Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of Aerosolized (AS) Colistin as Adjunctive Treatment Versus Intravenous Colistin Alone in the Treatment of Ventilator-associated Pneumonia (VAP) Caused by Multidrug-resistant Gram-negative Bacteria

Protocol summary

Study aim

Evaluation of the efficacy and safety of aerosolized (AS) colistin in conjunction with IV colistin in patients with Ventilator-associated Pneumonia (VAP), caused by Multidrug Resistant (MDR) Gram Negative Bacteria (GNB)

Design

Two arm parallel group clinical trial with blinded outcome assessment was conducted on patients with VAP in Intensive Care Unit (ICU) ward. Twenty seven patients allocated into intervention or control group.

Settings and conduct

The study was conducted on patients with VAP admitted to ICU ward at Masih Daneshvari Hospital in Tehran. Patients in intervention group received IV Colistin based on (Glomerular filtration rate) along with aerosolized Colistin 2 million units three times a day. In the control group only IV Colistin was administered. For all patients Creatinine clearance, Procalcitonin (PCT), Sputum culture and Clinical Pulmonary Infection Score (CPIS) were measured at specified period of time. Investigator, outcome assessors, and data analyser were blind to the study groups untill the end of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient above 18 years, diagnosed with VAP، positive culture for MDR-GNB and sensitive to colistin Exclusion criteria: Pregnant or lactated Patient, patient with septic shock

Intervention groups

Intervention group: Patients in this group received IV Colistin based on Glomerular filtration rate (GFR) with aerosolized Colistin, 2 million units three times a day. Control group: Only received IV Colistin.

Main outcome variables

Evaluation of correlation between antibiotic initiation and the time of negative Sputum culture; Comparison of improvement in clinical signs of infection among intervention and control groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151227025726N9**
Registration date: **2018-08-15, 1397/05/24**
Registration timing: **retrospective**

Last update: **2018-08-15, 1397/05/24**
Update count: **0**

Registration date

2018-08-15, 1397/05/24

Registrant information

Name

Farzaneh Dastan

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-04-04, 1395/01/16

Expected recruitment end date

2018-04-05, 1397/01/16

Actual recruitment start date

2016-04-04, 1395/01/16

Actual recruitment end date

2017-05-20, 1396/02/30

Trial completion date
empty

Scientific title
Evaluation of Aerosolized (AS) Colistin as Adjunctive Treatment Versus Intravenous Colistin Alone in the Treatment of Ventilator-associated Pneumonia (VAP) Caused by Multidrug-resistant Gram-negative Bacteria

Public title
The Role of Aerosolized Colistin in the Treatment of Ventilator-associated Pneumonia, Caused by Multidrug-resistant Gram-negative Bacteria

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age above 18 years Antibiogram of positive culture that is sensitive to Colistin and resistant to all other antibiotics The new continuous pulmonary secretions based on lung radiography among patients who are received mechanical ventilation for at least 48 hours Fever above 38ºC without any specific reason White Blood Cell number more than 12000 cells or less than 4000 cells in each milliliter Purulent tracheal secretions

Exclusion criteria:
Pregnancy Breastfeeding Septic shock

Age
From **18 years** old to **100 years** old

Gender
Both

Phase
3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **34**
Actual sample size reached: **27**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
Investigator, outcome assessors, and data analyser were blind to the study groups untill the end of the study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of School of Pharmacy, Nursing, and midwifery; Shahid Beheshti University of Medica

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No. 2660, Vali-e Asr St., Niyayesh Junction, Tehran

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141556153

Approval date
2016-03-01, 1394/12/11

Ethics committee reference number
IR.SBMU.PHNM.1394.312

Health conditions studied

1

Description of health condition studied
Ventilator-associated Pneumonia (VAP)

ICD-10 code
J15

ICD-10 code description
Bacterial pneumonia, not elsewhere classified

Primary outcomes

1

Description
The correlation between antibiotic therapy initiation and the time of negative procalcitonin (PCT) test

Timepoint
Days of 0, 3, 5, 7 after antibiotic initiation

Method of measurement
Immunochromatographic test (PCT-Q)

2

Description
The correlation between antibiotic therapy initiation and the time of negative sputum culture

Timepoint
Days of 0, 4, 7 after antibiotic initiation

Method of measurement
Sputum culture

Secondary outcomes

1

Description
Duration of ICU stay

Timepoint
Daily

Method of measurement
By the date of admission and discharge mentioned in

Clinical records

2

Description
Time of fever discontinuation
Timepoint
Every other day
Method of measurement
Thermometer

3

Description
The correlation between antibiotic therapy initiation and the reduction of WBC
Timepoint
Every other day
Method of measurement
Hematologic test

4

Description
The correlation between antibiotic therapy initiation and improvement of PaO2/FiO2
Timepoint
Every other day
Method of measurement
By arterial and venous blood gasses (ABG and VBG)

5

Description
Chest X-Ray changes
Timepoint
Every other day
Method of measurement
By chest x-ray radiography

6

Description
Improvement of Clinical Pulmonary Infection Score (CPIS)
Timepoint
Every other day
Method of measurement
BY CPIS score

7

Description
All the adverse effects associated with the use of colistin including bronchospasm, neurotoxicity, and hypersensitivity reactions
Timepoint
Daily
Method of measurement
Clinical records

Intervention groups

1

Description
Intervention group: Received IV colistin (Colistimethate Sodium Injection, powder for solution parenteral 1000000 [IU] that belongs to Forest Laboratories Uk) based on Glomerular Filtration Rate (GFR) plus two million units of AS colistin , three times per day. Dose adjustments of IV Colistin were implemented based on table that belongs to Systematic review of the evidence for rational dosing of colistin. Prescribtion of IV colistin was countinued until the infection was completely resolved; AS colistin was prescribed only for a period of seven days (OMRON Mesh Nebulizer Model NE-U22). To prevent bronchospasm caused by nebulized colistin, patients were premedicated with salbutamol prior to administration of nebulized colistin.
Category
Treatment - Drugs

2

Description
Control group: Intravenous Colistin based on Glomerular Filtration Rate
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
National Research Institute of Tuberculosis and Lung Diseases, Dr. Masih Daneshvari Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Research Committee, School of Pharmacy, Shahid Beheshti 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
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Pharmacy student
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

Not applicable