

Evaluation of new anti-infective drugs for the treatment and prevention of infections caused by the Mycobacterium avium complex. Infectious Diseases Society of America and the Food and Drug Administration.

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The bacteria of the Mycobacterium avium complex are ubiquitous; thus it is often difficult to distinguish environmental contamination from colonization or infection. Patients with either pulmonary or disseminated infection may be enrolled in clinical trials. Disseminated disease occurs mostly in patients infected with the human immunodeficiency virus. In general, a randomized, active-control, double-blinded clinical trial is preferred; there should at least be a blinded evaluator. With regard to immunosuppressed populations, new antimycobacterial drugs need to be evaluated not only for the treatment but also for the prevention of disease. For trials of prophylaxis a placebo-controlled design is ethical until a drug is proven effective; then the use of an active-control regimen is appropriate. Since no regimen has been approved by the U.S. Food and Drug Administration for treatment or prevention of disease caused by the M. avium complex, demonstration of the superiority of the study regimen to the control regimen should be the objective of the clinical trial.