Connecting Resources for Urban Sexual Health
NCT02183909
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Statistical Analysis Plan

Descriptive statistics (frequencies, means, medians) will be used to characterize endpoint variables. Univariate tests of association (T test, Chi square) will be used to test for association between demographic variables and key endpoints such as adherence, early cessation of regimen, and frequency of adverse events, as well as between assigned PEP regimen and these endpoints. Changes in quality of life will be tested for association with early regimen cessation and with assigned PEP regimen. Changes in serum creatinine will be summarized with descriptive statistics (mean, standard deviation) and compared to historical data from clinical trials.

Secondary Endpoints(s):
- To assess the renal safety or Stribild® or Genvoya® or unbranded elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide PEP
- To document the side effect profiles of Stribild® or Genvoya® or unbranded elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide given as PEP to HIV-1 seronegative adults
- To assess adherence to Stribild® or Genvoya® or unbranded elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide PEP in a high risk population of HIV-1 seronegative adults
- Early cessation of regimen
- Frequency of adverse events
- Change from baseline in quality of life
- HIV-1 seroconversion
- Change from baseline in serum creatinine and eGFR
- Markers of proximal tubulopathy (glycosuria, proteinuria > 1+)
- Self-reported adherence
- Reasons for non-adherence