IM Cabotegravir vs. TDF-FTC for PrEP in Cisgender Women

HPTN 084
**IM Cabotegravir versus TDF-FTC for PrEP in Cisgender Women**

**HPTN 084: Study Design**

- **Background**: Phase 3, double-blind, randomized, multinational trial to assess efficacy of long-acting IM cabotegravir (CAB) compared to daily oral tenofovir DF-emtricitabine (TDF-FTC) for HIV PrEP for cisgender women (assigned female sex at birth)

- **Setting**
  - 20 sites in 7 countries in Sub-Saharan Africa

- **Inclusion Criteria**
  - Cisgender women (assigned female sex at birth) 18-45 years of age
  - Sexually active (e.g. vaginal sex on ≥2 separate days in the 30 days prior to screening)
  - HBsAg-negative and willing to receive hepatitis B vaccination
  - HCV antibody negative
  - No contraindications to gluteal injections
  - Creatinine clearance of greater than or equal to 60 mL/min
  - ALT <2 x upper limit of normal (ULN) and total bilirubin ≤ 2.5 x ULN
  - Excluded if pregnant or breastfeeding

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**HPTN 084: Study Design**

- **Participants**
  - n = 3,224

### Study Design

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Step 2</th>
<th>Step 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 Weeks</td>
<td>Up to 185 weeks (3.5 Years)</td>
<td>48 weeks</td>
</tr>
</tbody>
</table>

#### Oral TDF-FTC Placebo
- Daily

#### Oral TDF-FTC Placebo
- Daily

#### Oral CAB Placebo
- Daily

#### Oral CAB 30 mg
- Daily

#### IM CAB 600 mg
- Weeks 5, 9, and every 8 weeks thereafter

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### HPTN 084: Selected Baseline Characteristics

<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
<th>Cabotegravir (n = 1,614)</th>
<th>TDF-FTC (n = 1,610)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age, years</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Age &lt;25 years, n (%)</td>
<td>814 (50.4%)</td>
<td>816 (50.7%)</td>
</tr>
<tr>
<td>Black/African race, n (%)</td>
<td>1,569 (97.2%)</td>
<td>1,554 (96.5%)</td>
</tr>
<tr>
<td>Sexual activity in past month (reported)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;2 sex partners, n (%)</td>
<td>878/1,609 (54.5%)</td>
<td>877/1,609 (54.8%)</td>
</tr>
<tr>
<td>Transactional sex, n (%)</td>
<td>658/1,609 (40.9%)</td>
<td>655/1,600 (40.9%)</td>
</tr>
<tr>
<td>Partner HIV(+) or unknown, n (%)</td>
<td>542/1,609 (33.7%)</td>
<td>558/1,600 (34.9%)</td>
</tr>
<tr>
<td>Anal sex, n (%)</td>
<td>90/1,609 (5.6%)</td>
<td>95/1,600 (5.9%)</td>
</tr>
</tbody>
</table>

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HPTN 084: Results

Number of HIV Infections: Risk Reduction

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Number of HIV Infections

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HPTN 084: Results

Number of HIV Infections: Risk Reduction

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HPTN 084: Results

HIV Incidence

<table>
<thead>
<tr>
<th>HIV Incidence (per 100 person years)</th>
<th>IM Cabotegravir</th>
<th>Oral Tenofovir DF-Emtricitabine</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.20</td>
<td>1.85</td>
</tr>
</tbody>
</table>

**Interpretation**: Although both products for HIV prevention were generally safe, well tolerated, and effective, cabotegravir was superior to TDF-FTC in preventing HIV infection in women.
IM Cabotegravir Tail-Phase Safety, Tolerability, and Pharmacokinetics

HPTN 077
Cabotegravir Levels After Last Dose of Cabotegravir

Patients with Detectable Plasma Cabotegravir (%)

<table>
<thead>
<tr>
<th>Weeks after Last Cabotegravir Injection</th>
<th>Female</th>
<th>Male</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>100</td>
<td>78</td>
</tr>
<tr>
<td>24</td>
<td>95</td>
<td>55</td>
</tr>
<tr>
<td>36</td>
<td>87</td>
<td>39</td>
</tr>
<tr>
<td>48</td>
<td>77</td>
<td>22</td>
</tr>
<tr>
<td>52/60</td>
<td>63</td>
<td>13</td>
</tr>
</tbody>
</table>

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