Preexposure Prophylaxis in Heterosexual Men and Women

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

• **Background**: Randomized, phase 3, double-blind, placebo-controlled trial that examined efficacy and safety of tenofovir DF-emtricitabine as preexposure prophylaxis for 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
  - 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

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

HIV-1 Infections (%): Modified Intention-to-Treat Analysis

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

Risk Reduction Compared with Placebo: Modified Intention-to-Treat Analysis

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

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

Number of Infections: As Treated Analysis

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

Risk Reduction Compared with Placebo: As Treated Analysis

Oral HIV 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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