

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

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Chancroid is a mucocutaneous infection caused by *Haemophilus ducreyi* that produces ulcerative lesions and enhances the efficiency of transmission of human immunodeficiency virus (HIV). Confirmation of infection by culture of *H. ducreyi* is essential in therapeutic trials. Minimal inhibitory concentrations of antibiotics for the isolate should be determined by agar dilution. Patients should be evaluated by appropriate laboratory tests for syphilis, infection with herpes simplex virus, gonorrhea, and (in North America) infection with *Chlamydia trachomatis*. The clinical history of the disease should be recorded and ulcers, buboes, and lymphadenitis mass described. Whenever possible, study participants also should be tested for HIV infection. Randomized, prospective, double-blind, active-control comparative clinical trials are preferred for evaluation of the safety and efficacy of new anti-infective drugs. Otherwise-healthy men and women should be enrolled in these studies. Patients with active syphilis or genital herpes should be excluded. Microbiological and clinical outcomes are paramount.