



In Search of Better Health

PRESS RELEASE

To: News Editors & Reporters

Subject: Doxycycline prophylaxis use low and did not prevent STIs among cisgender women

Date: Thursday, 21st December, 2023

NAIROBI, KENYA, Researchers from Kenya Medical Research Institute (KEMRI), University of Washington (UW), and Hennepin Healthcare Research Institute (HHRI) published results in the *New England Journal of Medicine*. 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. In February, Dr. Jenell Stewart presented initial results from the dPEP Kenya clinical trial at CROI demonstrating that doxycycline taken after sex does not prevent bacterial sexually transmitted infections (STIs) – chlamydia or gonorrhea – among cisgender women, but the reason for this had not yet been established.

Objective measure of doxycycline detection in hair samples indicate that use of doxycycline was low in this study. **“Doxycycline PEP needs to be studied further among people assigned female sex at birth. I am hopeful that it will work for everyone regardless of sex and gender, but in our study many women didn’t take the doxycycline they were given. We need STI prevention that is proven, accessible, and easy to use.”** said Dr. Jenell Stewart, the dPEP Kenya Study Director, Infectious Disease Physician at Hennepin Healthcare and University of Minnesota.

In addition to low use of doxycycline, antibiotic resistance offers an explanation for why gonorrhea wasn’t prevented. The rate of doxycycline resistant gonorrhea was very high, including 100% of the infections acquired prior to starting the study. This is much higher than rates in the US and France, currently estimated to be ~20% of cases. There are no known cases of antibiotic resistant chlamydia, and none were detected in this 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 wasn’t taken. We are actively working to find ways to support adherence that will work for and can be used by women,” said Prof. Elizabeth Bukusi, a Principal Investigator of the dPEP Kenya Study and Senior Principal Clinical Research Scientist at the Kenya Medical Research Institute and Professor at University of Washington in Departments of Global Health and Ob/Gyn.

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. The dPEP Kenya study team continues to understand why use of doxycycline was low and investigate new ways of delivering doxycycline prophylaxis that are acceptable and effective. Dr. Stewart is working with Dr. Cherie Blair, Assistant Professor of Infectious Diseases at UCLA, and the Adolescent Trials Network to secure funding for a study of doxycycline prophylaxis against STIs in people assigned female sex at birth regardless of gender in the United States.

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The Kenya Medical Research Institute (KEMRI) is a State Corporation established in Kenya in 1979 through the Science and Technology (Repealed) Act, Cap 250 of the Laws of Kenya operated under the Science Technology and Innovation Act, 2013 as the national body responsible for carrying out research in human health in Kenya. Currently, KEMRI operates under Legal Notice No. 35 of March 2021 KEMRI has grown from its humble beginning over 40 years ago to become a regional leader in human health research. The Institute currently ranks as one of the leading Centres of excellence in health research both in Africa as well as globally.

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