

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of effectiveness of inhaled thymus essential oil with placebo in preventing Ventilator Associated Pneumonia (VAP)

Protocol summary

Study aim

Determine the effect of inhaling thymus essential oil in preventing Ventilator Associated Pneumonia

Design

In this study, 106 patients are admitted to a hospital ventilator with entry conditions. The participants are randomly divided into two intervention and control groups and each participant is given a special code.

Settings and conduct

106 Patients under mechanical ventilation who are eligible for inclusion in the study are randomly assigned into intervention and placebo groups. In the intervention group, 15 drops (1 cc) of Thyme essential oil are nebulized every 12 hours for 10 days. In the placebo group, 15 drops (1 cc) of placebo are nebulized every 12 hours for 10 days. CPIS is evaluated on the fifth day to determine early VAP and on the tenth day to determine late VAP. Researchers and patients are unaware of the content of the drug package and are blind.

Participants/Inclusion and exclusion criteria

Propaganda and entry criteria: age 18 and above, under aggressive mechanical ventilation Non-compliance criteria: history of hypersensitivity, immune deficiency (WBC <4000), sepsis, acute phase cancer, trauma to the jaw and face and chest, patient with poor prognosis, and possible death of the patient. Exit criteria: positive secretion after first sampling after intubation, mechanical ventilation disconnection before 5 days, patient death

Intervention groups

In the intervention and control group, thyme and thyme oil are used respectively.

Main outcome variables

ventilator associated pneumonia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170220032672N2**

Registration date: **2018-04-23, 1397/02/03**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-23, 1397/02/03**

Update count: **0**

Registration date

2018-04-23, 1397/02/03

Registrant information

Name

Somayeh Valipour Dehkordi

Name of organization / entity

Shahed University of Tehran

Country

Iran (Islamic Republic of)

Phone

+98 21 6641 8587

Email address

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Recruitment status

Recruitment complete

Funding source

Shahed University

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of inhaled thymus essential oil with placebo in preventing Ventilator Associated

Pneumonia (VAP)

Public title

Effect of thymus essential oil in prevention of ventilator associated pneumonia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Aged 18 years and above Under invasive mechanical ventilation

Exclusion criteria:

Clinical Pulmonary Infection Score (CPIS) more than 6
history of allergy sepsis acute phase Cancer trauma to the jaw, face and chest

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization, individual randomization unit, randomized random-numbered randomization table, drop-offs by pharmacologist, randomly assigned drug or drug-free material from the researcher's eye according to the table. The researcher randomly employs a dropper from the oven bag each time. Dropper with codes 1 to 106; in the middle of the patient's death, the droplet code is declared to the pharmacologist and the same code is replaced with the contents in the bag.

Blinding (investigator's opinion)

Double blinded

Blinding description

The use of a dark dropper, the color of the drug, is not known; although the drug and the agent are mixed with a color on the basis of sesame oil and with amolsifiers. The drug is labeled by a scientist other than the researcher, and the researcher does not know the contents of the contents. The caregiver also No information is available on the contents of the dropper.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahed University

Street address

Shahed University, Opposite Holy Shrine of Imam Khomeini, Khalij Fars Expressway, P.O. Box 18155/159, Tehran, Iran

City

Tehran

Province

Chahar-Mahal-va-Bakhtiari

Postal code

3319118651

Approval date

2017-08-13, 1396/05/22

Ethics committee reference number

IR.Shahed.REC.1396.20

Health conditions studied

1

Description of health condition studied

Ventilator associated pneumonia

ICD-10 code

J17.8

ICD-10 code description

Pneumonia in other diseases classified elsewhere

Primary outcomes

1

Description

Percentage of patients with ventilator associated pneumonia

Timepoint

CPIS measurements at the beginning of the study (before the intervention) and 5th and 10th days after the began of intervention

Method of measurement

Clinical Pulmonary Infection Score (CPIS)

Secondary outcomes

1

Description

peak inspiratory pressure and plateau pressure

Timepoint

at the beginning of the study (before the intervention) and 5th and 10th days after the began of intervention

Method of measurement

monitoring of ventilator data

2

Description

SpO₂, SaO₂

Timepoint

at the beginning of the study (before the intervention) and 5th and 10th days after the began of intervention

Method of measurement

pulse oxymeter and arterial blood gas

3

Description

Rapid Shallow Breathing Index (RSBI)

Timepoint

at the beginning of the study (before the intervention) and 5th and 10th days after the began of intervention

Method of measurement

monitoring of ventilator data

Intervention groups

1

Description

Intervention group:15 drops or 1 cc thymus oil essential 1/2% on the basis of sesame oil with 9 cc distilled water every 12 hours for 10 days nebulizer.

Category

Prevention

2

Description

Control group: 15 drops or 1 cc placebo (containing distilled water in the base of the oil Sesame) with 9 cc distilled water every 12 hours for 10 days nebulizer.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar hospital; Kashani hospital

Full name of responsible person

Somayeh Valipour Dehkordi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Research Deputy: Dr. Zahra Kaysalari

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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

Shahed University

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

Hajar hospital

Full name of responsible person

Somayeh Valipour Dehkordi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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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 are confidential.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be 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

Clinical report: Published as final report and paper.

When the data will become available and for how long

Final report: After the study is completed. The article is published in the journal after admission.

To whom data/document is available

Final Report: Available under the Shahed University regulations. Article: After printing is accessible to all readers.

Under which criteria data/document could be used

The results of the study can be used in their research work. There is no specific condition.

From where data/document is obtainable

Final report: Visit the library of Shahed University. Article: Refer to the text printed in the journal.

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

Final Report: Referring to the Central Library of Shahed University and requesting the contents of the report in accordance with the library regulations. Article: Preparing an article from the journal site

Comments