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

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Giardia lamblia is a flagellate protozoan that produces symptoms by infecting the small bowel and biliary tract in the trophozoite form. Diagnosis is currently established by microscopic visualization of the organism in appropriate intestinal contents (stool, small-bowel contents, or biopsy specimen). Adult patients with diarrhea and one or more enteric symptoms may be enrolled in clinical trials of new drugs for the treatment of giardial disease. A randomized, double-blind, active-concurrent-control design is recommended. Post hoc stratification by age, immune status, chronicity of disease, and ease of establishing diagnosis (organism load) may be performed. Microbiological assessment 48 hours to 7 days after the completion of therapy is paramount for determining final outcome.