

Evaluation of new anti-infective drugs for the treatment of cholera. Infectious Diseases Society of America and the Food and Drug Administration.

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Cholera is an acute gastrointestinal infection caused by *Vibrio cholerae*. It is characterized by watery diarrhea that may lead to massive fluid loss, which in turn may result in hypotension, shock, and death within hours. Key to the treatment of cholera is fluid replacement. Anti-infective therapy decreases the severity and duration of diarrhea and the duration of shedding of *V. cholerae*. Enrolled patients should have diarrhea that is moderate to severe and a culture that ultimately yields *V. cholerae*. A prospective, randomized, active-controlled clinical trial is preferred. Studies should be double-blinded or evaluator-blinded. The rapidity with which the organism is eliminated from stool may be assessed. Both clinical and microbiological outcome should be determined. Assessment of microbiological eradication is paramount, since fluid replacement may suffice for treatment of signs and symptoms.