

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Comparing nebulized colistin with nebulized Amikacin- Fosfomycin as an adjunctive treatment of ventilator associated pneumonia due to multi drug resistant acinetobacter

Protocol summary

Study aim

Comparing nebulized colistin with nebulized Amikacin-Fosfomycin as an adjunctive treatment of ventilator associated pneumonia due to multi drug resistant acinetobacter

Design

A randomized, double-blind, parallel clinical trial

Settings and conduct

The study is being conducted in the ICU ward of Alzahra Hospital in Isfahan. Fosfomycin solution with 4% concentration (2 ml of this solution, 80 mg proportion) is introduced into the nebulizer jet chamber for patient use. This is accomplished by filtration using 100 nm filters at the appropriate pH (about 7) and with the appropriate tonicity of body fluids that do not cause irritation when inhaled. The Clinical Pulmonary Infection Score (CPIS) criterion is used to diagnose ventilator pneumonia. The criterion consists of 5 sections, each with a score of 0 to 2, and patients score between 0 and 10. The mortality rate, if any, and the duration of treatment and the patient's exit from the VAP, if any, are then recorded. The results are then analyzed by the statistician after being anonymized.

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 cholesterol-sensitive Acinetobacter baumannii Patient satisfaction Exclusion Criteria: Diagnosis Another concomitant disease Start treatment of acinetobacter

Intervention groups

The first group is inhaled Amikacin + fosfomycin and the second group is inhaled colistin, which is treated with intravenous meropenem and colistin. Each group included 30 patients with a total of 60 patients with ventilator pneumonia whose response to culturing of their highly secreted Acinetobacter baumannii was

selected from patients in the intensive care units of Al-Zahra Hospital.

Main outcome variables

Mortality rates, Duration of response to treatment , CPIS index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171230038142N13**

Registration date: **2020-03-02, 1398/12/12**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-02, 1398/12/12**

Update count: **0**

Registration date

2020-03-02, 1398/12/12

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

Comparing nebulized colistin with nebulized Amikacin-Fosfomycin as an adjunctive treatment of ventilator associated pneumonia due to multi drug resistant acinetobacter

Public title

Comparing nebulized colistin with nebulized Amikacin-Fosfomycin as an adjunctive treatment of ventilator associated pneumonia due to multi drug resistant acinetobacter

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 cholesterol-sensitive Acinetobacter baumannii Patient satisfaction

Exclusion criteria:

Diagnosis Another concomitant disease 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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are first conveniently and easily selected from the list of patients with ventilator pneumonia admitted to the ICU center of Alzahra Hospital in Isfahan and then divided into two groups of 30 each using double blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients admitted to the ICU are not aware of the therapeutic content and the data analyzer has no information about the name and other characteristics of the patients.

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

2019-04-17, 1398/01/28

Ethics committee reference number

IR.MUI.MED.REC.1398.139

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

ventilator associated pneumonia due to multi drug resistant acinetobacter

ICD-10 code

J95.851

ICD-10 code description

Ventilator associated pneumonia

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

Mortality rates

Timepoint

After completing the study

Method of measurement

Counting the number of patients

2**Description**

Duration of response to treatment

Timepoint

After completing the study

Method of measurement

Counting the number of days admitted and the number of patients saved

3**Description**

CPIS index
Timepoint
Before and after treatment
Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The inhaled Amikacin + phosphomycin treatment group (treated with intravenous meropenem and clistine) included 30 patients with ventilator-associated pneumonia, whose response to cultures of severely resistant acinetobacter baumannii was noted, among patients admitted to the intensive care unit of Alzahra Hospital. Phosphomycin solution with 4% concentration (2 ml of this solution, 80 mg proportion) is introduced into the nebulizer jet chamber for patient use. This is accomplished by filtration using 100 nm filters at the appropriate pH (about 7) and with the appropriate tonicity of body fluids that do not cause irritation when inhaled. The Clinical Pulmonary Infection Score (CPIS) criterion is used to diagnose ventilator pneumonia. The criterion consists of 5 sections, each with a score of 0 to 2, and patients score between 0 and 10.

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group: Inhaled clistine treatment group (treated with meropenem and intravenous clistine), including 30 patients with ventilator pneumonia, whose response to cultures of highly resistant acinetobacter baumannii was noted, was selected from patients in the intensive care units of Al-Zahra Hospital. Ventilator pneumonia diagnosis is used by the Clinical Pulmonary Infection Score (CPIS). The criterion consists of 5 sections each with a score of 0 to 2, and patients score between 0 and 10.

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, Sufeh Street.

City
Isfahan
Province
Isfahan
Postal code
81747-73461
Phone
+98 31 3668 0048
Email
a.hakamifard@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
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

Isfahan

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

Latest degree

Specialist

Other areas of specialty/work

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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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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

The information is shared two years after the results are published.

When the data will become available and for how long

The information is shared two years after the results are published.

To whom data/document is available

Doctors and Infectious Diseases

Under which criteria data/document could be used

Comparison of medication or other treatment with present conditions

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