

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 ampicisulbactam 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)

Phone

+98 21 8820 0087

Email address

sistanizadm@sbmu.ac.ir

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), fluoroquinolones, 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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Shahid Madani Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Tahereh Shams

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Velenjak Street, Shahid Chamran High Way

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info@sbmu.ac.ir

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

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Full name of responsible person

Mohammad Sistanizad

Position

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Web page address

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

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Reza Mosaed

Position

Resident