Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

The effect of Trachyspermum Ammi syrup on the prevention of ventilator-associated pneumonia in mechanically ventilated patients in the trauma intensive care units

Protocol summary

Study aim

To determine the effect of Trachyspermum Ammi syrup on the prevention of ventilator-associated pneumonia in mechanically ventilated patients in the trauma intensive care units

Design

The controlled clinical trial, with two parallel groups (one intervention and one control), triple-blind, randomized, phase 1, on 60 ICU patients (30 in each group). Excel software will be used for randomization.

Settings and conduct

Trauma patients in ICUs of Shahid Bahonar Hospital in Kerman, will be included in the study and will be randomly allocated to the intervention or control group. The patients in the intervention group will be given Trachyspermum Ammi syrup and the patients in the control group will be given placebo syrup for ten days through a gastric tube. The amount of VAP in the control and intervention groups will be evaluated on the fifth and tenth days. Blinding will be performed for patients, the researcher performing the intervention, the physician diagnosing VAP, and the researcher performing the statistical analysis.

Participants/Inclusion and exclusion criteria

Trauma patients in ICUs of Bahonar Hospital in Kerman, which have an oral endotracheal tube and receive mechanical ventilation for more than ten days, will be included in the study. Patients will recruited to the study according to inclusion and non-inclusion criteria.

Intervention groups

Intervention group: Gavage of Trachyspermum Ammi syrup 10%, from the first day of enteral feeding, 10 ml, three times a day for ten days Control group: Gavage of placebo syrup (containing all the basic ingredients of the syrup without adding Trachyspermum Ammi), from the first day of enteral feeding, 10 ml, three times a day for ten days

Main outcome variables

Ventilator-associated pneumonia will be assessed by an infectious disease specialist using the Clinical Lung Infection Scale (CPIS) on the fifth and tenth day of intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220204053931N2**
Registration date: **2022-05-11, 1401/02/21**
Registration timing: **prospective**

Last update: **2022-05-11, 1401/02/21**
Update count: **0**

Registration date

2022-05-11, 1401/02/21

Registrant information

Name

Farideh Razban

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 34 3132 5700

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-15, 1401/02/25

Expected recruitment end date

2022-07-16, 1401/04/25

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Trachyspermum Ammi syrup on the prevention of ventilator-associated pneumonia in mechanically ventilated patients in the trauma intensive care units

Public title
The effect of Trachyspermum Ammi syrup on the prevention of ventilator-associated pneumonia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having an oral endotracheal tube Receiving mechanical ventilation ICU hospitalization due to trauma
Exclusion criteria:
Having pneumonia at the time of admission Cardiopulmonary diseases Lung contusion Pulmonary thromboembolism Atelectasis Inflammatory diseases Digestive diseases Liver and biliary diseases History of allergies to herbal drugs Symptoms of pulmonary aspiration Weak immune system Substance abuse and addiction Extubation before 10 days Death or ICU discharge before 10 days Sudden change in hemodynamic status Complications such as hives, itching and skin rashes that can be a sign of allergy to Trachyspermum Ammi syrup
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
1
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
A simple randomization method will be used to allocate samples to the control and intervention groups. The single sequence of random numbers will be generated using Excel software. Sequences of random numbers in sealed envelopes will be provided to the researcher responsible for the intervention. Patients who have inclusion criteria and no exclusion criteria will be randomly assigned to the intervention or control group based on the sequences.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, due to placebo use, patients, the researcher performing the intervention, the physician evaluating the outcome of the intervention (VAP), and the researcher conducting the statistical analysis; will not know which patients are in the control group and which are in the intervention group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kerman University of Medical Sciences
Street address
Afzalipour hospital, Imam Khomeini highway
City
Kerman
Province
Kerman
Postal code
7616913355
Approval date
2022-04-16, 1401/01/27
Ethics committee reference number
IR.KMU.REC.1401.038

Health conditions studied

1

Description of health condition studied
Ventilator associated pneumonia
ICD-10 code
J09-J18
ICD-10 code description
Influenza and pneumonia

Primary outcomes

1

Description
Ventilator-associated pneumonia
Timepoint
Ventilator-associated pneumonia will be assessed on the fifth and tenth day of the intervention.
Method of measurement
Ventilator-associated pneumonia will be assessed by an

infectious disease specialist using the Clinical Lung Infection Scale (CPIS). CPIS includes six criteria, including temperature, white blood cell count, tracheal secretion, oxygenation, culture and smear of tracheal secretion, and chest x-ray. Each of criteria is given a score of zero to two. The maximum score of this tool is 10. VAP is diagnosed if the sum of scores is equal to or greater than 6.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Gavage of Trachyspermum Ammi syrup 10%, from the first day of enteral feeding, 10 ml, three times a day for ten days
Category
Treatment - Drugs

2

Description
Control group: gavage of placebo syrup (containing all the basic ingredients of the syrup without adding Trachyspermum Ammi), from the first day of enteral feeding, 10 ml, three times a day for ten days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
بیمارستان شهید باهنر
Full name of responsible person
دکتر مهدی احمدی نژاد
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr. Reza Malekpour Afshar
Street address
Vice chancellor of research and technology, Ebn-e-Sina Street, Somayyeh intersection
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vcr@kmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Dr. Mehdi Ahmadinejad
Position
Associate professor
Latest degree
Subspecialist
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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All of the individual participant data collected during the trial, after deidentification.

When the data will become available and for how long
Six months after the results will be published, the data will be available for 24 months. In special situations, the access period will be extended

To whom data/document is available
Researchers working in universities, scientific institutes and industry

Under which criteria data/document could be used
To conduct research

From where data/document is obtainable
Contact the following email: f_razban@kmu.ac.ir

What processes are involved for a request to access data/document
After reviewing the request by the research team and with the approval of the Vice-Chancellor for Research of Kerman University of Medical Sciences

Comments