

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

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Syphilis is caused by *Treponema pallidum*, a spirochetal bacterium pathogenic only for humans. The clinical course of disease is divided into three stages interspersed by periods of latency. Penicillin remains the treatment of choice for all stages of infection; tetracycline or erythromycin may be used as therapeutic alternatives in defined circumstances. Patients enrolled in clinical trials should be evaluated clinically, microscopically, and serologically for the presence of the spirochete. All participants, after undergoing counseling and giving informed consent, should be tested for infection with human immunodeficiency virus. Specific criteria exist for diagnosis of syphilis and response to therapy. It may be desirable to perform a small, uncontrolled, open trial of a new anti-infective drug for the collection of preliminary evidence of efficacy. A larger-scale, randomized, active-control comparative clinical trial is necessary to prove efficacy.