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

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Iran (Islamic Republic of)

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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
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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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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
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Person responsible for updating data

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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