Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

The efficacy and safety of intravenous colistin plus nebulized colistin against intravenous ampicillin-sulbactam plus nebulized colistin in treating ventilator associated pneumonia caused by Acinetobacter baumannii

Protocol summary

Study aim
Evaluating the efficacy and safety of intravenous colistin plus nebulized colistin against intravenous ampicillin-sulbactam plus nebulized colistin in treating ventilator associated pneumonia caused by Acinetobacter baumannii

Design
Two arm parallel group randomised trial with single blinded

Settings and conduct
Patients admitted to the intensive care unit of Imam Hossein Hospital in Tehran with ventilator-associated pneumonia are divided into two intervention groups and evaluate the efficacy and safety of them

Participants/Inclusion and exclusion criteria
Inclusion criteria: Participant with hospital admission days or endotracheal intubation days > 48 hours Pneumonia diagnosis as clinical features, biologic and radiographic evidences Sputum culture of Acinetobacter baumannii Exclusion criteria: Have received effective antibiotics for this episode of hospital acquired Pneumonia for more than 72 hours before study medication administration Patients on dialysis Immunodeficiency Sever Acute respiratory distress syndrome (PaO2/Fio2 < 100) Co-infection in another organs

Intervention groups
Intervention group: intravenous ampicillin-sulbactam 6 g every 6 hours plus nebulized colistin 2mIU every 8 hours Control group: intravenous colistin 9 mIU stat then 4.5 mIU every 12 hours plus nebulized colistin 2mIU every 8 hours

Main outcome variables
Microbiological evaluation; clinical and radiological symptoms evaluation; serum level of PCT

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120703010178N18**
Registration date: **2019-03-13, 1397/12/22**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-13, 1397/12/22**
Update count: **0**

Registration date
2019-03-13, 1397/12/22

Registrant information

Name
Mohammad Sistanizad

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-09, 1397/12/18

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

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The efficacy and safety of intravenous colistin plus nebulized colistin against intravenous ampicillin-sulbactam plus nebulized colistin in treating ventilator associated pneumonia caused by Acinetobacter baumannii

Public title
Comparison of intravenous colistin plus nebulized colistin against intravenous ampicillin-sulbactam plus nebulized colistin in treating ventilator associated pneumonia caused by Acinetobacter baumannii

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Participant with endotracheal intubation days > 48 hours Pneumonia diagnosis as clinical features (which include the new onset of fever (T > 38), purulent sputum, leukocytosis or leukopenia (WBC > 11000 cells/mm3 or < 4000 cells/mm3), biologic (microorganism concentration in sputum >□10□^5 CFU⁄ml) and radiographic evidences (new lung infiltrates) Sputum culture of Acinetobacter baumannii

Exclusion criteria:
History of hypersensitivity reactions to beta-lactam antibiotics or colistin Have received effective antibiotics for this episode of ventilator associated pneumonia for more than 72 hours before study medication administration Patients on dialysis Immunodeficiency (HIV with CD4 < 200 cells/mm3, ANC < 500/mm3، leukemia, lymphoma, chemotherapy within the last 3 weeks) Sever Acute respiratory distress syndrome (PaO2/Fio2 < 100) Endobronchial obstruction such as stenosis or mass in the endobronchial Sever bronchospasm Lung abscess Empyema Chest trauma Co-infection in another organs Comorbidities: cystic fibrosis، myasthenia or atelectasis Pregnancy and lactation

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **28**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of assigning each regimen to patients is randomized and random blocked blocks with block size 4 (using a permuted block randomization table).

Blinding (investigator's opinion)
Single blinded

Blinding description
Based on randomization table, patients will be recruited. Nurse will prepare medications based on physician's order. Patient's who will receive medications, are not aware of allocation in study arms.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences, Faculties of Pharmacy and Nursin

Street address
Faculty of pharmacy, Niayesh and Vali-e-Asr junction

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tehran

Province
Tehran

Postal code
1991953381

Approval date
2018-04-30, 1397/02/10

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1397.007

Health conditions studied

1

Description of health condition studied
Ventilator-Associated Pneumonia due to Acinetobacter baumannii

ICD-10 code
J15.6

ICD-10 code description
Pneumonia due to other aerobic Gram-negative bacteria

Primary outcomes

1

Description
microbiological evaluation

Timepoint
Before intervention and 4, 7 , 10 days after intervention

Method of measurement
Negative sputum culture for Acinetobacter

Secondary outcomes

1

Description

clinical signs evaluation

Timepoint

4, 7 , 10 days after intervention

Method of measurement

Removing clinical and improving radiological manifestations - Successful weaning from ventilator between days 5 to 14 - Negative sputum culture for acinetocanter

2

Description

side effects evaluation

Timepoint

Daily and until antibiotics are given

Method of measurement

Laboratory measurements Cr

3

Description

Procalcitonin level evaluation

Timepoint

before intervention and 4, 7 , 10 days after intervention

Method of measurement

Laboratory scaling

Intervention groups

1

Description

Intervention group: intravenous ampicillin sulbactam 6 g every 6 hours plus nebulized colistin 2 mIU every 8 hours

Category

Treatment - Drugs

2

Description

Control group: intravenous colistin 9 mIU stat then 4.5 mIU every 12 hours plus nebulized colistin 2 mIU every 8 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Intensive Care Unit, Imam Hussein medical center

Full name of responsible person

Mohammad Sistanizad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Sistanizad

Position

Associated Professor / Clinical Pharmacy Specialist

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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