

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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)

##### Phone

+98 86 3366 1308

##### Email address

nazaninamini69@yahoo.com

##### 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

## Public title

Effect of nebulized eucalyptus on ventilator associated pneumonia

## Purpose

Prevention

## Inclusion/Exclusion criteria

### 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

### Exclusion criteria:

nasal intubation

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: **70**

Actual sample size reached: **70**

## Randomization (investigator's opinion)

Randomized

## 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

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In this study, participants and evaluators of outcomes of the study are not aware of the allocation of groups

## Placebo

Used

## Assignment

Other

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Arak University of Medical Sciences

##### Street address

Arak University of Medical Sciences, Alamoll Huda Street, Railroad Street Arak Markazi Province

## City

Arak

## Province

Markazi

## Postal code

-

## Approval date

2014-07-14, 1393/04/23

## Ethics committee reference number

93-165-3

## Health conditions studied

### 1

#### Description of health condition studied

Ventilator associated pneumonia

#### ICD-10 code

J15.9

#### ICD-10 code description

Unspecified bacterial pneumonia

## Primary outcomes

### 1

#### Description

Ventilator associated pneumonia

#### Timepoint

Ventilator associated pneumonia are measured on fifth, ninth day and before extubation.

#### 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

## Secondary outcomes

empty

## Intervention groups

### 1

#### 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

#### Category

Prevention

### 2

#### Description

Control group: Ten ml normal saline are nebulized in

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

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Esfahan

**Province**

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**Postal code**

8174673548

**Phone**

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**Fax****Email**

Yazdannik@nm.mui.ac.ir

**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

**City**

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

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**Full name of responsible person**

Korosh Rezaei

**Position**

Instructor

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Master

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Nursery

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

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**Latest degree**

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**Other areas of specialty/work**

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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**