Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Clinical Evaluation of Two Regimens with Different Doses of Ampicillin/Sulbactam in Patients with Ventilator Associated Pneumonia Caused By Resistant Acinetobacter Baumannii

Protocol summary

Study aim

Evaluation the clinical effects of two regimens with different doses of ampicillin/sulbactam in patients with ventilator associated pneumonia caused by resistant Acinetobacter baumannii

Design

Randomized clinical trial with parallel groups on 60 patients. Block randomization method will be used trough online website.

Settings and conduct

This study is conducted in Loqman Hakim Hospital in Tehran. Patients are divided into two groups after evaluating the inclusion criteria. The first group receives meropenem at a dose of 1 g every 8 hours + colistin at dose of 4.5 million units every 12 hours + ampicillin sulbactam at a dose of 6 g every 6 hours, and the second group receives meropenem at a dose of 1 g every 8 hours + colistin at dose of 4.5 million units every 12 hours + ampicillin sulbactam injection at a dose of 9 grams every 6 hours.

Participants/Inclusion and exclusion criteria

In this study, patients over 18 years are included who their infection caused by a mechanical ventilation device and the resistant Acinetobacter baumannii. The patients sign an informed consent form before entering the study. Breastfeeding or pregnant patients were not included in the study.

Intervention groups

The first group (low dose): receiving Meropenem at a dose of 1 gram every 8 hours + Colistin injection 4.5 million units every 12 hours + Ampicillin/Sulbactam at a dose of 6 grams every 6 hours The second group (high dose): receiving Meropenem at a dose of 1 gram every 8 hours + Colistin 4.5 million units every 12 hours + Ampicillin/Sulbactam at a dose of 9 grams every 6 hours

Main outcome variables

The primary outcome in this study includes the percentage of patients who improved without changing their antibiotic regimen during the study as well as the mortality rate of patients at the end of the study.

General information

Reason for update

The study has been completed and a series of inclusion and exclusion criteria that were required during the study were set.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180802040665N2**
Registration date: **2024-02-28, 1402/12/09**
Registration timing: **prospective**

Last update: **2025-12-06, 1404/09/15**
Update count: **1**

Registration date

2024-02-28, 1402/12/09

Registrant information

Name

Ali Saffaei

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

2024-03-05, 1402/12/15

Expected recruitment end date

2024-08-05, 1403/05/15

Actual recruitment start date

2024-03-05, 1402/12/15

Actual recruitment end date

2025-03-21, 1404/01/01

Trial completion date

2025-04-21, 1404/02/01

Scientific title

Clinical Evaluation of Two Regimens with Different Doses of Ampicillin/Sulbactam in Patients with Ventilator Associated Pneumonia Caused By Resistant Acinetobacter Baumannii

Public title

Clinical Evaluation of Ampicillin/Sulbactam in Patients with Ventilator Associated Pneumonia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged more than 18 years old VAP diagnosis according to the IDSA guidelines (new pulmonary infiltration with clinical symptoms including fever, purulent secretions, leukocytosis, and decreased blood oxygen levels occurring after 48 hours of mechanical ventilation). Sign the informed consent form Reporting of resistance Acinetobacter in the pulmonary secretion (concurrent resistance to aminoglycosides, fluoroquinolones, cephalosporins, penicillins and carbapenems). Patients who received empiric antibiotic regimen consist of meropenem (at dose of 1000 mg IV q8h) and vancomycin (at dose of 15 mg/kg IV q12h) for the first 48 hours until the results of the culture are determined.

Exclusion criteria:

Breastfeeding and pregnant patients. Patients who have an infection of another source other than the infection caused by the mechanical ventilation device. Obese patients with body mass index more than 35. Patients who have a history of allergy to medicines in the therapeutic regimen. Patients with underlying lung diseases, immunocompromised patients, and those with recurrent lung infection. Patients presenting with sepsis at the commencement of the study, according to the 2021 sepsis campaign guidelines. Individuals with pre-existing pulmonary conditions, such as chronic obstructive pulmonary disease (COPD), lung cancer, or pulmonary thromboembolism (PTE). Patients whose antibiotic treatment may be altered in terms of dosage and administration schedule. Patients experiencing a hypersensitivity reaction during the course of the medication. Patients who have ceased medication for a duration of less than 10 days.

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **77**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method was used in this study. 15 blocks including 4 patients generated with online website. In each block, two patients will be assigned to group A and two patients will be assigned to group B.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice-Chancellor in Research Affairs - Shahid Beheshti University of Medical Sciences

Street address

3 rd floor, School of Medicine, Evin St, Shahid Chamran Highway

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Province

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Postal code

1983963113

Approval date

2023-08-01, 1402/05/10

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1402.094

Health conditions studied

1

Description of health condition studied

Ventilator associated Pneumonia

ICD-10 code

J95.851

ICD-10 code description

Ventilator associated pneumonia

Primary outcomes

1

Description

The percentage of patients who recovered without

changing their antibiotic regimen during the study.

Timepoint

10 days after the start of the study

Method of measurement

Relief of fever, reduction of purulent secretions and no need for vasopressor for at least 48 hours

2

Description

Mortality rate

Timepoint

10 days after the start of the study

Method of measurement

Evaluation of patients' medical records

Secondary outcomes

1

Description

The percentage of patients who manage to be weaned from mechanical ventilation or tolerate spontaneous breathing mode.

Timepoint

10 days after the start of the study

Method of measurement

Evaluation of patients' ventilators

2

Description

Length of stay in ICU

Timepoint

10 days after the start of the study

Method of measurement

Evaluation of patients' medical records

3

Description

Percentage of patients who develop the adverse drug reactions

Timepoint

Daily up to 10 days

Method of measurement

Examination of patients

Intervention groups

1

Description

Intervention group: receiving Meropenem injection at a dose of 1 gram every 8 hours + Colistin injection 4.5 million units every 12 hours + Ampicillin/Sulbactam injection at a dose of 9 grams every 6 hours

Category

Treatment - Drugs

2

Description

Control group: receiving Meropenem injection at a dose of 1 gram every 8 hours + Colistin injection 4.5 million units every 12 hours + Ampicillin/Sulbactam injection at a dose of 6 grams every 6 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim hospital

Full name of responsible person

Ilad Alavi Darazam

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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?

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
Zahra Sahraei

Position
Associate professor

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Specialist

Other areas of specialty/work
Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

Title and more details about the data/document
All potential data can be shared after blinding

When the data will become available and for how long
Six mounts after results published

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used

For research purposes and meta analysis

From where data/document is obtainable

Dr. Zahra Sahraei Valieasr St, Niyayesh Highway, Shahid Beheshti University of Medical Sciences, School of Pharmacy, 3rd floor, Department of Clinical Pharmacy Zip Code: 1996835113 Telephone: +982188200209 Email: z.sahraei@sbmu.ac.ir

What processes are involved for a request to access data/document

Official letter to the researchers, then after 7 days, their request will be answered.

Comments