

Evaluation of new anti-infective drugs for the treatment of acute pelvic inflammatory disease. Infectious Diseases Society of America and the Food and Drug Administration.

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Pelvic inflammatory disease (PID) is a syndrome unrelated to pregnancy or surgery and characterized by lower abdominal pain and tenderness, cervical motion tenderness, and adnexal tenderness. Fever, leukocytosis, and the results of laboratory tests are used to support the diagnosis. Participants in clinical trials should be stratified into two groups: those with and those without tubo-ovarian abscess--i.e., those with complicated and those with uncomplicated PID. Diagnostic studies and treatment should be directed at four major groups of pathogens: *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, anaerobic bacteria, and facultative bacteria such as *Escherichia coli*. Women requiring hospitalization should generally be treated as inpatients for at least 4-7 days; outpatient therapy should then be instituted to complete a 14- to 21-day course. Clinical and laboratory evaluations should be conducted daily during hospitalization and both 2-4 days and 2-4 weeks after the completion of therapy.