

Schedule of Events – Combination Prevention Arm (PrEP)																												
Study Visit	PICT (a)	PICT (b)	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12	V13	V14	V15	V16	V17	V18	V19	V20	V21	V22	V23	V24	V25	V26 EOS	
Study Month	-1		M0	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	M13	M14	M15	M16	M17	M18	M19	M20	M21	M22	M23	M24	
HCT (by RAPID test)	X			X		X			X			X			X			X			X			X			X	
Invitation to participate	X																											
Provide study information	X																											
Decline study participation	SoC																											
Informed consent process		X																										
TB assessment		X				X			X			X			X			X			X			X			X	
Syphilis test		X																										
STI assessment (+ as indicated)		X																										
Pregnancy assessment (+ as indicated)		X																										
Vitals		X																										
Medical History		X																										
Physical examination (+ as indicated)		X																										
Pap Smear (+ as indicated)																												
Confirmation of HIV ELISA (+ as indicated) ^a																												
Hepatitis B antigen		X																										
Creatinine clearance (Cockcroft-Gault formula)		X		X		X			X			X			X			X			X			X			X	
Full Blood Count (+ as indicated)																												
Plasma storage (drug level + resistance)		X				X			X			X			X			X			X			X			X	
Behavioural Questionnaire ^b		X				X			X			X			X			X			X			X			X	
Eligibility assessment		X																										
Confirmation of eligibility			X																									
Adherence Counselling			X			X			X			X			X			X			X			X			X	
Study medications dispensed			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Adverse event monitoring (+ as indicated)			X			X			X			X			X			X			X			X			X	
Study medications accountability			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

^a HIV Elisa will be performed to confirm HIV status and for quality control

^b Expanded questionnaire at 6mo, 12mo, 18mo and 24mo

Note: PICT (a) refers to HIV testing and consent, (b) refers to screening, history, and questionnaire; pregnancy screening includes test if indicated

Schedule of Events – Immediate Treatment Arm (ITx)																												
Study Visit	PICT (a)	PICT (b)	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12	V13	V14	V15	V16	V17	V18	V19	V20	V21	V22	V23	V24	V25	V26 EOS	
Study Month	-1		0	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	M13	M14	M15	M16	M17	M18	M19	M20	M21	M22	M23	M24	
HCT (by RAPID test)	X																											
Invitation to participate	X																											
Provide study information	X																											
Decline study participation	SoC																											
Informed consent process		X																										
TB assessment		X																										
STI assessment (+ as indicated)		X																										
Syphilis test		X																										
Pregnancy assessment (+ as indicated)		X																										
Vitals		X																										
Medical History		X																										
Physical examination (+ as indicated)		X																										
Pap smear (+ as indicated)																												
Confirmation of HIV ELISA		X																										
Hepatitis B antigen		X																										
Creatinine clearance (Cockcroft-Gault formula)		X				X			X						X												X	
Plasma HIV-1 RNA (viral load) ^a		X							X						X												X	
CD4 cell count		X													X												X	
Full Blood Count (+ as indicated)																												
Plasma storage (resistance)		X				X			X			X			X			X			X			X			X	
Behavioural Questionnaire ^b		X				X			X			X			X			X			X			X			X	
Eligibility assessment		X																										
Confirmation of eligibility			X																									
Adherence Counselling			X			X			X			X			X			X			X			X			X	
Study medications dispensed			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Adverse event monitoring (+ as indicated)			X			X			X			X			X			X			X			X			X	
Study medications accountability			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

^aexpanded questionnaire at 6mo, 12mo, 18mo and 24mo

^bViral load monitoring may increase if viral increases, consult current national guidelines. Final viral load will be done at exit or M24, whichever comes first.

Note: PICT (a) refers to HIV testing and consent, (b) refers to screening, history, and questionnaire; pregnancy screening includes test if indicated