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Can children in hospital safely switch from antibiotics given through a vein to antibiotics taken by mouth? A study to assess whether this approach is practical, effective, and can reduce hospital stay and treatment costs in Egypt

Submission date
19/06/2026

Recruitment status
Recruiting

Registration date
23/06/2026

Overall study status
Ongoing

Last Edited
23/06/2026

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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Study information

Scientific Title
Clinical efficacy and safety of early intravenous-to-oral antimicrobial conversion versus continued intravenous therapy in hospitalised pediatric patients with mild to moderate infections

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 09/04/2026, Cairo University, Faculty of Medicine, Research Ethics Commitee (Kasr Al Aini, Cairo University, Cairo, 12613, Egypt; +20 2 35674835; kasralainyrec@kasralainy.edu.eg), ref: N-63-2026

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 1484422288; sas_ethics@hud.ac.uk), ref: SAS-SRIEC-05.06.2026WE_2

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
Hospitalised children with mild to moderate infections requiring antimicrobial therapy

Interventions
64 patients will be randomized & allocated using a computer-generated random sequence (1:1 ratio) and randomized to groups. Sealed opaque envelopes will be used. The CONSORT study flow diagram will be used.

Control arm: Continue the whole treatment duration with IV antibiotics, if indicated. This is the standard treatment in EGYPT.

Study arm: Convert antibiotics from IV to PO dosage form if antibiotics are still indicated and the patient is a candidate for IV to PO conversion. This is the WHO and CDC recommendation as an antimicrobial stewardship intervention.

Data will be collected from day 1 of admission and followed up every 24 hours using a designed data collection sheet. The patient will be followed up till discharge or at least 5 days, starting from the date the patient is eligible for the conversion.

Efficacy and safety of IV to PO antimicrobial conversion are the primary outcomes. Length of hospital stay, rate of re-admission of re-converted patients.

Intervention Type
Procedure/Surgery

Primary outcome(s)

1. Duration of IV and PO antibiotic therapy (days) measured using Medical record review at Baseline, day of eligibility of IV-to-PO switch, during the 7 days after conversion, day 14 follow-up

2. Total antibiotic duration (days) measured using Medical record review at Baseline, day of eligibility of IV-to-PO switch, during the 7 days after conversion, day 14 follow-up

3. Length of hospital stay (days) measured using Hospital administrative records at Baseline, day of eligibility of IV-to-PO switch, day 14 follow-up

4. Treatment success rate measured using Clinical assessment documented in medical records at Day of eligibility of IV-to-PO switch, during the 7 days after conversion, day 14 follow-up

5. Rate of antibiotic-related adverse events measured using Adverse event reporting in medical records at Baseline, during the 7 days after conversion, day 14 follow-up

6. Rate of recurrence within 14 days measured using Clinical assessment documented in medical records at Day 14 follow-up

7. Rate of reconverted patients to IV therapy measured using Medical record review at During the 7 days after conversion, day 14 follow-up

Key secondary outcome(s)

Completion date
08/04/2027

Eligibility

Key inclusion criteria
1. Age more than 1 month to 14 years of both sexes
2. Hospitalised patients with proven infection (community-acquired pneumonia (non-invasive ventilated patients) and uncomplicated urinary tract infection)
3. Requiring initiation and continuation of antimicrobials
4. Patient is vitally and hemodynamically stable
5. Afebrile for ≥24 hours
6. Tolerate enteral feeds and take medications orally

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
1 Months

Upper age limit
14 Years

Sex

All

Total final enrolment
0

Key exclusion criteria
1. Patients with GI disorders (e.g., obstruction, malabsorption, active GI bleeding, nothing by mouth (NPO), short gut syndrome, and continuous feeds that cannot be held if the antimicrobial agent has a food interaction)
2. CNS Disorders: seizures and risk of aspiration
3. Hemodynamic instability: hypotension or shock
4. Patients refusing oral medication
5. Febrile neutropenia<1000cells/mm³ or functional asplenia
6. Severe infection or deep-seated infection (e.g., meningitis, endocarditis, deep abscess, initiation of treatment in bone and joint infections, infected prosthesis)
7. Antibiotics are used as surgical prophylaxis

Date of first enrolment
20/06/2026

Date of final enrolment
08/04/2027

Locations

Countries of recruitment
Egypt

Sponsor information

Organisation
Cairo University hospitals

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