SCOPE

STRATEGIES TO COMBINE PREP WITH PREVENTION EFFORTS

FHI 360 Study #391449

Funder and Sponsors

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Collaborating Institutions

Family Health Options Kenya, Eldoret, Kenya
Kenya AIDS Control Project, Nairobi, Kenya

Study Population

The study population consists of HIV-antibody negative, female sex workers (FSWs) who are at least 18 years of age and who are newly or currently enrolled in an established HIV risk-reduction program for FSWs at the study sites.

Study Size

SCOPE aims to enroll 500 women who chose to use Truvada for PrEP as part of their HIV risk-reduction plan.

Study Design

SCOPE is a pilot, open-label, prospective cohort study.

Intervention

Eligible women who choose to add PrEP to their HIV risk-reduction plan will be provided with Truvada—a fixed-dose combination of emtricitabine (FTC; 200mg) and tenofovir disoproxil fumarate (TDF; 300mg)—and they will be asked to take it daily. All participants will receive individual integrated counseling on sexual health, HIV risk reduction, and PrEP adherence.

Study Objectives

The primary objectives are to:

1) Describe the patterns of adherence (based on tenofovir concentrations) to a regimen of daily oral Truvada among female sex workers who are currently or newly enrolled in established HIV-prevention programs
2) Assess the feasibility of integrating PrEP into existing HIV-prevention programs for female sex workers

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The secondary objectives are to:

1) Describe self-reported and electronically monitored patterns of adherence to a regimen of daily oral Truvada among FSWs who are currently or newly enrolled in established HIV-prevention programs
2) Assess the correlation between drug-level adherence data and participant self-reported adherence data to potentially identify reliable measures of self-reported adherence
3) Assess the impact of PrEP on HIV risk-taking behavior
4) Identify factors associated with adherence to PrEP
5) Describe contraceptive use
6) Assess resistance to TDF or FTC among seroconverters
7) assess birth outcomes among women who choose to continue PrEP during pregnancy

Duration and Follow-up

Each participant will be followed for a minimum of six months, up to a maximum of nine months. Each participant will visit the study site four weeks after enrollment and will then be followed every three months until the end of study follow-up.

Pregnancy

Participants who become pregnant will be offered the opportunity to stop taking Truvada, and they will be counseled on the risks and benefits of taking Truvada during pregnancy. Participants who choose to take Truvada during pregnancy will be followed monthly while they are pregnant. Infants who are born to women who were exposed to Truvada during pregnancy will be followed for up to one year.

Seroconversion

Participants who are infected with HIV during the study will be taken off Truvada permanently; they will be asked to come to the study site to be tested for viral load and viral resistance at 6 and 12 weeks after seroconversion is detected. Thereafter, women will visit the study site according to their routine program schedule. (The existing risk-reductions programs provide ongoing care for HIV-positive women in addition to HIV risk-reduction services for HIV-negative women.) HIV care and support is available at the program clinics, and additional referrals will be provided if needed.

Study timeline

Study results are expected in August 2014.