

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 Ampicillin-sulbactam 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 ampicillin-sulbactam 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

#### Street address

Shahid Madani Street

#### City

Tehran

#### Province

Tehran

#### Postal code

1617763141

#### Phone

+98 21 7343 2309

#### Email

sistanizadm@sbmu.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Tahereh Shams

#### Street address

Velenjak Street, Shahid Chamran High Way

#### City

Tehran

#### Province

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#### Postal code

1985717443

#### Phone

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#### Fax

+98 21 8887 3794

#### Email

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

#### Street address

Department of Clinical Pharmacy, Faculty of Pharmacy, Niayesh Highway

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sistanizadm@sbmu.ac.ir

#### Web page address

## Person responsible for scientific 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**

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## 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

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Fax****Email**

reza.mosaed1990@gmail.com

**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