographic data (age, sex) and baseline data are recorded in the checklist at the beginning of the study. The followers and evaluators are not aware of the allocation of the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: oral intubation; 18-65 years old; lack of pulmonary infection, allergy to herbal compounds ,sepsis, pulmonary thromboembolism, atelectasis, GI inflammatory disease, and severe hepatic disease.

Intervention groups

Intervention group: Four ml of 5% eucalyptus will be diluted in 10 ml normal saline and will be nebulized in about 20 minutes through mechanical ventilator. This work will be performed every 8 hours until extubation. Control group: Ten ml normal saline will be nebulized in about 20 minutes through mechanical ventilator. This work will be performed every 8 hours until extubation.

Main outcome variables

Ventilator associated pneumonia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180107038251N3**

Registration date: **2019-08-09, 1398/05/18**

Registration timing: **retrospective**

Last update: **2019-08-09, 1398/05/18**

Update count: **0**

Registration date

2019-08-09, 1398/05/18

Registrant information

Name

Nazanin Amini

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2014-11-22, 1393/09/01

Actual recruitment start date

2014-07-23, 1393/05/01

Actual recruitment end date

2014-11-22, 1393/09/01

Trial completion date

2014-11-22, 1393/09/01

Scientific title

Effect of nebulized eucalyptus on ventilator associated pneumonia in ventilated patients		Arak University of Medical Sciences, Alamoll Huda Street, Railroad Street Arak Markazi Province	
Public title	Effect of nebulized eucalyptus on ventilator associated pneumonia	City	Arak
Purpose	Prevention	Province	Markazi
Inclusion/Exclusion criteria		Postal code	-
Inclusion criteria:	18-65 years old oral intubation Under ventilation for at least 3 days and up to 14 days lack of pulmonary infection, sepsis, pulmonary thromboembolism, atelectasis, Gastrointestinal inflammatory disease and severe hepatic disease. no allergy to herbal compounds	Approval date	2014-07-14, 1393/04/23
Exclusion criteria:	nasal intubation	Ethics committee reference number	93-165-3
Age	From 18 years old to 65 years old	Health conditions studied	
Gender	Both	1	
Phase	3	Description of health condition studied	Ventilator associated pneumonia
Groups that have been masked	- Participant - Outcome assessor	ICD-10 code	J15.9
Sample size	Target sample size: 70 Actual sample size reached: 70	ICD-10 code description	Unspecified bacterial pneumonia
Randomization (investigator's opinion)	Randomized	Primary outcomes	
Randomization description	Simple Randomization with Flip the coin method we used from this method for creating random sequence, that way we considered one of study groups as milk and other group as line and based on sample size we threw the coin and randomly assigned subjects to two groups	1	
Blinding (investigator's opinion)	Double blinded	Description	Ventilator associated pneumonia
Blinding description	In this study, participants and evaluators of outcomes of the study are not aware of the allocation of groups	Timepoint	Ventilator associated pneumonia are measured on fifth, ninth day and before extubation.
Placebo	Used	Method of measurement	Measurement of variables is based on Modified Clinical Pulmonary Infection Score (MCPIS) checklist. The instrument includes five criteria including temperature, white blood cell count, tracheal secretion , oxygenation, chest radiography, each score is 0 to 2, and total score is 10. If total score is equal to or greater than 6, pneumonia is detected
Assignment	Other	Secondary outcomes	empty
Other design features		Intervention groups	
Secondary Ids	empty	1	
Ethics committees		Description	Intervention group: Four ml of 5% eucalyptus are diluted in 10 ml normal saline and are nebulized in about 20 minutes through mechanical ventilator. This work is performed every 8 hours until extubation
1		Category	Prevention
Ethics committee		2	
Name of ethics committee	Ethics committee of Arak University of Medical Sciences	Description	Control group: Ten ml normal saline are nebulized in
Street address			

about 20 minutes through mechanical ventilator. This work is performed every 8 hours until extubation.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital, Isfahan University of Medical Sciences

Full name of responsible person

Dr. Ahmadreza Yazdannik

Street address

Alzahra hospital, Azadi Square, Hezar-Jerib street, Isfahan

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Research Deputy of Arak University of Medical Sciences

Street address

Faculty of Nursing and Midwifery, Arak University of Medical Sciences, Sardasht, Arak Markazi Province

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Nazanin Amini

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Not applicable

Title and more details about the data/document

Some of information about the main outcomes are
shared after the article is published.

When the data will become available and for how long

After publishing article

To whom data/document is available

Researchers working in academic institute and industry
professionals

Under which criteria data/document could be used

To conduct further research in this field or use it in
patients

From where data/document is obtainable

nazaninamini69@yahoo.com

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

After sending email

Comments