

A Study to Evaluate the Safety and Tolerability of Eravacycline in Pediatric Patients Aged 8 to 17 With Complicated Intra-abdominal Infections (cIAI)

NCT06794541

Status	RECRUITING
Phase	Phase 2
Sponsor	Tetraphase Pharmaceuticals, Inc
Enrollment	35 participants

Key Eligibility Criteria

Inclusion (20)

- Children from 8 to <18 years of age (as of the day of the informed consent [and assent, if applicable] is obtained), hospitalized for cIAI with one of the following diagnoses:
 - Intra-abdominal abscess (including hepatic and splenic abscesses).
 - Gastric or intestinal perforation associated with diffuse peritonitis.
 - Peritonitis: diffuse infection of the peritoneum (but not spontaneous bacterial peritonitis associated with cirrhosis and chronic ascites).
 - Appendicitis with perforation, peritonitis, or abscess (complicated appendicitis).
- ... and 15 more (see full listing online)

Exclusion (23)

- Patient is considered by the investigator to be unlikely to survive the trial period, and/or has any rapidly progressing disease or immediately life-threatening illness.
 - Patient's laboratory test results reveal alanine aminotransferase or aspartate transaminase >5x upper limit of normal range (ULN).
 - Patient's laboratory test results reveal total bilirubin >2xULN, unless isolated hyperbilirubinemia is directly related to the acute process.
 - Patient requires peritoneal dialysis, hemodialysis, or hemofiltration at screening. Patient has an estimated glomerular filtration rate (eGFR) <50 mL/minute/1.73 m².
 - Patient has previously received eravacycline or have enrolled previously in the current trial and been discontinued.
- ... and 18 more (see full listing online)

Locations (5 total)

UCLA Ronald Reagan University of California Los Angeles Medical Center, Los Angeles, California, United States
Children's Hospital of Orange County, Orange, California, United States
Ann and Robert H Lurie Children's Hospital of Chicago, Chicago, Illinois, United States
... and 2 more locations

<https://clinicaltrials.gov/study/NCT06794541>

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