Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Effect of nebulized eucalyptus on arterial blood gas and physiologic indexes of ventilated patients:A Double-Blind Randomized Clinical Trial

Protocol summary

Study aim

Determine the effect of eucalyptus nebulization on arterial blood gas and physiological indexes of ventilated patients

Design

Single blind randomized clinical trial with control group with 35 patients in each group

Settings and conduct

We performed a randomized single blind clinical trial study in three intensive care units of educational hospital. Seventy intubated patients were selected through purposive sampling and randomly divided into intervention and control groups (35 patients in each group). intervention group inhaled eucalyptus and control group inhaled normal saline. At end of study Glasgow Coma Scale and Arterial blood gases and peak inspiratory pressure and tidal volume of mechanical ventilaton device were assessed in both intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: oral intubation; 18-65 years old; No pulmonary infection ; No sepsis ; No pulmonary thromboembolism ; No atelectasis; No gasterointestinal inflammatory disease ; No severe hepatic disease; no allergy to herbal compounds. Exclusion criteria: -

Intervention groups

Intervention group: Four ml of 5% eucalyptus Made by Medicinal herbs department in Arak University 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

Vital signs ;Glasgow Coma Scale ;and Arterial blood gases analysis; Some Ventilator Indicators

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180107038251N2**
Registration date: **2019-07-20, 1398/04/29**
Registration timing: **retrospective**

Last update: **2019-07-20, 1398/04/29**
Update count: **0**

Registration date

2019-07-20, 1398/04/29

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

2014-08-11, 1393/05/20

Expected recruitment end date

2014-12-11, 1393/09/20

Actual recruitment start date

2014-08-11, 1393/05/20

Actual recruitment end date

2014-12-11, 1393/09/20

Trial completion date

2014-12-11, 1393/09/20

Scientific title

Effect of nebulized eucalyptus on arterial blood gas and physiologic indexes of ventilated patients:A Double-Blind Randomized Clinical Trial

Public title
Effect of nebulized eucalyptus on arterial blood gas and physiologic indexes
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Oral intubation 18-65 years old Lack of pulmonary infection No sepsis No pulmonary thromboembolism No atelectasis No gasterointestinal inflammatory disease No severe hepatic disease No allergy to herbal compounds
Exclusion criteria:
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **70**
Actual sample size reached: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple Randomization with tossing a coin method we used from this method for creating random sequence, so that we considered one of study groups (intervention) as heads and other group (control) as tails and based on sample size we threw the coin and subjects were randomly assigned to two groups
Blinding (investigator's opinion)
Single blinded
Blinding description
For elimination of the possibility of any probable bias due to the knowledge of study Outcome evaluator about the type of treatment we performed a single blind study. Eucalyptus and placebo (normal saline) had the same appearance on the nebulizer device and This device was delivered vapors directly to patient as a fully enclosed enclosure and the evaluator did not notice the smell of eucalyptus in the room ,so Outcome evaluator did not have any knowledge about the type of treatment.
Placebo
Used
Assignment
Parallel
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, Sardasht, Arak Markazi Province
City
Arak
Province
Markazi
Postal code
3848176341
Approval date
2014-07-14, 1393/04/23
Ethics committee reference number
IR.ARAKMU.REC.1393.165.3

Health conditions studied

1

Description of health condition studied
Arterial blood gases analysis in mechanical ventilated patients
ICD-10 code
Z99.1
ICD-10 code description
Dependence on respirator

Primary outcomes

1

Description
PH
Timepoint
Before intervention, three days after the start of intervention (third day),
Method of measurement
The GEM Premier 3000 device is used

2

Description
Hco3
Timepoint
Before intervention, three days after the start of intervention (third day)
Method of measurement
The GEM Premier 3000 device is used

3

Description
base excess
Timepoint
Before intervention, three days after the start of intervention (third day)
Method of measurement
The GEM Premier 3000 device is used

4

Description
Pao2
Timepoint
Before intervention, three days after the start of intervention (third day)
Method of measurement
The GEM Premier 3000 device is used

5

Description
Sao2
Timepoint
Before intervention, three days after the start of intervention (third day)
Method of measurement
The GEM Premier 3000 device is used

6

Description
Paco2
Timepoint
Before intervention, three days after the start of intervention (third day)
Method of measurement
The GEM Premier 3000 device is used

7

Description
Systolic blood pressure
Timepoint
Before intervention, three days after the start of intervention (third day)
Method of measurement
automatic blood pressure from Cardio set x-110 IEI device was used to measure blood pressure

8

Description
Diastolic blood pressure
Timepoint
Before intervention, three days after the start of intervention (third day)
Method of measurement
automatic blood pressure from Cardio set x-110 IEI device was used to measure blood pressure

9

Description
Temperature
Timepoint
Before intervention, three days after the start of intervention (third day)
Method of measurement
thermometer

10

Description
Respiratory rate
Timepoint
Before intervention, three days after the start of intervention (third day)
Method of measurement
respiratory rate per minute

11

Description
pulse rate
Timepoint
Before intervention, three days after the start of intervention (third day)
Method of measurement
pals oximeter

12

Description
level of consciousness
Timepoint
Before intervention, three days after the start of intervention (third day)
Method of measurement
Glasgow Coma Scale

13

Description
peak inspiratory pressure
Timepoint
Before intervention, three days after the start of intervention (third day)
Method of measurement
Ventilator respiratory parameter

14

Description
Tidal volume
Timepoint
Before intervention, three days after the start of intervention (third day)
Method of measurement
Ventilator respiratory parameter

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Four ml of 5% eucalyptus made by medicinal herbs department in arak university 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.

Category

Rehabilitation

2

Description

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.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital in Isfahan medical university

Full name of responsible person

Ahmadreza Yazdannik

Street address

Soffeh Blvd, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

Street address

Deputy of research and technology,Arak University of Medical Sciences,Basij Sq, Sardasht, Arak ,Markazi Province ,Iran

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alikamaliir@yahoo.com

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

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Full name of responsible person

Korosh Rezaei

Position

Instructor

Latest degree

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Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact
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Position
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Anesthesiology
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nazaninamini69@yahoo.com

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
No more information
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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Partial information about main outcomes are shared
When the data will become available and for how long
After publishing the results
To whom data/document is available
All people have access
Under which criteria data/document could be used
-
From where data/document is obtainable
nazaninamini69@yahoo.com
What processes are involved for a request to access data/document
After sending email
Comments