Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

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

Protocol summary

Study aim

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

Design

A randomized, double-blind, placebo-controlled clinical trial

Settings and conduct

The study is being conducted in the ICU ward of Alzahra Hospital in Isfahan. 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. 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 65 Diagnosis of ventilator pneumonia for the patient Diagnosis of cholesterol-sensitive Acinetobacter baumannii Exclusion criteria: Diagnosis Another concomitant disease The patient died before the response Start treatment of acinetobacter

Intervention groups

The first group is inhaled tobramycin + phosphomycin and the second group is inhaled colistin, which is treated with intravenous meropenem and clistine. 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 rate, duration of treatment, CPIS score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171230038142N11**
Registration date: **2020-02-19, 1398/11/30**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-19, 1398/11/30**
Update count: **0**

Registration date

2020-02-19, 1398/11/30

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

2020-06-19, 1399/03/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

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

Public title
Comparing nebulized colistin with nebulized Tobramycin-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 Ages between 20 and 65 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 The patient died before the response
Age
From **20 years** old to **60 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
Isfehan
Postal code
81746-73461
Approval date
2019-06-02, 1398/03/12
Ethics committee reference number
IR.MUI.MED.REC.1398.405

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 tobramycin + 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.

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81747-73461

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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.

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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

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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
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
Compare information available with other medications or other therapies
From where data/document is obtainable
Email a.hakamifard@med.mui.ac.ir and obtain permission from Isfahan University of Medical Sciences
What processes are involved for a request to access data/document
Email a.hakamifard@med.mui.ac.ir and obtain permission from Isfahan University of Medical Sciences
Comments