

Study examines vulnerability of gonorrhea to older antibiotic drug

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A new clinical research study seeks to determine whether a rapid molecular diagnostic test can reliably identify gonorrhea infections that may be successfully treated with a single dose of an older antibiotic, ciprofloxacin. The study will enroll up to 381 men and women diagnosed with untreated Neisseria gonorrhoeae. It is sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. The study is being conducted by the NIAID-funded Sexually Transmitted Infections Clinical Trials Group at four sites: one each in San Francisco, and Philadelphia, and two in Los Angeles.

The Centers for Disease Control and Prevention estimates that more than 800,000 new gonococcal infections occur in the United States each year. Fewer than half of these infections are detected, and antibiotic-resistant infections are a growing problem. People treated for gonorrhea must now receive two drugs—one orally (azithromycin) and another as an injection (ceftriaxone)—to hedge against the possibility that they may harbor a strain resistant to one of the two drugs. The availability of a greater variety of treatments for gonorrhea—and a tool to pinpoint the best treatment option for each individual—would benefit patients and also potentially help slow the development of drug resistance, say the study authors.

In this new trial, scientists will employ a rapid molecular assay using swabbed samples from participants' infection sites to determine whether they are infected with gonorrhea of a specific genetic profile (genotype), *gyrA* serine 91. Participants with that strain who agree to take part in the study will receive one dose of oral ciprofloxacin (500 mg), and will return for clinical and laboratory assessments within 5 to 9 days to determine if they are cured. Participants who remain infected will be referred for standard treatment.

If the *gyrA* serine 91 genotype proves to be a reliable marker of vulnerability to ciprofloxacin, healthcare providers may be able to reintroduce ciprofloxacin as a viable treatment for gonorrhea in some cases.

Provided by NIH/National Institute of Allergy and Infectious Diseases



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