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A study comparing two antibiotic combinations to determine which is more effective and safer for treating drug-resistant bacterial infections in children

Submission date
19/06/2026

Recruitment status
Recruiting

Registration date
27/06/2026

Overall study status
Ongoing

Last Edited
26/06/2026

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

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N-51-2026

Study information

Scientific Title
Clinical efficacy and safety of ceftazidime/avibactam–aztreonam compared with colistin–meropenem in pediatric patients with carbapenem-resistant Enterobacterales infections

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 07/03/2026, Cairo University, Faculty of Medicine, Research Ethics Committee (Cairo University, Cairo, 12613, Egypt; +20 (0)235674835; kasralainyrec@kasralainy.edu.eg), ref: N-51-2026

2. Approved 05/06/2026, Huddersfield University, School of Applied Sciences Research Integrity and Ethics Committee (School of Applied Sciences University of Huddersfield Queensgate, Huddersfield, HD1 3DH, United Kingdom; +44 (0)1484422288; sas_ethics@hud.ac.uk), ref: SAS-SRIEC-05.06.2026WE_1

Primary study design
Interventional

Allocation

Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Carbapenem-resistant Enterobacterales infections in hospitalized patients

Interventions
Case group:
Arm A (control group):
Meropenem + colistin, the standard treatment for carbapenem-resistant enterobacterals (CRE) in Egypt.

Dosage given and frequency of administration:
Meropenem: standard paediatric dosing per weight 40 mg/kg/dose every 8 hours; maximum dose: 2,000 mg/dose
Colistin: weight-based IV dosing per hospital protocol and renal function.
Mild to moderate infections: 75,000 IU/kg every 12 hours in normal renal function.
Severe or life-threatening infections: 75,000 IU/kg every 8 hours in normal renal function.
Renal impairment: dose adjustment according to hospital protocol.
Duration: 7–14 days, depending on the site of infection.

Arm B (case group):
Ceftazidime–avibactam and aztreonam as a combination treatment for CRE recommended by the Infectious Diseases Society of America guidelines.

Dosage given and frequency of administration:
Ceftazidime–avibactam: standard paediatric dosing per weight and age.
Infants ≥3 months to <6 months: 40 mg ceftazidime/kg/dose every 8 hours.
Infants ≥6 months, children, and adolescents <18 years: 50 mg ceftazidime/kg/dose every 8 hours, maximum dose 2000 mg ceftazidime/dose.
Adolescents ≥18 years: 2000 mg ceftazidime every 8 hours.

Aztreonam: standard paediatric dosing per weight.
Mild to moderate infection: 30 mg/kg every 8 hours, maximum 3000 mg/day
Severe infections: 40 mg/kg every 8 hours, maximum 8000 mg/day
Duration: 7–14 days, depending on the site of infection.

Follow-up for all treatment arms: baseline and daily follow-up of the following:
1. Hemodynamic stability markers such as heart rate, blood pressure, the need to use vasoactive agents, and the mode of oxygenation
2. Organ dysfunction markers in renal and liver failure, such as urine output, creatinine, ALT, AST, albumin and bilirubin
3. Sepsis markers such as fever, C-reactive protein (CRP), white blood cells (WBCs), platelet count, and shift left
4. Microbial clearance and eradication after 7-14 days

Randomisation process:
A computer-generated random sequence (1:1 ratio) and sealed, opaque envelopes will be used for randomisation and allocation. Stratification by infection type (bloodstream vs non-bloodstream) may be applied if there is sufficient sample size for subgroup analysis. The CONSORT study flow diagram will be used.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Meropenem, colistin, ceftazidime, avibactam, aztreonam

Primary outcome(s)
1. Clinical success rate measured using the resolution of symptoms and no need for antibiotic change at days 7-14

2. Microbiological eradication measured using follow-up cultures at days 7 and 14

3. Mortality measured using the total number of infection-related deaths in that arm divided by the total number of enrolled patients in that arm and multiplying by 100 at days 7, 14 and 28

4. Time to fever resolution measured using a thermometer at baseline and over 72 hours

5. Length of ICU Stay (LOS) at hospital discharge and up to 90 days, defined as the median of the number of days in the ICU from admission until discharge, measured using data from records, collected at one timepoint at the end of the study

6. Incidence of acute kidney injury (AKI) measured using the Kidney Disease Improving Global Outcomes (KDIGO) criteria at baseline and during the therapy duration

7. Adverse events (nephrotoxicity, hepatotoxicity, hypersensitivity reactions, and other treatment-related adverse events) throughout the treatment period (7-14 days) and up to 72 hours after the follow-up period measured using routine clinical practice during hospitalisation (nephrotoxicity and hepatotoxicity) and data recording, collected at one timepoint at the end of the study

8. Sepsis markers measured using WBC count, CRP, platelet count, and shift left count at baseline and every other day for 14 days

Key secondary outcome(s)

Completion date
08/03/2027

Eligibility

Key inclusion criteria
1. Age more than 3 months for both sexes
2. Hospitalized patients with a proven infection
3. Culture or BioFire showed carbapenem-resistant Enterobacterales (CRE)

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 Months

Upper age limit
16 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Co-infection with other microorganisms in conjunction with CRE
2. Empirical use
3. Duration of treatment combination is less than 48 hours
4. Expected survival is less than 48 hours
5. Known allergy to study drugs
6. Renal replacement therapy

Date of first enrolment
20/06/2026

Date of final enrolment
06/03/2027

Locations

Countries of recruitment
Egypt

Sponsor information

Organisation
Cairo University hospitals

ROR
https://ror.org/058djb788

Funder(s)

Funder type

Funder Name
Cairo University Hospitals

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			19/06/2026	No	No