

Safety and Adherence to Intermittent Pre-Exposure Prophylaxis (PrEP) for HIV-1 in African Men Who Have Sex with Men and Female Sex Workers

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Abstract:

Background: Little is known about safety of and adherence to intermittent HIV PrEP regimens, which may be more feasible than daily dosing in some settings. We present safety and adherence data from the first trial of an intermittent PrEP regimen among Kenyan men who have sex with men (MSM) and female sex workers (FSW). Methods/Principal Findings: MSM and FSW were randomized to daily oral FTC/TDF or placebo, or intermittent (Monday, Friday and within 2 hours after sex, not to exceed one dose per day) oral FTC/TDF or placebo in a 2:1:2:1 ratio; volunteers were followed monthly for 4 months. Adherence was assessed with the medication event monitoring system (MEMS). Sexual activity data were collected via daily text message (SMS) queries and timeline followback interviews with a onemonth recall period. Sixty-seven men and 5 women were randomized into the study. Safety was similar among all groups. Median MEMS adherence rates were 83% [IQR: 63–92] for daily dosing and 55% [IQR:28–78] for fixed intermittent dosing ($p = 0.003$), while adherence to any post-coital doses was 26% [IQR:14–50]. SMS response rates were low, which may have impaired measurement of post-coital dosing adherence. Acceptability of PrEP was high, regardless of dosing regimen. Conclusions/Significance: Adherence to intermittent dosing regimens, fixed doses, and in particular coitally-dependent doses, may be more difficult than adherence to daily dosing. However, intermittent dosing may still be appropriate for PrEP if intracellular drug levels, which correlate with prevention of HIV acquisition, can be attained with less than daily dosing and if barriers to adherence can be addressed. Additional drug level data, qualitative data on adherence barriers, and better methods to measure sexual activity are necessary to determine whether adherence to post-coital PrEP could be comparable to more standard regimens.