IM Cabotegravir vs. 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 in cisgender women.

- **Setting**
  - 20 sites in Sub-Saharan Africa, including 7 in South Africa.

- **Inclusion Criteria**
  - Cisgender women (born female)
  - Age 18-45 years
  - 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.

Investigational

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HPTN 084: Study Design

n = 3,224

### Step 1
- Oral TDF-FTC Placebo Daily
- Oral CAB 30 mg Daily

### Step 2
- Oral TDF-FTC Placebo Daily
- IM CAB 600 mg Every 4 weeks x 2, then every 8 weeks

### Step 3
- Oral TDF-FTC Daily
- Oral CAB Placebo Daily
- IM CAB Placebo Every 4 weeks x 2, then every 8 weeks

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HPTN 084: Baseline Characteristics

• **Age**
  - Average age of 26 years
  - 57% were ≤25 years of age

• **Partners**
  - 87% lived with partner
  - 55% reported ≥2 partners in past month
  - 34% had partners that were HIV+ or had unknown status

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HPTN 084: Results (n = 3,127 included in analysis)

![Graph showing HIV Infections for IM Cabotegravir and Oral Tenofovir DF-Emtricitabine.](image)

IM Cabotegravir versus TDF-FTC for PrEP in Cisgender Women
HPTN 084: Results (n = 3,127 included in analysis)

**Investigator’s Conclusion:** Long-acting injectable cabotegravir was more effective than daily oral tenofovir DF-emtricitabine in preventing HIV infection in cisgender women.

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