Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Comparison of two antibiotic regimens in patients with positive Ventilator-associated pneumonia caused by Acinetobacter: an open-label clinical trial

Protocol summary

Study aim
The purpose of this study is to compare two antibiotic regimens in patients with positive Ventilator-associated pneumonia caused by Acinetobacter.

Design
This study is a clinical trial with parallel groups, without blinding, in which people are randomly divided into two groups of 51 people by Randomized Allocation Software.

Settings and conduct
This study will be conducted in Bandar Abbas Shahid Mohammadi Hospital affiliated with Hormozgan University of Medical Sciences. After explaining the study to the patient's companions and obtaining informed consent, the patients are placed in one of the two intervention groups and the treatment begins.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients over 18 years of age, Acinetobacter infection confirmed by a physician, hospitalization in the intensive care unit, have a history of sensitivity to antibiotics in the laboratory, and obtain informed consent from the patient's companion. Non-entry criteria: All patients with a history of receiving an organ or bone marrow transplant, being treated for HIV, receiving another antibiotic from another hospital in less than 72 hours, pregnancy, having an incurable disease, blood malignancy without Having a treatment plan, Resistance to antibiotic treatment, Having another infection along with Ventilator-Associated Pneumonia.

Intervention groups
All patients receive 9 million units of colistin as a loading dose and then 4.5 million units of colistin every 12 hours as an intravenous infusion over one hour. Group 1: In addition, they receive 6 grams of ampicillin sulbactam every 6 hours as a three-hour intravenous infusion. Group 2: In addition, they receive 2 grams of meropenem (every 8 hours) in the form of intravenous infusion over three hours. treatment process continues for 2 weeks.

Main outcome variables
Determining the effectiveness of the intervention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221102056386N2**
Registration date: **2023-04-17, 1402/01/28**
Registration timing: **prospective**

Last update: **2023-04-17, 1402/01/28**
Update count: **0**

Registration date
2023-04-17, 1402/01/28

Registrant information

Name
Narjes Seddighi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 917 185 1678

Email address
narjes.seddighi80@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-20, 1402/01/31

Expected recruitment end date
2023-12-21, 1402/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of two antibiotic regimens in patients with positive Ventilator-associated pneumonia caused by Acinetobacter: an open-label clinical trial

Public title
Comparison of two antibiotic regimens in patients with positive VAP caused by Acinetobacter
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Ventilator-Associated Pneumonia (VAP) confirmed by a doctor age 18 or older Hospitalization in the intensive care unit (ICU) obtaining informed consent from the patient or the patient's companion history of sensitivity to antibiotics in the laboratory
Exclusion criteria:
Organ transplant or bone marrow transplant Being treated for human immunodeficiency virus (HIV) Receiving another antibiotic from another hospital within less than 72 hours Pregnancy Having an incurable disease Blood malignancy without a treatment plan Resistance to therapeutic antibiotics Having another infection along with Ventilator-associated pneumonia (VAP)
Age
From **18 years** old
Gender
Both

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **102**
Randomization (investigator's opinion)
Randomized
Randomization description
It will be explained to all participants before the start of the study that they will be randomly divided into two intervention groups (A) and (B). The random block allocation method is used to randomly divide the samples. In this trial, we will have two groups of 4 blocks (2 participants in drug group A and 2 in drug group B). The randomization tool is also random sequence generation software (random allocation software), which in addition to simple randomization, this random sequence generation software are capable of generating random sequences by the block method. Blocked randomization is for the purpose of making sure that precisely equal number of participants enter the intervention groups at consecutive but equal time intervals.
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
Ethics committee of Hormozgan University of Medical Sciences
Street address
Research and Technology Vice-Chancellor Building, Hormozgan University of Medical Sciences Campus, Imam Hossein Blvd.
City
Bandarabbas
Province
Hormozgan
Postal code
7919693116
Approval date
2023-03-11, 1401/12/20
Ethics committee reference number
IR.HUMS.REC.1401.411

Health conditions studied

1

Description of health condition studied
Acinetobacter infection
ICD-10 code
J15.8
ICD-10 code description
Pneumonia due to other specified bacteria

Primary outcomes

1

Description
Determining the effectiveness of the intervention
Timepoint
During the study period
Method of measurement
Examination of clinical symptoms during the intervention period

Secondary outcomes

1

Description

Comparison of hospitalization in ICU and hospital

Timepoint

Duration of the study

Method of measurement

check list

2

Description

The effect of treatment on the duration of the patient's recovery during the intervention period

Timepoint

Duration of the study

Method of measurement

Clinical symptoms and laboratory tests

3

Description

mortality

Timepoint

end of the study

Method of measurement

check list

4

Description

kidney function

Timepoint

duration of the study

Method of measurement

Measurement of creatinine and blood urea nitrogen levels

Intervention groups

1

Description

Intervention group 1: Patients in this group receive 9 million units of colistin as a loading dose and then 4.5 million units of colistin every 12 hours as an intravenous infusion within one hour. In addition, they receive 6 grams of ampicillin sulbactam every 6 hours as a three-hour intravenous infusion, and the treatment process continues for 2 weeks. 51 patients will enter this group.

Category

Treatment - Drugs

2

Description

Intervention group 2: Patients in this group receive 9 million units of colistin as a loading dose and then 4.5 million units of colistin every 12 hours as an intravenous infusion within one hour. In addition, they receive 2 grams of TDS meropenem (every 8 hours) in the form of intravenous infusion over three hours, and the treatment process lasts for 2 weeks. 51 patients will enter this group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

The Great Prophet Research and Educational Complex Research Center

Full name of responsible person

Elham Barahimi

Street address

The Great Prophet Research and Educational Complex Research Center, Shahid Mohammadi Hospital, Jomhory Blvd, Old Airport, Bandar Abbas, Iran

City

Bandar Abbas

Province

Hormozgan

Postal code

7919693116

Phone

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dr.berahimi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

vali alipoor

Street address

Vice Chancellor Deputy of research and technology, Campus of University of Medical Sciences, Nabout Town, in front of Kargaran Sports Club, at the beginning of Imam Hossein Boulevard, Bandar Abbas, Iran

City

Bandar Abbas

Province

Hormozgan

Postal code

79151

Phone

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Email

research@hums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Bandare-abbas 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

saeed shoja

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

bacteriology

Street address

Vice Chancellor Deputy of research and technology, Campus of University of Medical Sciences, Nabout Town, in front of Kargaran Sports Club, at the beginning of Imam Hossein Boulevard, Bandar Abbas, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Elham Berahimi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for updating data

Contact

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Narjes Seddighi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Laboratory Medicine

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City

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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

the data will be collected by the colleagues participating in the project

When the data will become available and for how long

6 month

To whom data/document is available

corresponding Author: Dr. Elham Berahimi, Dr. Saeed Shoja

Under which criteria data/document could be used

Only for data collection and analysis

From where data/document is obtainable

corresponding Author: Dr. Elham Berahimi, Dr. Saeed Shoja

What processes are involved for a request to access

data/document

Written request and request of the project manager and main collaborators (Dr. Elham Berahimi, Dr. Saeed Shoja, Narjes Seddighi)

Comments