

Efficacy and Safety of Colistimethate Sodium for Injection in The Treatment of Carbapenem-Resistant Enterobacteriaceae Infection

NCT06051513

Status	RECRUITING
Phase	Not Applicable
Sponsor	Southeast University, China
Enrollment	404 participants

Key Eligibility Criteria

Inclusion (9)

- Patients who can provide written informed consent or their informed consent can be provided by legal guardian
- Patients who are hospitalized
- Adults e18 years and d85 years of age
- Patients suspected of or diagnosed with hospital-acquired pneumonia (HAP, in a patient hospitalised for more than 48 hours or developing within 7 days after discharge from a hospital) or bloodstream infection caused carbapenem-resistant enterobacteriaceae (CRE) based on the culture results of the sample collected 5 days before the randomization or rapid diagnostic detection.
- Rapid testing of respiratory or blood specimens should be used to enable early identification of CRE infection pneumonia. Patients can be randomized based on the results of the rapid test while awaiting results of cultures from the local laboratory. However, if the sample does not grow CRE in the local microbiology laboratory culture, these patients will be withdrawn from the study drug treatment.

... and 4 more (see full listing online)

Exclusion (14)

- Patients who received polymyxin for more than 48 hours in the 72 hours prior to randomization.
- Patients who received antibiotics more than 24 hours in the 72 hours prior to randomization, and after treatment conditions of patients improved.
- Patient with history of serious allergy, hypersensitivity (eg, anaphylaxis), or any serious reaction to Colistimethate Sodium for Injection or other ingredients of it.
- Evidence of active concurrent pneumonia requiring additional antimicrobials treatment caused by Streptococcus pneumoniae Haemophilus influenzae Methicillin-resistant staphylococcus aureus Vancomycin-resistant enterococcus Mycoplasma pneumonia Legionella pneumophila, respiratory syncytial virus, influenza virus, parainfluenza virus, Middle East Respiratory Virus, Mycobacteria, Aspergillus, Mucormycosis, Candida, etc. If these organisms are identified but it is deemed by the Investigator that no treatment is warranted and their presence does not significantly change the prognosis of the patient, then the patient may be considered for this study.
- Patients who are diagnosed with primary lung cancer (including small cell lung cancer/non-small cell lung cancer patients) or other malignancy transferred to the lungs or other known post obstructive pneumonia. Patients who is known or suspected of active tuberculosis, cystic fibrosis, lung abscess, pyothorax or obstructive pneumonia.

... and 9 more (see full listing online)

Locations (15 total)

Anhui Provincial People's Hospital, Hefei, Anhui, China
The First Hospital of Anhui Medical University, Hefei, Anhui, China
Jinjiang Municipal Hospital, Jinjiang, Fujian, China
... and 12 more locations

<https://clinicaltrials.gov/study/NCT06051513>

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