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 ≥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 ≥ 3: a decrease of at least 30%; .for baseline SOFA <3: stable or decreased SOFA score -PaO2/FiO2 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

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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 siezure 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 envelops

Blinding (investigator's opinion)

Single blinded

Blinding description

،he 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 forum

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
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3313148166
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Majid Saeedi
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Vice chancellor for research and Technology of Mazandaran University of Medical Sciences, Moallem square
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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
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Full name of responsible person
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Position
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Latest degree
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Other areas of specialty/work
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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