

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Comparison of the clinical effectiveness of the two different doses of Meropenem in critically ill patients with hospital acquired or ventilator associated pneumonia: a randomized single-blind clinical trial

#### Protocol summary

##### Study aim

Comparison of the clinical effectiveness of two different regimens of the extended infusion of Meropenem in critically ill patients with hospital-acquired or ventilator-associated pneumonia

##### Design

In this research, which designed a parallel single-blind randomized clinical trial, 62 eligible patients randomize in two subgroups of APACHE II  $\geq 20$ , APACHE II  $< 20$ , to receive one of the interventions. A code is allocated to each participants.

##### Settings and conduct

This study is conducted in the intensive care unit of Imam Khomeini educational hospital in Sari between 2018-19. The person who does the meropenem MIC test is blind to the interventions.

##### Participants/Inclusion and exclusion criteria

Critically ill patients who are admitted to the intensive care unit and suffered from hospital-acquired or ventilator-associated pneumonia had an indication to receive meropenem because probable infection with multi-drug resistance gram-negative bacteria enrolled in the study. Patients with renal dysfunction and in risk of developing seizure are excluded from the study.

##### Intervention groups

The interventions arm receive the infusion of Meropenem 3 g TDS, and the control arm receive the infusion of Meropenem 2 g TDS.

##### Main outcome variables

Clinical success ( Time Frame: 7 days ) defined as the following, all measured at 7 days: - Patient alive - Complete or relative depletion of pneumonia sign and symptoms (leukocytosis, fever, sputum, dyspnea and tachypnea) - Systolic blood pressure  $> 90$  mmHg without need for vasopressor support - Stable or improved SOFA score, define as: .for baseline SOFA  $\geq 3$ : a decrease of at least 30%; .for baseline SOFA  $< 3$ : stable or decreased

SOFA score -PaO<sub>2</sub>/FiO<sub>2</sub> ratio stable or improved

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100107003014N19**

Registration date: **2018-04-27, 1397/02/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-04-27, 1397/02/07**

Update count: **0**

##### Registration date

2018-04-27, 1397/02/07

##### Registrant information

##### Name

Shahram Ala

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 15 1354 3083

##### Email address

sala@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-21, 1397/02/01

##### Expected recruitment end date

2019-04-20, 1398/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Comparison of the clinical effectiveness of the two different doses of Meropenem in critically ill patients with hospital acquired or ventilator associated pneumonia: a randomized single-blind clinical trial

**Public title**  
Comparison of the clinical effectiveness of the two different doses of Meropenem in pneumonia

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Critically ill patients admitted to the intensive care unit  
Patients with hospital acquired or ventilator associated pneumonia  
Indication to receive Meropenem between 18 and 70 years old

**Exclusion criteria:**  
Pregnant or breastfeeding women  
Acute or chronic renal failure  
Epilepsy or history of seizure  
CNS infection  
Immune-compromised or using immunomodulator agents  
Known allergy to carbapenems

**Age**  
From **18 years** old to **70 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Investigator

**Sample size**  
Target sample size: **62**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Block randomization with sealed envelopes

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
The investigator who does the meropenem MIC test on bacteria which had been cultured from patients' sputum samples is blind to which patients receive which interventions.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Mazandaran University of Medical Sciences

**Street address**

Moalem Sq.

**City**

Sari

**Province**

Mazandaran

**Postal code**

۳۳۹۷۱-۴۸۱۵۷

**Approval date**

2018-04-18, 1397/01/29

**Ethics committee reference number**

IR.MAZUMS.REC.97.82

**Health conditions studied**

1

**Description of health condition studied**

Bacterial pneumonia

**ICD-10 code**

J15

**ICD-10 code description**

Bacterial pneumonia, not elsewhere classified

**Primary outcomes**

1

**Description**

Clinical success

**Timepoint**

7 days after intervention

**Method of measurement**

Collecting data form

**Secondary outcomes**

1

**Description**

All-cause mortality

**Timepoint**

7, 14 and 28 days after intervention

**Method of measurement**

Data collecting form

2

**Description**

Clinical success with modification

**Timepoint**

7 and 14 days after intervention

**Method of measurement**

Data collecting form

### 3

**Description**

Time to weaning

**Timepoint**

28 days

**Method of measurement**

Data collecting form

### 4

**Description**

Time to intensive care unit discharge

**Timepoint**

28 days

**Method of measurement**

Data collecting form

### 5

**Description**

Time to hospital discharge

**Timepoint**

28 days

**Method of measurement**

Data collecting form

## Intervention groups

### 1

**Description**

Intervention group: Meropenem 3 gram every 8 hours, 3 hours extended infusion for 7 days

**Category**

Treatment - Drugs

### 2

**Description**

Control group: Meropenem 2 gram every 8 hours, 3 hours extended infusion for 7 days

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Imam Khomeini hospital

**Full name of responsible person**

Shahram Ala

**Street address**

Razi Street

**City**

Sari

**Province**

Mazandaran

**Postal code**

3313148166

**Phone**

+98 11 3336 1700

**Email**

info@emamhospital.ir

**Web page address**

http://imamhospital.mazums.ac.ir/

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Majid Saeedi

**Street address**

Vice chancellor for research and Technology of Mazandaran University of Medical Sciences, Moallem square

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Sari

**Province**

Mazandaran

**Postal code**

4815733971

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+98 11 3325 7230

**Email**

pajooheshi@mazums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Sari 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Shahram Ala

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work****Street address**

Payambar Azam University Complex, Mazandaran

University of Medical Sciences, Faculty of Pharmacy,  
Km 18 Khazar Abad Road, Sari, Mazandaran, Iran

**City**

Sari

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Medical Pharmacy

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sala@mazums.ac.ir

**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