

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

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Cases of osteomyelitis can be divided into four categories: acute hematogenous, vertebral, secondary to a contiguous focus of infection without vascular disease, and secondary to a contiguous focus of infection with vascular disease. Each category may be further divided into acute and chronic forms. Clinical symptoms persisting for $>$ or $=$ 10 days correlate roughly with the development of necrotic bone and chronic osteomyelitis. Patients enrolled in clinical trials should generally be $>$ or $=$ 12 years of age. Prior antimicrobial treatment does not exclude patients if the culture of a bone sample obtained at the time of enrollment yields pathogenic bacteria. Randomized, double-blind, active-control comparative studies are encouraged. Clinical outcome should be assessed during therapy and within 5-9 days, 4-6 weeks, and 11-13 months after completion of therapy. In the final assessment, clinical appraisal is paramount.