

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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 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 during 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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+98 21 6695 4715

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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

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Web page address

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