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: Study Design**

- **n = 2499 MSM or TG Women**
- **Sexual Contact**
  - Blue: Tenofovir DF-Emtricitabine
  - Gray: Placebo

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iPrEx Trial: Results (Intent-to-Treat)

Preexposure Prophylaxis (PrEP) for HIV Prevention in MSM

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


HIV Infections

<table>
<thead>
<tr>
<th>Condition</th>
<th>Number of Infections</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>64</td>
</tr>
<tr>
<td>Tenofovir DF-Emtricitabine</td>
<td>36</td>
</tr>
</tbody>
</table>

P = 0.005

↓ 44%
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iPrEx Trial: Results

Detectable Drug Levels in Patients on Tenofovir DF-Emtricitabine

**A. Intracellular Emtricitabine Levels**

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

**B. Intracellular Tenofovir-DF 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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