

Evaluation of new anti-infective drugs for the treatment of febrile episodes in neutropenic patients. Infectious Diseases Society of America and the Food and Drug Administration.

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Publication year: 1992

Journal: Clinical infectious diseases : an official publication of the Infectious Diseases Society of America

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Society: Infectious Diseases Society of America

Origin country: United States

Target countries: United States

DOI: 10.1093/clind/15.supplement_1.s206

PMID: 1477232

Source: <https://pubmed.ncbi.nlm.nih.gov/1477232/>

The use of empirical antimicrobial therapy has significantly reduced the morbidity and mortality associated with untreated infections in febrile neutropenic patients. This guideline describes clinical trials of the safety and efficacy of new antimicrobial drugs in this population of patients. Fever and neutropenia should be precisely defined in each protocol. Patients should be randomized to treatment with a new or active-control drug regimen, stratified on the basis of type of cancer and age, and treated until resolution--as defined in the protocol--is attained. Outcome should be assessed both for cases with a defined microbial etiology and for those without. Final microbiological outcome is important for cases with identified pathogens, but clinical outcome is paramount.