HPTN 084−01 − Safety, Tolerability and Acceptability of Long−Acting Cabotegravir for the Prevention of HIV among Adolescent Females − A Sub−study of HPTN 084
LIVE Open Report − May 19, 2022
Visit Cutoff Date: May 19, 2022
Table O1 − Screening Summary by Site

	Overall	MU−JHU	Spilhaus	Ward 21
Total Participants Screened	73	23	25	25
Eligible and enrolled	55/73 (75.3%)	17/23 (73.9%)	20/25 (80.0%)	18/25 (72.0%)
Eligible/Not enrolled	4/73 (5.5%)	4/23 (17.4%)	0/25 (0.0%)	0/25 (0.0%)
Ineligible	14/73 (19.2%)	2/23 (8.7%)	5/25 (20.0%)	7/25 (28.0%)
Incomplete screening	0/73 (0.0%)	0/23 (0.0%)	0/25 (0.0%)	0/25 (0.0%)
Ineligible[1] participants who failed to meet one or more of the inclusion/exclusion criteria				
I1. Assigned female at birth	0/14 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/7 (0.0%)
I2. At enrollment, below 18 years of age	0/14 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/7 (0.0%)
I3. At enrollment, body weight > 50 kg (110 lbs.)	0/14 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/7 (0.0%)
I4. Willing to provide written informed assent/consent for the study and/or able to obtain written parental/guardian	0/14 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/7 (0.0%)
I5. Self−reported sexual activity with a male (oral, anal or vaginal) in the past 12 months	1/14 (7.1%)	0/2 (0.0%)	0/5 (0.0%)	1/7 (14.3%)
I6a. Non−reactive / negative HIV test results	1/14 (7.1%)	0/2 (0.0%)	0/5 (0.0%)	1/7 (14.3%)
I6b. Absolute neutrophil count > 799 cells/mm3	0/14 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/7 (0.0%)
I6c. Platelet count > 100,000/mm3	0/14 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/7 (0.0%)
I6d. Hemoglobin > 11g/dL	2/14 (14.3%)	0/2 (0.0%)	1/5 (20.0%)	1/7 (14.3%)
I6e. Calculated creatinine clearance > 60 mL/minute using modified Schwartz equation	0/14 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/7 (0.0%)
I6f. Alanine aminotransferase (ALT) < 2.0 times the upper limit of normal (ULN) (< grade 1) and total bilirubin (Tbili) < 2.5 x ULN	0/14 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/7 (0.0%)
I6g. Hepatitis B virus (HBV) surface antigen (HBsAg) negative and accepts vaccination	1/14 (7.1%)	1/2 (50.0%)	0/5 (0.0%)	0/7 (0.0%)
I6h. HCV Antibody negative	0/14 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/7 (0.0%)
I7. Willing to undergo all required study procedures	2/14 (14.3%)	1/2 (50.0%)	0/5 (0.0%)	1/7 (14.3%)
I8. Negative beta human chorionic gonadotropin preg. test (sensitivity < 25 mIU/mL) performed (and results known) on enr. day & before initiating study product	2/14 (14.3%)	0/2 (0.0%)	0/5 (0.0%)	2/7 (28.6%)
I9. Agree to use LA contraception (IUD, IUS, or non−oral hormone−based), during trial & 48 wk. after ending the LA injectable/30 d. after ending oral study product	1/14 (7.1%)	0/2 (0.0%)	1/5 (20.0%)	0/7 (0.0%)
E1. Co−enrollment in any other HIV interventional research study or other concurrent studies	0/14 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/7 (0.0%)
E2. Currently receiving PrEP from a non−study source	0/14 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/7 (0.0%)
E3. Past or current participation in HIV vaccine trial with exception for participants who can provide documentation of receipt of placebo	0/14 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/7 (0.0%)
E4. Exclusively had sex with biological females in lifetime	0/14 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/7 (0.0%)
E5a. In the last 6 months (at the time of screening): self−reported unprotected anal or vaginal intercourse with someone known to be HIV−infected	0/14 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/7 (0.0%)
E5b. In the last 6 months (during screening): self−reported illicit injection drug use of any kind or stimulant use	0/14 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/7 (0.0%)
E5c. In the last 6 months (during screening): active or planned use of any substance use which would hinder study participation	0/14 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/7 (0.0%)
E5d. In the last 6 months (during screening): self−report of > 5 different sexual partners (anal or vaginal)	0/14 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/7 (0.0%)
E6. Known history of clinically significant cardiovascular disease	0/14 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/7 (0.0%)
E7. Inflammatory skin conditions that compromise the safety of intramuscular (IM) injections	0/14 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/7 (0.0%)

[1] Participants could have multiple reasons for not being enrolled.

Source: SCHARP (Surabhi) − /trials/hptn/p084−01/analysis/atlas/code/open/t_screening_summary.sas, SAS Version 9.4 (19MAY2022,5:15)

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E8. Tattoo or other dermatological condition overlying the buttock region that may interfere with interpretation of injection site reactions	0/14 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/7 (0.0%)
E9. Current or chronic history of liver disease or known hepatic or biliary abnormalities	0/14 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/7 (0.0%)
E10. Known history of clinically significant bleeding	0/14 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/7 (0.0%)
E11. A history of seizure disorder, per self−report	0/14 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/7 (0.0%)
E12. Medical, social, or other condition that would interfere with the conduct of the study or the safety of the participant	2/14 (14.3%)	0/2 (0.0%)	1/5 (20.0%)	1/7 (14.3%)
E13. Plans to move out of the geographic area within the next 18 months or otherwise unable to participate in study visits, according to the site investigator	0/14 (0.0%)	0/2 (0.0%)	0/5 (0.0%)	0/7 (0.0%)
E14. Pregnant or currently breastfeeding at the time of screening or intends to become pregnant and/or breastfeed while on study	2/14 (14.3%)	0/2 (0.0%)	2/5 (40.0%)	0/7 (0.0%)

[1] Participants could have multiple reasons for not being enrolled.

Source: SCHARP (Surabhi) − /trials/hptn/p084−01/analysis/atlas/code/open/t_screening_summary.sas, SAS Version 9.4 (19MAY2022,5:15)