

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Ampicillin-sulbactam basecompared Colistin Basefor the treatment of acintobacter resistant to carbapenems in ventilator associated pneumonia

Protocol summary

Study aim

Aim of this study is Ampicillin-sulbactam basecompared Colistin Basefor the treatment of acintobacter resistant to carbapenems in ventilator associated pneumonia .

Design

This study is clinical trial and double blind. patients will be divided in 2 groups by simple randomization.Groups are parallel.The number of patients is 66.

Settings and conduct

Patients with ventilator associated pneumonia in Valiasr hospital in Arak will enter this study. This study is double blind. Researcher who complete questionnaire and analyzer and participant are blind (double blind).

Participants/Inclusion and exclusion criteria

Inclusion criteria:Ages over 16 years, ventilator-induced pneumonia with carbapenem-producing acinetobacter
Exclusion criteria:Failure to complete the course of treatment and discontinuation of treatment (due to drug complications and death, etc.), dissatisfaction

Intervention groups

Intervention group 1: Cholestine plus Carbapenem is prescribed in doses based on renal clearance and milligram in kilogram and converted to millions of units intravenously. We inject 500 gram Imipenem every 6 hours and meropenem 1 gram every 8 hours.
Intervention group 2:We inject Ampicillin / sulbactam and Carbapenem. We inject 9 grams of ampicillin / sulbactam three times daily, which can be adjusted based on renal clearance.

Main outcome variables

White blood cell count, erythrocyte sedimentation rate, culture of lung secretions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N126**

Registration date: **2019-12-17, 1398/09/26**

Registration timing: **retrospective**

Last update: **2019-12-17, 1398/09/26**

Update count: **0**

Registration date

2019-12-17, 1398/09/26

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Ampicillin-sulbactam basecompared Colistin Basefor the

treatment of acintobacter resistant to carbapenems in ventilator associated pneumonia

Public title

Ampicillin-sulbactam basecompared Colistin Basefor the treatment of acintobacter resistant to carbapenems in ventilator associated pneumonia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ages over 16 years Ventilator-induced pneumonia with carbapenem-producing acinetobacter

Exclusion criteria:

Failure to complete the course of treatment and discontinuation of treatment (due to drug complications and death, etc.) Dissatisfaction

Age

From **16 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with randomization with envelopes in two groups A and B. In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind). Outcome assessor and analyzer don't aware from grouping.The person evaluating the outcome is unaware of the grouping. Groups A and B are available to analyzer and outcome assessor.In order to blind in two groups, the syringe covered with white paper on which they are written A and B.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics comittee of Arak University of Medical Sciences

Street address

Ethics comittee, Research center, Payambar Azam complex, Basij squre ,Sardasht,Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2018-06-17, 1397/03/27

Ethics committee reference number

IR.ARAKMU.REC.1397.089

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

White blood cell count

Timepoint

First study, third day, seventh day and 14th day

Method of measurement

Blood test

2

Description

erythrocyte sedimentation rate

Timepoint

First study, third day, seventh day and 14th day

Method of measurement

Blood test

3

Description

Culture of lung secretions

Timepoint

First study, third day, seventh day and 14th day

Method of measurement

Culture of lung secretions test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cholestine plus Carbapenem is prescribed in doses based on renal clearance and milligram in kilogram and converted to millions of units intravenously. We inject 500 gram Imipenem every 6 hours and meropenem 1 gram every 8 hours.

Category

Treatment - Drugs

2

Description

Intervention group: We inject Ampicillin / sulbactam and Carbapenem. We inject 9 grams of ampicillin / sulbactam three times daily, which can be adjusted based on renal clearance.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr Masoumeh Sofian

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Masoumeh Sofian

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Masoumeh Sofian

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

They have to write letters to the professors and the university

Comments