Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of safety and effectiveness of Levofloxacin/Colistin regimen with Levofloxacin/high dose Ampicillin-sulbactam infusion in treatment of Ventilator-Associated Pneumonia due to multi drug resistant Acinetobacter

Protocol summary

Study aim
Effectiveness of Levofloxacin with high dose Ampibactam infusion in treatment of Ventilator-Associated Pneumonia due to Acinetobacter

Design
Two arm parallel group randomized trial (control and intervention groups), blinded and outcome assessment

Settings and conduct
Acinetobacter ventilator-associated pneumonia patients admitted to the intensive care unit of Imam Hossein Hospital in Tehran are divided into two intervention and control groups and evaluated.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Participant has received mechanical ventilation for > 48 hours; Acute Physiology and Chronic Health Evaluation (APACHE) II score > 8; CPIS score >6; Sputum Culture of MDR acinetobacter Exclusion criteria: History of moderate or severe hypersensitivity reactions to beta-lactam antibiotics or colistin; Kidney injury defined as GFR<30ml/min (day 0 to 3 of the study); Have received appropriate antibiotics for this episode of ventilator-associated pneumonia for more than 96 hours before study medication administration; Concomitant infection in another organ; Acute respiratory distress syndrome; Has any of the following conditions: chest trauma with a fracture of the sternum or both; Has lung cancer within the last 2 years; Chronic bronchitis with an increase in severity within the last 30 days; Patients who are on treatment of respiratory tuberculosis on treatment; Suspected atypical pneumonia; Patients with cystic fibrosis or severe burns to greater than 15% of the body

Intervention groups
Interventional group will receive ampisulbactam plus levofloxacin and control group will receive colistin plus levofloxacin

Main outcome variables
serum level of ESR; serum level of CRP; serum level of PCT; CPIS Score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120703010178N15**
Registration date: **2018-04-23, 1397/02/03**
Registration timing: **registered_while_recruiting**

Last update: **2018-04-23, 1397/02/03**
Update count: **0**

Registration date
2018-04-23, 1397/02/03

Registrant information

Name
Mohammad Sistanizad

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8820 0087

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-12-01, 1396/09/10

Expected recruitment end date
2018-11-30, 1397/09/09

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

Scientific title
Comparison of safety and effectiveness of Levofloxacin/Colistin regimen with Levofloxacin/high dose Ampicillin-sulbactam infusion in treatment of Ventilator-Associated Pneumonia due to multi drug resistant Acinetobacter

Public title
Comparison of Levofloxacin/Colistin with Levofloxacin/high dose Ampicillin-sulbactam infusion in treatment of Ventilator-Associated Pneumonia due to multi drug resistant Acinetobacter
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Participant has received mechanical ventilation for > 48 hours Acute Physiology and Chronic Health Evaluation (APACHE) II score of more than 8 CPIS score >6 ETT culture of MDR acinetobacter ('MDR Acinetobacter spp.' will be defined as the isolate resistant to at least three classes of antimicrobial agents as below:all penicillins and cephalosporins (including inhibitor combinations), fluroquinolones, and aminoglycosides.)
Exclusion criteria:
History of moderate or severe hypersensitivity reactions to beta-lactam antibiotics or colistin Kidney injury defined as GFR<30ml/min (day 0 to 3 of the study) Have received antibiotics for this episode of ventilator-associated pneumonia for more than 96 hours before study medication administration co-infection in another organs Acute respiratory distress syndrome Has any of the following conditions: chest trauma with a fracture of the sternum, ribs, or both Has lung cancer within the last 2 years chronic bronchitis with an increase in severity within the last 30 days tuberculosis on treatment suspected atypical pneumonia cystic fibrosis and severe burns to greater than 15% of the body
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
The method of assigning each regimen to patients is randomized and random blocked blocks with block size 6 (using a permuted block randomization table).
Blinding (investigator's opinion)
Single blinded
Blinding description
outcome assessors
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
City
Tehran
Province
Tehran
Postal code
1991953381
Approval date
2017-02-17, 1395/11/29
Ethics committee reference number
IR.SBMU.PHNM.1395.604

Health conditions studied

1

Description of health condition studied
Ventilator-Associated Pneumonia due to multi drug resistant Acinetobacter
ICD-10 code
J15.6
ICD-10 code description
Pneumonia due to other aerobic Gram-negative bacteria

Primary outcomes

1

Description
30% Decreasing in CPIS score
Timepoint
Before intervention and 4, 7 , 10 days after intervention
Method of measurement
CPIS score

Secondary outcomes

1

Description
Evaluation of ESR & CPR change in infection treatment
Timepoint
before intervention and 4, 7 , 10 days after intervention
Method of measurement
Laboratory scaling

Intervention groups

1

Description
Intervention group: Amp Ampicillin-sulbactam 6g 4 times a day with Amp Levofloxacin 750mg Daily
Category
Treatment - Drugs

2

Description
Control group: Amp Colistin 9000000 unit stat and then Amp Colistin 4500000 unit two times a day with Amp Levofloxacin 750mg daily
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
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Tahereh Shams
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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
Department of Clinical Pharmacy, Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammad Sistanizad
Position
Associated Professor / Clinical Pharmacy Specialist
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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