

Evaluation of new anti-infective drugs for the treatment of selected infections of the skin and skin structure. Infectious Diseases Society of America and the Food and Drug Administration.

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No method for classifying infections of the skin and skin structure is uniformly accepted. Therefore, each protocol for the evaluation of new anti-infective drugs must include definitions of the skin and skin-structure infections to be treated. Clinical findings may suggest the etiology. Cultures should be performed by the best available technique. Because the yield of pathogens from sites of skin and skin-structure infection is often low, monitoring of the clinical response to therapy is paramount. Randomized, double-blind, active-control comparative studies are needed, and maintenance of blinding is recommended, even with a change in the route of administration of the study and/or control drugs. The period of follow-up should be defined for each type of infection.