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

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FEM-PrEP Study: Results

Study stopped early due to lack of efficacy

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FEM-PrEP Study: Adherence

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

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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