

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Investigating and comparing the therapeutic outcomes of two treatment regimens of cholestin instillation (through the bronchoscope) versus standard treatment in patients with ventilator-associated pneumonia (VAP) with resistant gram-negative bacilli.

Protocol summary

Study aim

Determination and comparison of mortality in two treatment regimens of cholestin instillation (via bronchoscope) versus standard treatment (cloestine nebulizer) in patients with ventilator-associated pneumonia (VAP) with resistant gram-negative bacilli.

Design

Clinical trial, with parallel groups, randomized, phase 3 on 48 patients. Random numbers were used for randomization.

Settings and conduct

The study will be conducted at Imam Khomeini Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Patient consent, patients aged 18 to 75, under mechanical ventilation and eligible for the diagnosis of ventilator-associated pneumonia.

Intervention groups

Clostin instillation: This group of lung involvement areas is identified by fiberoptic bronchoscopy (based on the zones or segments of the lung identified in the radiology image or based on the location of secretions under direct view with a bronchoscope). These patients, in addition to the usual treatment (venous meropenem 2 grams three times a day and intravenous cholestin 4.5 million units twice a day, whose dose will be adjusted according to kidney function). After suctioning the secretions, the tip of the bronchoscope is wedged in the affected area and 300,000 units of Cleistin is prescribed for each affected lung segment with a concentration of 1,000,000 units per milliliter for three days. **Cholestine nebulizer group:** In addition to intravenous meropenem 2 grams three times a day and intravenous cholestin 4.5 million units twice a day and a cholestin nebulizer of 2,000,000 units three times a day for at least three days.

Main outcome variables

Mortality of patients and the number of days of hospitalization in intensive care units

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120527009886N3**

Registration date: **2023-04-11, 1402/01/22**

Registration timing: **prospective**

Last update: **2023-04-11, 1402/01/22**

Update count: **0**

Registration date

2023-04-11, 1402/01/22

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

02161192663-02161192828

Email address

mohammady_mm@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-18, 1402/01/29

Expected recruitment end date

2023-05-19, 1402/02/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating and comparing the therapeutic outcomes of two treatment regimens of cholestin instillation (through the bronchoscope) versus standard treatment in patients with ventilator-associated pneumonia (VAP) with resistant gram-negative bacilli.

Public title

Investigating and comparing the therapeutic outcomes of two regimens of cholestin therapy through a bronchoscope versus standard treatment in patients with lung infection

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with ventilator-associated pneumonia Age between 18 and 75 years Patients who developed pulmonary infection with gram-negative bacilli resistant to several antibiotic drugs after 48 hours of intubation.

Exclusion criteria:

Age older than 75 or younger than 18 years Patients with adult respiratory distress syndrome (ARDS) according to the Berlin criteria P/F ratio less than 100 Septic shock requires a dose of norepinephrine with a dose greater than 0.25 Mcg/KG/MIN Patients with infection with other microorganisms

AgeFrom **18 years** old to **75 years** old**Gender**

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **20****Randomization (investigator's opinion)**

Randomized

Randomization description

A computer-generated randomization sequence will be used to allocate eligible participants to either the bronchoscopy group or the standard treatment group. The sequence will be generated by a statistician not involved in the study, using a random number generator with varying block sizes to ensure balance between the two groups. The allocation will be concealed in opaque sealed envelopes, and the study personnel responsible for enrolling participants will open the envelopes sequentially and allocate the participant to the corresponding group. To further reduce the possibility of allocation bias, neither the participants nor the study personnel will be informed of the allocation sequence until after the participant has given informed consent and baseline measurements have been obtained.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Teharn University of medical sciences

Street address

Tehran Province, Tehran, District 6, Pour Sina St, P94V+8MF, Iran

City

Tehran

Province

Tehran

Postal code

1416634793

Approval date

2023-04-02, 1402/01/13

Ethics committee reference number

IR.TUMS.IKHC.REC.1402.004

Health conditions studied**1****Description of health condition studied**

Ventilator Associated Pneumonia

ICD-10 code

J95.851

ICD-10 code description

Ventilator associated pneumonia

Primary outcomes**1****Description**

Mortality rate

Timepoint

After the start of treatment until the discharge or death of the patient

Method of measurement

Questionnaire

Secondary outcomes**1****Description**

The number of days hospitalized in the intensive care

unit
Timepoint
After initiation of treatment until discharge or death from the intensive care unit
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: Instillation Bronchoscopy
Category
Treatment - Drugs

2

Description
Control group: Clostin nebulizer
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hopsital
Full name of responsible person
Mostafa Mohammadi
Street address
Keshavarz BlvD, Dr Qarib St
City
Tehran
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Postal code
1419733141
Phone
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Email
mohammady_mm@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Deputy of Research and Technology.
Street address
North Kargar St., intersection of Keshavarz Blvd
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Phone
+98 21 8889 6696
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icedu@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mostafa Mohammadi
Position
Professor of critical care
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Title and more details about the data/document

Data will be coded and will be shared.

When the data will become available and for how long

Starting in September 2023

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

Email should be sent from an academic institutions and 1 month will be lasted from sending email and getting data.

From where data/document is obtainable

Email Morteza Foroomandi

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

Email should be sent from an academic institutions and 1 month will be lasted from sending email and getting data.

Comments