Abstract

Background

Prospective clinical trial data regarding routine HIV-1 viral load (VL) monitoring of antiretroviral therapy (ART) in non-research clinics of Sub-Saharan Africa are needed for policy makers.

Methods

CLinic-based ART Diagnostic Evaluation (CLADE) is a randomized, controlled trial (RCT) evaluating feasibility, superiority, and cost-effectiveness of routine VL vs. standard of care (clinical and immunological) monitoring in adults initiating dual nucleoside reverse transcriptase inhibitor (NRTI)+non-NRTI ART. Participants were randomized (1:1) at 7 predominately rural, non-research, district-level clinics of western Kenya. Descriptive statistics present accrual patterns and baseline cohort characteristics.

Results

Over 15 months, 820 adults enrolled at 7 sites with 86ï 152 enrolled per site. Monthly site enrollment ranged from 2ï 92 participants. Full (100%) informed consent compliance was independently documented. Half (49.9%) had HIV diagnosed through voluntary counseling and testing. Study arms were similar: mostly females (57.6%) aged 37.6 (SD = 9.0) years with low CD4 (166 [SD = 106]) cells/m^3). Notable proportions had WHO Stage III or IV disease (28.7%), BMI <18.5 kg/m^2 (23.1%), and a history of tuberculosis (5.6%) or were receiving tuberculosis treatment (8.2%) at ART initiation. In the routine VL arm, 407/409 (99.5%) received baseline VL (234,577 SD = 151,055 copies/ml). All participants received lamivudine; 49.8% started zidovudine followed by 38.4% stavudine and 11.8% tenofovir; and, 64.4% received nevirapine as nNRTI (35.6% efavirenz).

Conclusions

A RCT can be enrolled successfully in rural, non-research, resource limited, district-level clinics in western Kenya. Many adults presenting for ART have advanced HIV/AIDS, emphasizing the importance of universal HIV testing and linkage-to-care campaigns.