Preexposure Prophylaxis in Men who have Sex with Men

iPrEx Trial
Preexposure Prophylaxis (PrEP) for HIV Prevention in MSM

iPrEx Trial: Study Design

**Study Design: iPrEx**

- **Background**: Randomized, placebo-controlled trial that examined efficacy and safety of tenofovir DF-emtricitabine as preexposure prophylaxis in HIV-seronegative men (or transgender women) who have sex with men

- **Inclusion Criteria** (2499 enrolled)
  - 18 years of age or older
  - HIV-seronegative
  - Men (or transgender women) who have sex with men
  - Evidence of high-risk for HIV acquisition

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

Note: 10 subjects infected with HIV at onset of study

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iPrEx Trial: Results (Intent-to-Treat)

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iPrEx Trial: Results (Modified Intent-to-Treat)

Preexposure Prophylaxis (PrEP) for HIV Prevention in MSM

iPrEx Trial: Results

Detectable Drug Levels in Patients on Tenofovir DF-Emtricitabine

A. Intracellular Emtricitabine-Diphosphate Level

- 3/34 Detectable (9%)
- 22/42 Detectable (52%)

B. Intracellular Tenofovir-Diphosphate Levels

- 2/34 Detectable (6%)
- 21/42 Detectable (50%)

Adjusted relative risk reduction (any detectable level) = 95%

Conclusions: “Oral tenofovir DF-emtricitabine provided protection against the acquisition of HIV infection among the subjects. Detectable blood levels strongly correlated with the prophylactic effect.”
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