

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

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These guidelines describe the design and implementation of clinical trials to assess the safety and efficacy of anti-infective drugs for the treatment of infective endocarditis. Identification and enrollment of patients in clinical trials is based on a modification of traditional criteria. To accrue a sufficient number of patients, only those with streptococcal or staphylococcal endocarditis should be included in studies. Results of treatment with approved drugs allow for projection of expected bacteriologic cure rates and survival rates. Prospective randomized, double-blind studies are recommended. These guidelines are based on the premise that future protocols may include shorter courses of therapy, combinations of drugs, or progression from parenteral to oral therapy. Clinical response is judged as cure, failure, or indeterminate; there is no "improved" category. Microbiologic response is categorized as eradication, persistence, or relapse. When a patient has shown no clinical evidence of active disease for a protracted period, there may be no need to perform a posttreatment blood culture; for such patients, the microbiologic response is termed presumptive eradication. Several months of follow-up may be necessary to detect late relapses.