Long-acting injectable CAB for HIV prevention in cisgender women

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HPTN 084 Study Design

HIV, pregnancy testing and safety assessments at each product administration visit; additional post injection safety visits
Real-world adherence counselling support aligned with national guidelines

Outcome:
HIV incidence
### Primary outcome: HIV incidence

40 infections over 3892 person-years  
Pooled HIV incidence 1.03 (0.73, 1.4) per 100 person-years

<table>
<thead>
<tr>
<th></th>
<th>CAB</th>
<th>TDF/FTC</th>
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<tbody>
<tr>
<td>HIV infections</td>
<td>4</td>
<td>36</td>
</tr>
<tr>
<td>Person-years</td>
<td>1,953</td>
<td>1,939</td>
</tr>
<tr>
<td>HIV incidence (95% CI)</td>
<td>0.2 (0.06, 0.52)</td>
<td>1.86 (1.3, 2.57)</td>
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*Wald test z statistic – 4.20, efficacy stopping bound (z scale) – 3.61*
Cumulative HIV incidence – ITT

Women in the CAB group had an 89% lower risk of HIV infection, compared to TDF/FTC group.
CAB LA likely conferred an adherence advantage

Overall, 62% detectable TFV, 46% >40ng/ml

Longitudinal CAB cohort data pending
• PK and HIV virology testing currently in progress to understand infection on injection and in TDF/FTC group
Conclusions and next steps

- Both agents highly effective in preventing HIV; overall incidence 1%
- CAB was superior to daily oral TDF/FTC in preventing HIV in cisgender women;
- Both products were safe and well tolerated; ISR CAB > TDF/FTC
- Ongoing laboratory analysis will provide insights into breakthrough infections
- Protocol amendment under development to offer open-label CAB LA
  - Includes optional oral lead in
  - Includes option to consent for active dosing through pregnancy
  - Includes HIV RNA testing as part of screening algorithm
Acknowledgments

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HPTN 084 Study team
• 20 sites in 7 countries in sub-Saharan Africa
• Community advisory boards and partners

… and our study participants!

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