

Clinical trial: Doxycycline does not prevent STIs among cisgender women

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Researchers from the University of Washington (UW), Kenya Medical Research Institute (KEMRI), and Hennepin Healthcare Research Institute (HHRI) announced results at CROI from a clinical trial

demonstrating that doxycycline taken after sex does not prevent bacterial sexually transmitted infections (STIs)—chlamydia or gonorrhea—among cisgender women.

The dPEP Kenya Trial was conducted in Kisumu, Kenya, to evaluate the effectiveness of [doxycycline](#) postexposure prophylaxis (PEP) to prevent bacterial STIs. The results of the study have been highly anticipated, as this is the first study of doxycycline PEP among cisgender women, following multiple studies that showed a high level of STI protection with doxycycline use among cisgender men and [transgender women](#) in France and the United States.

Differences in anatomy, [antibiotic resistance](#), and adherence offer possible explanations for the lack of efficacy among cisgender women when it worked for cisgender men and transgender women, and the research team is working to understand the potential role of these differences. "Doxycycline PEP didn't work for cisgender women in Kenya, but the need for STI prevention is increasing around the world," said Dr. Jenell Stewart, the dPEP Kenya Study Director, Infectious Disease Physician at Hennepin Healthcare and University of Minnesota.

Biological differences between the vagina/cervix and rectum may explain why doxycycline didn't prevent STIs in cisgender women; however, the approach to treatment of STIs doesn't differ by sex. Antibiotic resistance offers an explanation for why gonorrhea wasn't prevented, but it doesn't explain why chlamydia wasn't prevented. There are no known cases of antibiotic resistant chlamydia; however, the rate of doxycycline resistant gonorrhea was very high, including 100% of the infections acquired prior to starting the study.

Self-reported adherence was high but imperfect and frequency and timing of doxycycline use among cisgender women in the trial is being evaluated further. All participants were also taking daily HIV PrEP pills

(a medicine to prevent HIV), and none of the participants got HIV during the year they were in the study.

At a single site in Kisumu, Kenya, the study enrolled 449 cisgender women who were taking daily oral HIV pre-exposure prophylaxis (PrEP) and were randomized to receive doxycycline or standard of care. 18% of participants had an STI at the time they entered the study and over the course of the study the rate of STIs remained high—an annual incidence of 27%, which is comparable to rates among men who have sex with men in high income countries.

There were 109 new STIs diagnosed, 50 among those using doxycycline PEP compared to 59 among those randomized to no doxycycline and standard of care, during the course of the 12-month follow-up. Most, 78%, of the new STIs diagnosed were chlamydia, 35 among people taking doxycycline PEP and 50 among standard of care, which was not statistically different. Only one new case of syphilis was diagnosed in this study, consistent with other studies in the region, and therefore, the impact of doxycycline PEP on preventing syphilis among cisgender women could not be evaluated.

"The results from the study are deeply disappointing, and we are committed to understanding why doxycycline PEP did not work in this population and also determining the next steps for how to identify prevention tools that will work for and can be used by women," said Prof. Elizabeth Bukusi, a Principal Investigator of the dPEP Kenya Trial and Senior Principal Clinical Research Scientist at the Kenya Medical Research Institute.

Bacterial STIs in women can lead to lasting and severe consequences including [pelvic inflammatory disease](#), [chronic pain](#), infertility, pregnancy complications, and increased susceptibility to HIV. While the study team continues to investigate the potential role of biological and

behavioral differences to explain why doxycycline PEP did not work, it is clear that [cisgender](#) women need primary STI prevention strategies.

More information: Conference: www.croiconference.org/

Provided by Hennepin Healthcare Research Institute

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