

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 Ventilator-Associated Pneumonia with multidrug-resistant Acinetobacter Baumannii 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 Ventilator-Associated Pneumonia with multidrug-resistant Acinetobacter Baumannii 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 sensitive 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 Ventilator-Associated Pneumonia with multidrug-resistant Acinetobacter Baumannii in Alzahra Intensive Care Units

Public title

Evaluating the effect of nebulizing colistine with nebulizing colistin-fosfomycin in comparison to nebulizing colistine in Ventilator-Associated Pneumonia with multidrug-resistant Acinetobacter Baumannii 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 sensitive 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

Isfahan

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

Ventilator-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

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Isfahan

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

Isfahan

Postal code

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

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Person responsible for updating data

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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

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