Preexposure Prophylaxis in Heterosexual Men and Women

TDF2 Study
Oral PrEP for Heterosexual Men and Women in Botswana
TDF2 Study: Background

Study Design: TDF2

- **Background**: Randomized, phase 3, double-blind, placebo-controlled trial that examined efficacy and safety of tenofovir DF-emtricitabine as preexposure prophylaxis in sexually-active heterosexual men and women in Botswana

- **Inclusion Criteria** (1,219 enrolled)
  - 18-39 years of age
  - HIV-1-negative and sexually active
  - Normal serum and hematologic tests
  - Negative HBsAg
  - No chronic medical illnesses
  - Female not pregnant or breast-feeding

- **Treatment Arms**:
  - Placebo: 1 pill daily
  - Tenofovir DF-emtricitabine: 1 pill daily

Oral PrEP for Heterosexual Men and Women in Botswana
TDF2 Study: Background

1,219 HIV-Seronegative, Heterosexual Men and Women

Placebo
(n = 608)

Tenofovir DF-Emtricitabine
(n = 611)

n = 557
n = 662

Oral PrEP for Heterosexual Men and Women in Botswana
TDF2 Study: Results (Modified Intention-to-Treat)

Oral PrEP for Heterosexual Men and Women in Botswana
TDF2 Study: Results (As Treated)

Modified analysis that excluded 3 patients identified as infected with HIV at enrollment

Oral PrEP for Heterosexual Men and Women in Botswana
TDF2 Study: Results (Effects on Bone)

**Conclusions**: "Daily tenofovir DF-emtricitabine prophylaxis prevented HIV infection in sexually active heterosexual adults. The long-term safety of daily tenofovir DF-emtricitabine prophylaxis, including the effect on bone mineral density, remains unknown."

**A Vaginal Ring Containing Dapivirine for HIV-1 PrEP Ring Study: Conclusions**

**Conclusions**: “Among women in sub-Saharan Africa, the dapivirine ring was not associated with any safety concerns and was associated with a rate of acquisition of HIV-1 infection that was lower than the rate with placebo.”

The National HIV Curriculum is an AIDS Education and Training Center (AETC) Program supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling $800,000 with 0% financed with non-governmental sources. This project is led by the University of Washington’s Infectious Diseases Education and Assessment (IDEA) Program.

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