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

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TDF2 Study: Background

1,219 HIV-Seronegative, Heterosexual Men and Women

Placebo
(n = 608)

Tenofovir DF-Emtricitabine
(n = 611)

n = 557

n = 662

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TDF2 Study: Results (Modified Intention-to-Treat)

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

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.”

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