Version 5.0 and LOA#1 Overview

HPTN 084:
A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women

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15 February 2024
HPTN All Sites Call
Edits of Significance

• Added two injections to Step 6
• Updated CAB LA risk language

Other Noteworthy Edits

• Clarified pregnancy activities during all steps
• Simplified consent form
• Included lab section and HIV testing algorithm
Appendix VIII: Schedule of Evaluations for Step 6 Procedures for Participants on Maintenance Doses of CAB LA weeks 49-96 (or Weeks 49-112)

**Table Footnote:**
# At Week 96, site staff must determine whether the PPT can access CAB LA locally, outside of the trial. If the PPT has access to CAB LA, Week 96 will be the final visit. If local access to CAB LA is delayed for any reason, offer the PPT up to two additional injections on the study (Weeks 104 and 112).
Protocol v5: CAB LA Risk Language Update

- Allergic Reaction
- Suicide
Protocol v5: Pregnant PPT Data Collection

The protocol now includes clearer text explaining the data to be collected for all pregnant PPTs:

- Ultrasound at 12 weeks
- At birth
- At 48 weeks post delivery
- All SAEs
Protocol v5: Remaining Updates

- Simplified consent form
- Included lab section and HIV testing algorithm

SECTION 9.0 (MODIFIED FROM THE MAIN PROTOCOL)

Laboratory procedures are described below and in the SSP for any participant who has a reactive or positive HIV test after enrollment.

9.1 Local Laboratory Specimens

The following types of tests will be performed at the local laboratory:

- HIV testing (see SSP Manual)
- Pregnancy testing (see below)
- HBV and HCV testing to include HBsAg, HBsAb, HBeAg (if positive), HCV antibody tests
- Complete blood count (CBC) with differential
- Chemistry testing (blood urea nitrogen (BUN) or urea, creatinine, CPK, glucose, calcium, phosphorous, amylase, lipase)
- LFTs (AST, ALT, T Bil, alkaline phosphatase)
- Fasting lipid profile (total cholesterol, high-density lipoprotein (HDL), triglycerides, low-density lipoprotein (LDL)) - calculated or measured
- Syphilis serology testing
Edits of Significance

- Removed cholesterol testing from Step 6 SOE
- Updated text in Pharmacology Section

Housekeeping Edits

- Corrected typographical errors
• Removed cholesterol testing