

Evaluation of new anti-infective drugs for the treatment of diarrhea caused by *Entamoeba histolytica*. Infectious Diseases Society of America and the Food and Drug Administration.

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Entamoeba histolytica causes colonic infection that ranges from asymptomatic carriage to invasive disease with infection of extraintestinal organs, particularly the liver. The disease occurs in both sporadic and epidemic forms. Diagnosis requires visualization of trophozoites or cysts by microscopic examination of stool, colonic scrapings, or biopsy specimens. Patients with either asymptomatic or symptomatic disease may be eligible for clinical trials. A prospective, randomized, double-blind, placebo-controlled study design is recommended for asymptomatic carriers and an active-concurrent-control study design for symptomatic patients. Final outcome should be assessed 48 hours to 7 days after completion of therapy. Assessment of microbiological outcome is paramount.