A really (really) rapid overview of the HPTN 083 results

Long-acting injectable CAB vs. daily oral TDF/FTC for PrEP among MSM and TGW

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HPTN 083 Study Design

**Step 1:**
- Screening day and informed consent
- Every day for 5 weeks
  - Group A: CAB
  - Group B: CAB

**Step 2:**
- Weeks 5 and 9
  - Every 2 months for approximately 3 years
  - TDF/FTC (Every day)

**Step 3:**
- Every day for 1 year
  - Group A: TDF/FTC
  - Group B: TDF/FTC

TDF/FTC pill, Cabotegravir (CAB) injection, Placebo for TDF/FTC pill, Placebo for cabotegravir (CAB) injection
HIV Incidence: CAB vs. TDF/FTC

**HIV Incidence**

- **CAB**
  - 13 Infections
  - Hazard Ratio: 1.22
  - 3205 PY
  - 3187 PY

- **TDF/FTC**
  - 39 Infections
  - 0.41

**Hazard Ratio (95% CI)**

- **CAB**
  - Hazard Ratio: 0.75
  - Superiority

- **TDF/FTC**
  - Hazard Ratio: 1.23
  - Non-Inferiority

Cl, confidence interval
Cabotegravir Arm

**A**

- **A1**: K65R, M184V, L100I, K103N, P225H
- **A2**: WT, E138K, Q148K
- **A3**: WT
- **A4**: WT

**B**

- **B1**: Y181C, H221Y
- **B2**: WT
- **B3**: WT
- **B4**: N/A
- **B5**: WT

**C**

- **C1**: L74I, Q148R, L74I, E138K, G140G/S, Q148R
- **C2**: WT
- **C3**: E138A, Q148R

**D**

- **D1**: WT
- **D2**: N/A
- **D3**: K103N
- **D4**: G140A, Q148R

**Legend**

- `≥8xPA-IC90`
- `4xPA-IC90 - <8xPA-IC90`
- `1xPA-IC90 - <4xPA-IC90`
- `>LLoQ - <1xPA-IC90`
- `BLQ`
- First HIV positive visit
- First site positive visit
- First HIV positive visit and first site positive visit
- CAB injection
- TDF/FTC dispensed
- First genotyping test
- Second genotyping test

**Weeks since enrollment**

- 0 10 20 30 40 50 60 70 80 90 100 110 120 130 140
TFV/FTC Arm

First HIV positive visit and first site positive visit
First site positive visit
First HIV positive visit
HIV genotyping test

TFV-DP ≥1250 fmol/punch
TFV-DP ≥700 - <1250 fmol/punch
TFV-DP ≥350 - <700 fmol/punch
TFV-DP >LLOQ - <350 fmol/punch
TFV-DP BLQ

First HIV positive visit
First site positive visit
First HIV positive visit and first site positive visit
HIV genotyping test

Weeks since enrollment

M184I
K103N
M184V, K103N
G190S
K65R, Y181C, G190A, H221Y
M184V, K103N, P225H
K103N
K103S
M184I
M184I/V
Conclusions

• Both agents highly effective for HIV prevention
• The PrEP regimen containing CAB-LA was superior to a daily oral regimen of TDF/FTC in HPTN 083 and HPTN 084
• CAB-LA was generally well tolerated despite injection site reactions
• 1/4, 0/5, 2/3, and 2/4 Acute (Prevalent), Distant from CAB, Oral-lead-in, and On-time injection participants developed INSTI resistance
  • Tail phase seroconversion did not result in INSTI resistance
  • Breakthrough at high and expected CAB concentrations resulted in INSTI resistance
• CAB is the first long-acting injectable agent to demonstrate robust HIV prevention efficacy
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HPTN 083 Study Team

Community Program Managers
Community Educators & Recruiters, CAB Members

Our 43 Sites in 7 countries

...and our Study Participants!

Questions? Email rlandovitz@mednet.ucla.edu or @doc_in_a_box
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