Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing efficacy and safety of Meropenem/Ampicillin-sulbactam and Meropenem/Colistin in treatment of ventilator associated pneumonia due to resistant gram negative microorganisms

Protocol summary

Summary

Objective: The main goal of this study is to compare the safety and efficacy of ampicillin/sulbactam and colistin in the treatment of ventilator-associated pneumonia (VAP) due to multidrug resistant gram negative organisms. Design: Randomized, single-blind, interventional, multicenter, phase III clinical trial This is a prospective study in adult (18-65 years old) critically ill patients with VAP. 40 patients patients hospitalized in ICU with ventilator-associated pneumonia (VAP) due to multidrug resistant gram negative organisms, will be recruited. Patients are randomly assigned to receive meropenem/ampicillin/sulbactam (2 g Q 8h/3 g Q 4h) or meropenem/colistin (2 g Q 8h/9 MU stat then 4.5 MU BD) intravenously. Dosage was adjusted according to creatinine clearance. The radiological findings, laboratory data and microbiological results at baseline, 48h and 2 weeks after antibiotic therapy are used for the evaluation of the regimens efficacy. Incidence rates of adverse drug reactions durig the study phase are considered for safety evaluation of the antibiotic regimens.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201509213449N19**
Registration date: **2015-12-04, 1394/09/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-12-04, 1394/09/13

Registrant information

Name

Hossein Khalili

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing efficacy and safety of Meropenem/Ampicillin-sulbactam and Meropenem/Colistin in treatment of ventilator associated pneumonia due to resistant gram negative microorganisms

Public title

Antibiotic regimens for treatment of resistant pneumonia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Adult patients (18-65 years old) with ventilator-associated pneumonia due to multidrug

resistant gram negative organisms will be included. Exclusion criteria: Infection with gram negative organism with meropenem MIC > 8 µg/ml; Infection with gram negative organism with colistin MIC > 2 µg/ml; Patients with an allergy to each of two antibiotic regimens

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single 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 Tehran University of Medical Sciences

Street address
Ghods Ave. Tehran University of Medical Sciences, Tehran, Iran

City
Tehran

Postal code

Approval date
2015-10-03, 1394/07/11

Ethics committee reference number
IR.TUMS.REC.1394.867

Health conditions studied

1

Description of health condition studied
Pneumonia

ICD-10 code
J15.0

ICD-10 code description
Pneumonia due to Klebsiella pneumoniae

2

Description of health condition studied
Pneumonia

ICD-10 code
J15.1

ICD-10 code description
Pneumonia due to Pseudomonas

3

Description of health condition studied
Pneumonia

ICD-10 code
J15.6

ICD-10 code description
Pneumonia due to other aerobic Gram-negative bacteria

Primary outcomes

1

Description
Clinical response of pneumonia to treatment regimen

Timepoint
At day 2, day 7, day 17

Method of measurement
Evaluation of fever, blood cells, pulmonary secretions, oxygenation status

2

Description
Microbiological response to treatment regimen

Timepoint
At day 2, day 7

Method of measurement
Tracheal secretion culture

3

Description
Clinical outcome of patients

Timepoint
day 7, day 14, day 21, day 28

Method of measurement
28 days patients' follow-up

4

Description
Duration of ICU stay

Timepoint
day 7, day 14, day 21, day 28

Method of measurement
28 days patients' follow-up

Secondary outcomes

empty

Intervention groups

1

Description
Colistin 9MIU loading dose as iv infusion over 1 hour then 4.5MIU every 12 hour as iv infusion over 1 hour+Meropenem 2g every 8 hour as iv infusion over 3 hours for 14 days
Category
Treatment - Drugs

2

Description
Ampicillin-Sulbactam 3g every 4 hour as iv infusion over 1 hour and Meropenem 2g every 8 hour as iv infusion over 3 hours for 14 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Hossein Khalili
Street address
Keshavarz Blvd.
City
Tehran

2

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Hossein Khalili
Street address
Keshavarz Blvd.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Tehran University of Medical Sciences
Full name of responsible person
Masoud Yunesian
Street address
Vice Chancellor for Research, Tehran University of Medical Sciences, Ghods Ave., Tehran, Iran
City
Tehran

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran university of Medical Sciences
Full name of responsible person
Hossein Khalili
Position
Pharm.D, PHD
Other areas of specialty/work
Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave., Tehran, Iran
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Person responsible for updating data

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty