

Evaluation of new anti-infective drugs for the treatment and prevention of tuberculosis.

Infectious Diseases Society of America and the Food and Drug Administration.

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This guideline addresses the evaluation of new antimycobacterial drugs in the treatment and prevention (secondary prophylaxis) of infection by *M. tuberculosis*. Patients may be enrolled in clinical trials on the basis of clinical and/or microbiological criteria. A therapeutic regimen will likely include a combination of drugs; a randomized, active-control, comparative clinical trial is recommended. If appropriate samples can be obtained for culture during follow-up without placing the patient at unwarranted risk, the assessment of microbiological outcome is paramount. Prophylaxis will probably require a single drug, and a similar study design is preferred.