# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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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**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
**Street address**
Qarani street
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mehdia50@gmail.com

## 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**
Anesthesiology
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Nursery

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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**