HPTN 083−01 − Safety, Tolerability and Acceptability of Long−Acting Cabotegravir for the Prevention of HIV among Adolescent Males − A sub−study of HPTN 083
Atlas Open Report − July 18, 2023
Visit Cutoff Date: July 18, 2023
Table O1 − Screening Summary by Site

	Overall	Aurora	Boston	Chicago − AYAR	Memphis
Total Participants Screened	12	1	5	5	1
Eligible and enrolled	8/12 (67%)	1/1 (100%)	3/5 (60%)	3/5 (60%)	1/1 (100%)
Eligible/Not enrolled	0/12 (0%)	0/1 (0%)	0/5 (0%)	0/5 (0%)	0/1 (0%)
Ineligible	4/12 (33%)	0/1 (0%)	2/5 (40%)	2/5 (40%)	0/1 (0%)
Incomplete Screening	0/12 (0%)	0/1 (0%)	0/5 (0%)	0/5 (0%)	0/1 (0%)
Ineligible [1] participants who failed to meet one or more of the inclusion criteria					
Assigned male at birth (includes MSM, TGW, and gender non−conforming people)	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
At enrollment, aged below 18 years	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
At enrollment, body weight >= 35 kg (77 lbs.)	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
Willing to provide written informed assent/consent for the study and/or able to obtain written parental/guardian informed consent	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
Self−reported sexual activity with a male (oral or anal) in the past 12 months	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
Willing to undergo all required study procedures	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
Willing to stop PrEP (if currently on it), prior to enrollment and agree to switch to oral CAB for the lead−in period and CAB LA injections	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
In general, good health, as evidenced by the following laboratory values. Mark all that apply	2/4 (50%)	0/0 (−%)	1/2 (50%)	1/2 (50%)	0/0 (−%)
Non−reactive / negative HIV test results	1/4 (25%)	0/0 (−%)	1/2 (50%)	0/2 (0%)	0/0 (−%)
Absolute neutrophil count > 799 cells/mm3	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
Platelet count >= 100,000/mm3	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
Hemoglobin >= 11g/dL	1/4 (25%)	0/0 (−%)	0/2 (0%)	1/2 (50%)	0/0 (−%)
Calculated creatinine clearance >= 60 mL/minute using modified Schwartz equation (<= grade 2)	1/4 (25%)	0/0 (−%)	1/2 (50%)	0/2 (0%)	0/0 (−%)
Alanine aminotransferase (ALT) < 2.0 times the upper limit of normal (ULN) and total bilirubin (Tbili) <= 2.5 x ULN	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
Hepatitis B virus (HBV) surface antigen (HBsAg) negative and accepts vaccination	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
HCV Antibody negative	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
Ineligible [1] participants who met one or more of the exclusion criteria					
Co−enrollment in any other HIV interventional research study or other concurrent studies	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
Currently receiving PrEP from a non−study source	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
Past or current participation in HIV vaccine trial with exception for participants who can provide documentation of receipt of placebo	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
Exclusively had sex with biological females in lifetime	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
In the last 6 months (during screening): self−reported unprotected anal intercourse with someone known to be HIV−infected	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
In the last 6 months (during screening): self−reported illicit injection drug use of any kind or stimulant use	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
In the last 6 months (during screening): active or planned use of any substance use which would hinder study participation	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
In the last 6 months (during screening): self−report of > 5 different sexual partners (anal or vaginal)	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
Known history of clinically significant cardiovascular disease	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
Inflammatory skin conditions that compromise the safety of intramuscular (IM) injections	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
Tattoo or other dermatological condition overlying the buttock region that may interfere with interpretation of injection site reactions	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
Current or chronic history of liver disease or known hepatic or biliary abnormalities	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
Known history of clinically significant bleeding	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
Surgically−placed or injected buttock implants or fillers, per self−report.	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
A history of seizure disorder, per self−report	1/4 (25%)	0/0 (−%)	0/2 (0%)	1/2 (50%)	0/0 (−%)

[1] Participants could have multiple reasons for not being enrolled.
Source: SCHARP (Calins) − /trials/hptn/p083−01/analysis/atlas/code/open/t_screening_summary.sas, SAS Version 9.4 (18JUL2023,13:58)

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Medical, social, or other condition that would interfere with the conduct of the study or the safety of the participant	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)
Plans to move out of the geographic area within the next 18 months or otherwise unable to participate in study visits	0/4 (0%)	0/0 (−%)	0/2 (0%)	0/2 (0%)	0/0 (−%)

[1] Participants could have multiple reasons for not being enrolled.
Source: SCHARP (Calins) − /trials/hptn/p083−01/analysis/atlas/code/open/t_screening_summary.sas, SAS Version 9.4 (18JUL2023,13:58)