Tenofovir DF-Emtricitabine PrEP for African Women

FEM-PrEP
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The FEM-PrEP Study: Background

**Study Design: FEM-PrEP**

- **Background**: Randomized, double-blind, placebo-controlled trial that examined efficacy and safety of tenofovir DF-emtricitabine as preexposure prophylaxis in HIV-negative women in Kenya, South Africa, and Tanzania
- **Inclusion Criteria** (2120 enrolled)
  - 18-35 years of age
  - Negative HIV-1-antibody test
  - Increased risk for HIV: ≥1 vaginal sex acts in prior 2 weeks or >1 sex partner in prior month
  - Excluded if pregnant or breastfeeding
  - Excluded if HBsAg or abnormal hepatic function
  - Excluded if abnormal renal function
- **Treatment Arms**:
  - Placebo: 1 pill daily
  - Tenofovir DF-emtricitabine: 1 pill daily

**Placebo**
(n = 1058)

**Tenofovir DF-Emtricitabine**
(n = 1062)

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FEM-PrEP Study: Results

Study stopped early due to lack of efficacy

Proportion of Participants with Target Plasma Tenofovir Level (≥10 ng/mL)

- **Seroconverters in TDF-FTC arm**
  - Beginning of infection window: 26%
  - End of infection window: 21%
  - Both visits: 15%

- **Uninfected controls**
  - Beginning of infection window: 35%
  - End of infection window: 37%
  - Both visits: 24%

Conclusions: “In conclusion, prophylaxis with tenofovir DF–emtricitabine did not reduce the rate of HIV infection and was associated with increased rates of side effects, as compared with placebo. Despite substantial counseling efforts, drug adherence appeared to be low.”
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