

# 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)

##### Phone

+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**

+98 917 159 2783

##### **Email**

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**

+98 76 3333 7192

##### **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  
**City**  
bandar abbas  
**Province**  
Hormozgan  
**Postal code**  
79151  
**Phone**  
+98 76 3333 7192  
**Email**  
shojasaeed@gmail.com

## 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  
**Street address**  
Educational and Research Complex of the Great  
Prophet , Shahid Mohammadi Hospital, Jomhory Blvd,  
Old Airport, Bandar Abbas, Iran  
**City**  
bandar abbas  
**Province**  
Hormozgan  
**Postal code**  
7919693116  
**Phone**

+98 76 3333 7192  
**Email**  
dr.berahimi@gmail.com

## 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  
**Street address**  
Southern Mission, Faculty of Paramedicine, Student  
Research Committee  
**City**  
bandar abbas  
**Province**  
Hormozgan  
**Postal code**  
7916839319  
**Phone**  
+98 76 3366 6367  
**Email**  
narjes.seddighi80@gmail.com

## 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**