

Original Research Article

Excellent retention, virologic and clinical outcomes after transitioning from an antiretroviral treatment clinical trial to locally-provided care and treatment in Africa

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ABSTRACT

Background: Little is known about outcomes among clinical trial participants following completion of study-provided care and treatment in resource limited settings. We sought to describe outcomes among HIV clinical trial participants after transitioning to local routine care in Africa.

Methods: In the OCTANE study, 741 women with CD4 <200 cells/mm³ in 7 African countries were randomized to initiate antiretroviral treatment (ART) with tenofovir/emtricitabine (TDF/FTC) plus either lopinavir/ritonavir (LPV/r) or nevirapine (NVP). When study-specified ART ended (48-191 weeks after study entry), participants transitioned to locally-provided HIV care and non-study ART. Consenting participants were interviewed and had toxicity labs, CD4 and HIV-1 RNA testing, and clinical outcomes assessed at 12 and 72 weeks after transition to local care.

Results: Five hundred thirteen (77%) of the 669 women in follow-up at completion of the interventional trial participate in the extended follow-up. 513 women, 476 (93%) had HIV-1 RNA <400 cp/mL at time of transition, and 489 (95%) completed follow-up. Seventy-seven women (19%) had a total of 99 antiretroviral regimen changes during post-trial follow-up. 30% of the 99 regimen changes-were due to lack of local drug availability. Thirteen (3%) women had Grade ≥3 laboratory abnormalities and 3 experienced worsening of the WHO HIV stage. Two women died. Eighty-nine percent of 484 with results had HIV-1 RNA ≤400 cp/mL at 72 weeks after transition to local non-study HIV care and treatment.

Conclusions: The vast majority of women were able to continue key components of their ART and to maintain virologic suppression through 72 weeks of locally-provided post-study care.

Trial registration: ClinicalTrials.gov NCT00089505

Keywords: HIV, Antiretroviral therapy, Post clinical trial care, Resource limited settings

INTRODUCTION

In 2015, approximately 13.5 million (85%) of the 15.8 million persons receiving antiretroviral treatment (ART) resided in resource limited settings (RLS), including 10.7 million in sub Saharan Africa alone.¹ This added burden to the healthcare infrastructure in RLS has prompted decentralization and task-shifting of HIV care and ART to improve access and efficiency.²⁻⁴ Given the burden of HIV in RLS, it is critical to conduct ethical clinical trials in these settings in order to answer locally relevant questions, and to understand the efficacy and tolerability of treatments in diverse populations. Ideally, following the end of a clinical trial, participants should receive treatment of comparable quality.⁵⁻¹¹ Even when a drug or treatment offered in a clinical trial is theoretically accessible to a population, little is known about its actual dissemination and uptake after trial completion in the setting of routine local standard of care. Clinical trials are sometimes conducted in specialized research clinics that are better resourced.⁵ Local non-study laboratory monitoring, equipment and human resources may be particularly limited. Patient and structural factors such as willingness to attend a clinic, transportation barriers, and cost of care may also constitute barriers to ongoing care. Ancillary care that is sometimes provided as part of a clinical trial can be an important motivator for trial participants and may be less accessible after transition to local SOC which may affect retention in HIV care.⁶

We therefore prospectively assessed outcomes among HIV-1-infected African women as they transitioned from an ART clinical trial, the ACTG A5208 (optimal combination therapy after nevirapine exposure [OCTANE]) study, to routine non-study supported HIV care.

METHODS

OCTANE was a Phase III study comprising two concurrent, randomized, open-label linked ART trials (referred to as “Trial 1” and “Trial 2”). The two trials were designed to evaluate the hypothesis that prior single dose nevirapine (sdNVP) prophylaxis used for the prevention of mother- to- child transmission (PMTCT) of HIV compromises the subsequent virologic response to non-nucleoside reverse transcriptase inhibitor (NNRTI)-based treatment when mothers need ART for their own health. In brief, 741 women were enrolled into the OCTANE study. All study participants signed an informed consent before study participation. The manuscript was reviewed and signed off by all authors. Trial 1 was conducted among 241 women who had taken sdNVP for PMTCT at least 6 months prior to trial enrollment. The trial was designed to test the superiority of lopinavir/ritonavir (LPV/r)-based ART over NVP-based ART. However, the implication of any difference found in Trial 1 needed to be evaluated in the context of the magnitude of difference, if any, between LPV/r-and NVP-based regimens in women with no prior exposure to

sdNVP. Thus Trial 2 was conducted among 500 women without prior sdNVP exposure and was designed to test the equivalence of LPV/r-containing ART with NVP-containing ART. OCTANE study methods have been described previously.^{13,14}

HIV-1-infected women at least 18 years of age who were not pregnant or breastfeeding were consented and enrolled at ten sites in seven African countries (three sites in South Africa; two in Kenya; and one each in Zimbabwe, Botswana, Zambia, Malawi, and Uganda). Participants had screening CD4+ cell count (CD4) less than 200 cells/mm³ and were ART-naïve (with the exception of sdNVP exposure in Trial 1 participants; up to 10 weeks of prior zidovudine [ZDV] exposure was permitted in both Trials). Additional eligibility criteria have been previously published.^{13,14}

At study entry, participants in both trials were randomized to receive either NVP or lopinavir/ritonavir (LPV/r), each in combination with tenofovir (TDF) plus emtricitabine (FTC) (co-formulated as Truvada). In cases of virologic failure or toxicity, participants could switch from NVP to second-line treatment with LPV/r or vice versa, at the discretion of local investigators. Zidovudine (ZDV) and didanosine (DDI) were also study provided. EFV, provided by the study, was temporarily substituted for NVP and LPV/r during rifampin-containing tuberculosis treatment and for 30 days after stopping rifampin. Women re-started NVP or LPV/r (their pre-TB treatment ART regimen) 30 days after completion of TB treatment. Prior to initiating the OCTANE trial, each site was required to provide written assurance that participants would be able to access ART locally, at the completion of the trial. The OCTANE study was approved by all relevant local and US institutional review boards and other relevant country-specific regulatory committees. The ClinicalTrials.gov identifier was NCT00089505.

All participants were followed in the clinical trial until 48 weeks after the last participant was enrolled (with provision of study drug during that period). Therefore, participants had different follow-up times on-trial, depending on when they enrolled. The primary study end point was time to virologic failure (defined as confirmed plasma HIV-1 RNA level less than 1 log₁₀ cp/mL below baseline at 12 weeks or confirmed HIV-1 RNA level at least 400 cp/mL at 24 weeks or longer after treatment start) or death. Clinical assessments, hematology and chemistry, adherence (through self-reported missed doses in the past 4 days and pill counts), CD4 cell count and HIV-1 RNA tests were evaluated at baseline and throughout the study.

The protocol was amended 18 weeks to the completion of study-provided ART to include evaluation of outcomes after participants were transitioned to local non-study-provided HIV care and ART programs (using generic and/or brand drugs). This post-trial follow-up is the focus

of the analysis presented in this paper. Participants provided written informed consent for extended post-trial follow-up. Consenting participants were evaluated at 12, 48 and 72 weeks after transition to local care had occurred (in person at the local research site at 12 and 72 weeks, and either in person or by phone interview at 48 weeks). Information on type and location of care, clinical outcomes, CD4 count, HIV-1 RNA and hematology and chemistry laboratory tests was collected.

RESULTS

Of the 741 participants who started randomized ART in the OCTANE study, 669 (90%) were still in follow-up when study-provided ART ended. The remaining 72 participants had died (20; [3%]) or had been lost to follow-up (52; [7%]).

Five hundred and thirteen (77%) of the 669 participants in follow-up when study-provided ART ended were enrolled for post-trial follow-up after transition to locally provided HIV care/ART. Because of delays in obtaining the necessary ethical and regulatory approvals, one site in South Africa did not enroll any participants and two other sites in South Africa enrolled about half of participants still in trial follow-up. At the other 7 sites at which timely regulatory approvals were obtained, between 84% and 100% of participants still in trial follow-up were enrolled in post-trial follow-up. The proportions of eligible participants who enrolled in post-trial follow-up were similar for both trials (75% for Trial 1 and 77% for Trial 2) and for randomization arms (77% for both NVP and LPV/r arms) as seen in Figure 1.

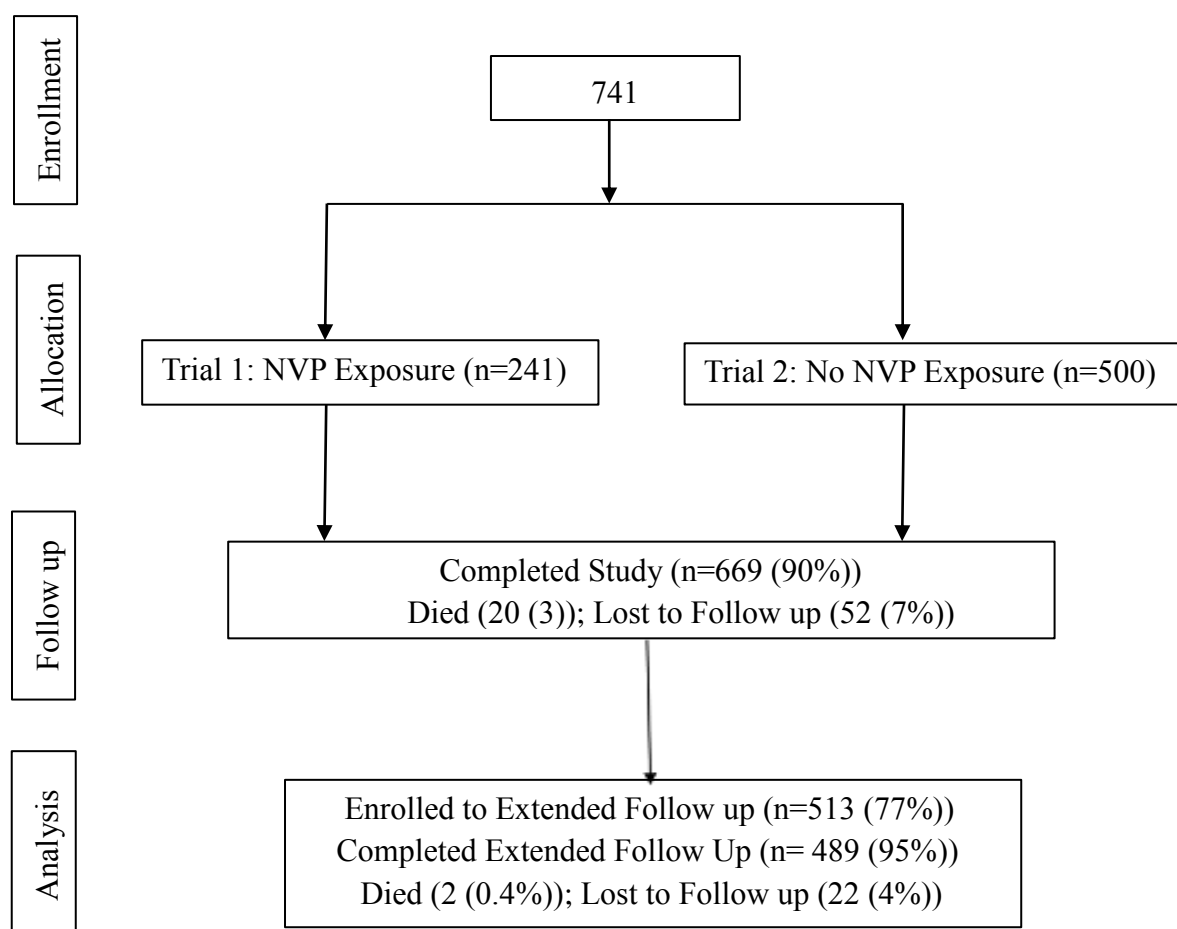


Figure 1: The OCTANE study consort diagram.

Characteristics of participants (at the time of original enrollment to the randomized trials) were similar as in Table 1 for those who did/did not enroll into post-trial follow-up, except that those who enrolled were on average approximately one year older (34 compared to 33 years). After exiting the trial, participants received local non-study provided HIV care and treatment at 57 health facilities including: health centers (n=24, 42 %); district (n=9, 16%), regional (n=6, 11%), missionary (n=5, 9%)

and national (n=2, 4%) hospitals; and others (n=11, 19%). The proportion of participants seen in each type of health facility was: health centers (49%), national (14%), district (8%), regional (4%), missionary (2%) hospitals and others (23%). In these local non-study funded health facilities, the participants were managed by nurses (39%), physicians (33%), clinical officers (26%), or counselors (2%). Routine care visits at most health facilities occurred every 3 months or less, except for 8 facilities where visits were symptom-based and 2 facilities where

visits were scheduled every 6 months. Forty-eight facilities (84%) monitored CD4 cell counts every 3 or 6 months during ART including 18 (32%) that also monitored HIV-1 RNA every 3 or 6 months; the remainder did not have routine monitoring of either CD4 count or HIV-1 RNA. Twelve (21%) clinics had HIV

drug resistance testing available, including 4 (7%), 11 (19%) and 9 (16%) which tested at failure of first, second and third line regimens, respectively. Thirty-two facilities (56%) undertook hematology, liver function and creatinine toxicity monitoring every 3 or 6 months; the remainder measured these as clinically indicated.

Table 1: Pre-ART (pre-trial baseline) characteristics in women taking part in post-trial follow-up care (N=513).

Characteristic	Mean (SD) or Number (%)
Age (years)	34 (7)
Baseline CD4 (cells/mm ³)	130 (68)
HIV-1 RNA (log ₁₀ copies/ml)	5.07 (0.63)
WHO HIV stage (%)	
I	212 (41)
II	150 (29)
III	135 (26)
IV	16 (3)
Hepatitis B surface antigen positive (%)	38 (7)
Prior single dose NVP exposure (%)	161 (31)
Pre-ART NVP resistance* (%)	19 (12)
Most common HIV subtypes* (%)	
A1	29 (18)
C	102 (64)

* From Trial 1 participants only (N=160)

Table 2: Outcomes in 513 women participating in post-trial follow-up.

Type of regimen	n (at end of study-provided ART)	n (after transition)	n (%) changing this regimen after transition	n (%) missing ≥1 day ART in 4 days prior to wk 72 interview (n=504)	Mean CD4 increase at 72 wks (cells/mm ³) (n=483 values)	HIV-1 RNA <400 cp/mL at 72 wks after transition (n,%) (n=484 values)
NVP-containing	189	196	6/196 (3%)	1/191 (1%)	26	158/180 (92%)
LPV/r-containing	313	298	6/298 (2%)	9/295 (3%)	32	250/287 (87%)
EFV-containing	10	19	5/19 (26%)	1/18 (6%)	93	17/17 (100%)
Overall	513*	513	17/513 (3%)	11/504 (2%)	32	432/484 (89%)

*1 participant was on zidovudine/lamivudine+TDF

At the time of ending study-provided ART, 313 (61%), 189 (37%) and 10 (2%) of the 513 women were taking LPV/r, NVP- and EFV-containing ART, respectively, and 1 woman was taking a regimen of nucleoside reverse transcriptase inhibitors (NRTIs) only.; 467 (91%) were also still taking TDF/FTC and a further 13 (3%) were taking TDF with another NRTI. After transition to locally-provided ART, most women continued the LPV/r or NVP that they were taking when completing the period of study-provided drug: 295 (94%) of the 313 continued LPV/r and 185 (98%) of the 189 continued NVP. Furthermore, 433 (91%) of the 480 women taking TDF at the end of study-provided ART were able to continue TDF in combination with other antiretrovirals. However, of the 467 taking TDF/FTC at the end of study-provided ART, only 151 (32%) continued TDF/FTC while 257 (55%) changed to TDF in combination with lamivudine

(3TC). Limited local availability of TDF/FTC was the most common reason for its discontinuation (in 32% of the 57 study clinics). The remaining 59 (13%) women taking TDF/FTC at the end of study-provided ART switched to d4T/3TC (n=37) or ZDV/3TC (n=22).

Overall, after transition to local care, the locally-provided regimen included LPV/r for 299 (58%) of the 513 women, NVP for 196 women (38%), and EFV for the other 18 women (4%). The most common NRTI components of the ART taken after transition to local care were TDF/3TC for 262 women (51%) and TDF/FTC for 152 women (30%).

Of the 513 women followed after transition to local care, 489 (95%) completed 72 weeks of follow-up; 22 women (4%) were lost to follow-up and the remaining 2 women

died (both had emergency caesarean section, one due to abruptio placenta and the other due to pulmonary embolism and pulmonary hypertension).

During post-trial follow up, 77 (15%) women had modifications to at least 1 antiretroviral drug, including 62 (12%) for whom only one NRTI was altered. There were few changes in antiretrovirals other than NRTIs during follow-up: only 6 (2%) of 299 women changed from LPV/r, and only 6 (3%) of 196 women changed from NVP. Among the 77 women with changes, a total of 99 antiretroviral regimen changes occurred. The most common reasons for these regimen changes were: drug stock-out (30%), pregnancy (21%), newly-available medication (13%), adverse event (10%), operational error (6%), virologic failure (3%), and need for concomitant tuberculosis treatment (3%). The adverse events prompting antiretroviral change included four participants with lipodystrophy, four with neuropathy, one with lactic acidosis and one increased creatinine. Overall 11/504 (2%) of participants reported missing to take ARVs for more than one day, four days prior to week 72 interview.

At the end of study-provided ART as given in Table 2, 476 (93%) of the 513 women had HIV-1 RNA \leq 400 copies/mL. Among women with results available, the virologic suppression rate remained high during follow-up: 459 (92%) of 499 women and 432 (89%) of 484 women had HIV-1 RNA \leq 400 copies/mL at 12 and 72 weeks after transition to local care, respectively. The rates were similar among women who were on locally-provided LPV/r- and NVP-containing regimens initially after transitioning to local care (87% and 92% at 72 weeks, respectively). CD4 count remained stable during the 72 weeks of follow-up after transition to local care increasing by a mean of 32 cells/mm³ [95% CI: 16, 48 cells/mm³] to 458 cells/mm³, with similar mean changes for locally-provided LPV/r and NVP-containing regimens (32 and 26 cells/mm³, respectively). Only 3(0.5%) of 513 women experienced worsening WHO HIV stage during the 72 weeks of follow-up: one woman from stage II to stage III and two women from stage III to stage IV.

At the end of 72 weeks of follow up, after transition to local care, women experienced a small increase in BMI (mean 0.6 kg/m², among women starting locally-provided LPV/r and 0.7 kg/m² among women starting locally-provided NVP) and a small decline in total cholesterol (mean 4.4 mg/dL and 3.1 mg/dL, respectively).

A total of 68 women reported 94 new diagnoses (excluding pregnancies/pregnancy outcomes) during the 72 weeks of follow-up. The most common new diagnoses (affecting 4 or more women) were: malaria (12 women), pulmonary tuberculosis (9), eye, ear, nose disease (6), vulvovaginal candidiasis (5), hematologic disease (n=4) and bacterial pneumonia (n=4). Fifty one women became pregnant during post-trial follow-up.

Thirteen (3%) of the 513 women had Grade 3 or 4 laboratory test abnormalities at the study evaluations at weeks 12 and/or 72, including 7 with neutropenia, 5 with anemia, 1 with lactic acidosis, and 1 with hypoalbuminemia (who also had anemia).

DISCUSSION

We found that after transitioning from a clinical trial to locally-provided care and treatment, the vast majority of women enrolled in an ART trial in 7 sub-Saharan African countries were able to continue key components of their ART regimens, and exhibited excellent retention and virologic and immunologic outcomes through 72 weeks post-transition.

The ultimate goal of conducting a clinical trial is to help advance clinical care in the populations in which the trials are conducted.¹² Putting trial results into practice remains a daunting challenge in many resource constrained settings: treatment access and safety monitoring may not be consistently available as part of the local standard of care. There is however an obligation to protect research participants, and a general consensus that participants in HIV treatment trials should have continuing post-trial access to effective ART.¹⁵

A review of ART programs in 13 countries in sub-Saharan Africa found that median retention rates were only 86% at 6 months, and decreased to 80% at 12 months, 77% at 24 months, and 72% at 36 months.¹⁷ In 2015, the proportion of viral load tests with undetectable HIV-1 RNA in countries recently initiating routine viral load monitoring scale-up was 94% in Uganda, 86% in Namibia, 84% in Malawi, 83% in Kenya and 78% in South Africa.^{1,16,18} In the OCTANE study, after 72 weeks of follow up while receiving local SOC, and despite the fact that women were followed up in 57 different health facilities with varying capacities and monitoring programs, the retention rate was 95% (489 out of 513). Similarly the viral suppression rate was 89% (432 of the 484 of the women with measurements), thus demonstrating high retention and viral suppression rates in a decentralized health care delivery system with task shifting.

In summary, our findings provide encouraging evidence that HIV clinical trial participants in resource limited settings (women in sub-Saharan Africa in this instance) are able to transition relatively seamlessly to local care and treatment, and to maintain virologic suppression on locally-available ART.

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