Urine Tenofovir Point-of-care Test to Identify Patients in Need of ART Adherence Support (UTRA Study)

NCT05333679

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STATISTICAL ANALYSIS:

SAMPLE SIZE:

We assessed sample size based on the primary effectiveness outcome of this pilot RCT e.g. sustained virologic suppression with real-time monitoring via the urine assay and adherence counselling in the intervention arm compared to the standard-of-care adherence counselling arm. We expect 80% suppression (VL<50 copies/mL) in the control group; a sample size of 200 (intervention and control) will enable us to detect an increase in suppression to 93% with 80% power. Our actual precision will likely be better because of multiple observations per person and the contribution of within-person changes to the overall estimate.

PRIMARY OUTCOME

The primary outcome is the proportion of participants in each arm achieving viral suppression to <50 copies/ml by month 12.

SECONDARY OUTCOME

Secondary outcomes include retention in care at month 12; viral suppression (<50 copies/mL) at month 6; and feasibility and acceptability measured at enrollment, and months 6 and 12 with standardized questionnaires.

ANALYSIS PLAN

We will assess the suppression rates (VL< 50 copies/mL) in both study arms using an intention-to-treat analysis. Missing values for suppression will be imputed using chained equations which will include the history of previous suppression and dispensation and will also include baseline characteristics such as sex and age. The suppression and retention analysis will be analyzed by logistic regression extension of generalized estimating equations with a robust variance estimate.