

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 ventilator 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 gastrointestinal 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

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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 gastrointestinal 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

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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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak 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

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

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

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Latest degree

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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

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 DictionaryUndecided - 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