

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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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

Protocol v5: Two More Injections

Appendix VIII: Schedule of Evaluations for Step 6-Procedures for Participants on Maintenance Doses of CAB LA weeks 49-96 (or Weeks 49-112)

Time in Step 6 ^{±±}	Week 56	Week 64	Week 72	Week 80	Week 88	Week 96 [#]	Week 104	Week 112
ADMINISTRATIVE PROCEDURES								
Informed Consent	X						X	
Locator information	X	X	X	X	X	X	X	X
Acceptability assessment			X			X		
Behavioral assessment			X			X		X
HIV prevention counseling	X	X	X	X	X	X	X	X
Offer condoms per local SOC	X	X	X	X	X	X	X	X
CLINICAL EVALUATIONS & PROCEDURES								
Medical history, concomitant medications, targeted physical exam (with pulse, BP, weight and BMI calculated at each visit)	X	X	X	X	X	X	X	X
Blood collection	X	X	X	X	X	X	X	X
Urine collection ¹	X	X	X	X	X	X	X	X
Vaginal swab collection ²			X			X		X
Adherence counseling ³	X	X	X	X	X	X	X	X
Administer CAB LA	X	X	X	X	X	X	X	X
LOCAL LABORATORY EVALUATIONS & PROCEDURES								
HIV testing ⁴	X	X	X	X	X	X	X	X
HIV viral load testing ⁵	X	X	X	X	X	X	X	X
Pregnancy testing, only if indicated ¹	X	X	X	X	X	X	X	X
Chemistry testing ⁹						X		X
Liver function testing ⁶						X		X
Syphilis testing			X			X		X
GC/CT and TV testing ²			X			X		X
Plasma storage ^{7,8}	X	X	X	X	X	X	X	X
DBS storage ³	X	X	X	X	X	X	X	X



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

1. Why is the research study being updated?

The team is updating the research study to make two changes. Those changes are highlighted in grey so that you can easily see them in this document. The first change is to add new CAB LA side effects. Those side effects are explained later in this document and the team at your study site will talk with you about them. The second change being made is to add two more CAB LA injections at the end of the second open label period for any participants who cannot yet access CAB LA locally.

- 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, HBcAb (total), 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, TBili, alkaline phosphatase)
- Fasting lipid profile (total cholesterol, high-density lipoprotein (HDL), triglycerides, low-density lipoprotein (LDL)) – calculated or [measured](#)
- Syphilis serologic testing

Edits of Significance

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



Housekeeping Edits

- Corrected typographical errors

HPTN 084, LOA#1: Remaining Updates

• Removed cholesterol testing

d. Step 6

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Time in Step 6	Week 56	Week 64	Week 72	Week 80	Week 88	Week 96 ⁶	Week 104	Week 112
ADMINISTRATIVE PROCEDURES								
Informed Consent	X						X ³	
Locator information	X	X	X	X	X	X	X	X
Acceptability assessment			X			X		X
Behavioral assessment			X			X	X	X
HIV prevention counseling	X	X	X	X	X	X	X	X
Offer condoms per local SOC	X	X	X	X	X	X	X	X
CLINICAL EVALUATIONS & PROCEDURES								
Medical history, concomitant medications, targeted physical exam (with pulse, BP, weight and BMI calculated at each visit)	X	X	X	X	X	X	X	X
Blood collection	X	X	X	X	X	X	X	X
Urine collection ¹	X	X	X	X	X	X	X	X
Vaginal swab collection ²			X			X		X

³ Refer to the SSP Manual.

⁴ The HIV testing algorithm is provided in the protocol, [Section 3.1](#) laboratory. At least one HIV test must be available the same day as

⁵ Viral load testing will be conducted as indicated in the SOE; or if Viral load testing will be performed regardless of HIV status or the with an assay with a lower limit of quantification of 50 copies/mL of

⁶ AST, ALT, total bilirubin, ~~cholesterol~~.

⁷ Stored plasma may be used for Quality Assurance testing, possible LC.