Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Evaluating the effect of nebulizing colistine with nebulizing colistin-fosfomycin in comparison to nebulizing colistine in Ventillator-Associated Pneumonia with multidrug-resistant Acinetobacter Baumanii in Alzahra Intensive Care Units

Protocol summary

Study aim
Evaluating the effect of nebulizing colistine with nebulizing colistin-fosfomycin in comparison to nebulizing colistine in Ventillator-Associated Pneumonia with multidrug-resistant Acinetobacter Baumanii in Alzahra Intensive Care Units

Design
A randomized, double-blind, clinical trial

Settings and conduct
The study is being conducted at Alzahra Hospital in Isfahan. Ventilator pneumonia is diagnosed using the Clinical Pulmonary Infection Score (CPIS) score (0 to 10 points), which requires a culture of lung samples to assist in the clinical diagnosis of ventilator pneumonia (VAP). Tracheal Aspirate (TA) is a low-grade, invasive procedure for culture specimens, which is collected through a sterile suction catheter of the sputum sample. Within a maximum of 48 hours when the culture test results indicate Colistin-sensitive acinetobacter, the study is initiated and the patient is given intravenous meropenem, intravenous Colistin, and inhaled fosfomycin. Completion criteria: Fever, reduced lung discharge, or radiographic changes. The information becomes available to the analyzer after being unmarked.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patient hospitalization in ICU Age between 20 and 85 Diagnosis of ventilator pneumonia for the patient Diagnosis of colistin sensetive Acinetobacter baumannii Patient satisfaction Exclusion Criteria: Diagnosis Another concomitant disease Start treatment of acinetobacter

Intervention groups
The first group received inhaled Colistin and the second group received inhaled Colistin-fosfomycin treated with meropenem and intravenous choline. Each group included 39 patients with ventilator pneumonia whose response to culturing of their latent secretions was strongly resistant to Acinetobacter baumannii.

Main outcome variables
CPIS score, disease severity, response to treatment.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171230038142N12**
Registration date: **2020-02-23, 1398/12/04**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-23, 1398/12/04**
Update count: **0**

Registration date
2020-02-23, 1398/12/04

Registrant information

Name
Khosro Tavakol

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3792 9134

Email address
tavakol@nm.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-23, 1398/06/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of nebulizing colistine with nebulizing colistin-fosfomycin in comparison to nebulizing colistine in Ventillator-Associated Pneumonia with multidrug-resistant Acinetobacter Baumanii in Alzahra Intensive Care Units

Public title

Evaluating the effect of nebulizing colistine with nebulizing colistin-fosfomycin in comparison to nebulizing colistine in Ventillator-Associated Pneumonia with multidrug-resistant Acinetobacter Baumanii in Alzahra Intensive Care Units

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient hospitalization in ICU Age between 20 and 85 Diagnosis of ventilator pneumonia for the patient Diagnosis of colistin sensetive Acinetobacter baumannii Patient satisfaction

Exclusion criteria:

Diagnosis Another concomitant disease The patient died before the response Start treatment of acinetobacter

Age

From **20 years** old to **85 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will first be selected by convenience sampling from the ICU ward of Alzahra Hospital in Isfahan. They will then be randomly divided into two groups using binary replacement blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are admitted to the ICU and are unaware of the course of treatment of other treatment groups and are only aware of their treatment, and the analyzer does not know the patients and the treatment content.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave.

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2019-06-02, 1398/03/12

Ethics committee reference number

IR.MUI.MED.REC.1398.404

Health conditions studied

1

Description of health condition studied

Ventillator-Associated Pneumonia

ICD-10 code

J95.851

ICD-10 code description

Ventilator associated pneumonia

Primary outcomes

1

Description

Duration of treatment

Timepoint

Upon completion of treatment and response to treatment

Method of measurement

Counting the days of hospitalization and receiving treatment until the response arrives

2

Description

Illness severity

Timepoint

Before and after taking the drug

Method of measurement

Based on CPIS criteria

3

Description
Response to treatment
Timepoint
Before and after taking the drug
Method of measurement
Based on microbial eradication criteria

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first group is treated with inhaled Colistin, along with meropenem and intravenous Colistin. The study included 39 patients with ventilator pneumonia whose response to culturing of their secretions was strongly resistant to Acinetobacter baumannii. Intervention may be termination of fever, reduction of lung discharge or radiographic changes.
Category
Treatment - Drugs

2

Description
Intervention group:The second group is treated with inhaled Colistin-fosfomycin in combination with intravenous meropenem and Colistin. The study included 39 patients with ventilator pneumonia whose response to culturing of their secretions was strongly resistant to Acinetobacter baumannii. Intervention may be termination of fever, reduction of lung discharge or radiographic changes.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital in Isfahan
Full name of responsible person
Atusa Hakami Fafd
Street address
Al-Zahra Hospital, Sofah Boulevard.
City
Esfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 0048
Email
khalili@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Ziba Farajzadegan
Street address
Vice-Chancellor for Research of School of Medicine,. Isfahan University of Medical Sciences,. Hezar Jarib Ave.
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 8597
Email
dean@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Atusa Hakami Fafd
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
Street address
Al-Zahra Hospital, Sofah Boulevard.
City
Esfahan
Province
Isfehan
Postal code

81746-73461

Phone
+98 31 3668 0048

Email
a.hakamifard@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Atusa Hakami Fafd

Position
Assistant Professor

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Other areas of specialty/work
Infectious diseases

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81746-73461

Phone
+98 31 3668 0048

Email
a.hakamifard@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Atusa Hakami Fafd

Position
Assistant Professor

Latest degree
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Infectious diseases

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Province
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Postal code
81746-73461

Phone
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Email
a.hakamifard@med.mui.ac.ir

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
Two years after the results are shared.

When the data will become available and for how long
Two years after the results are shared.

To whom data/document is available
Doctors and Infectious Diseases

Under which criteria data/document could be used
Comparison of the new treatment with the present one

From where data/document is obtainable
Send an email to a.hakamifard@med.mui.ac.ir

What processes are involved for a request to access data/document
Send an email to a.hakamifard@med.mui.ac.ir

Comments