|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | | **OLA-guided therapy (n=492)** | |  | **Standard of Care**  **(n=495)** | | |
| Clinic site | |  |  |  | |  |  |
| Nairobi, Ngong Rd | | 331 | (67%) |  | | 336 | (68%) |
| Nairobi, Industrial Area | | 42 | (9%) |  | | 48 | (10%) |
| Maseno | | 119 | (24%) |  | | 111 | (22%) |
| Female | | 320 | (65%) |  | | 321 | (65%) |
| Age (years) | | 38 (32-46) | |  | | 37 (30-45) | |
| 2-24 | | 33 | (7%) |  | | 53 | (11%) |
| 25-34 | | 152 | (31%) |  | | 162 | (33%) |
| 35-49 | | 224 | (45%) |  | | 215 | (43%) |
| ≥50 | | 83 | (17%) |  | | 65 | (13%) |
| Education, adults onlya | |  |  |  | |  |  |
| Less than primary | | 47 | (10%) |  | | 37 | (8%) |
| Primary | | 180 | (37%) |  | | 169 | (36%) |
| Secondary | | 131 | (27%) |  | | 141 | (30%) |
| Some College/Technical | | 123 | (26%) |  | | 123 | (26%) |
| Marital status, adults onlya | |  |  |  | |  |  |
| Single | | 91 | (19%) |  | | 73 | (15%) |
| Married/Committed relationship | | 263 | (55%) |  | | 270 | (58%) |
| Divorced/Separated/Widowed | | 127 | (26%) |  | | 127 | (27%) |
| Unemployed, adults onlya | | 51 | (11%) |  | | 41 | (9%) |
| Sexual partners in past yearb | |  |  |  | |  |  |
| None or never had sex | | 173 | (37%) |  | | 182 | (38%) |
| 1-2 | | 284 | (60%) |  | | 289 | (60%) |
| ≥3 |  | 12 | (3%) |  | | 12 | (2%) |
| ART-naïve | | 460 | (94%) |  | | 463 | (94%) |
| CD4 cells per uL | | 233 (116-311) | |  | | 231 (113-318) | |
| Plasma HIV RNA (log10 copies per µL) | | 10·8 (9·2-12·1) | |  | | 10·7 (9·1-11·8) | |
| % Resistance of mutation with highest frequency in individual’s HIV quasispeciesc | |  |  |  | |  |  |
| ≥10% | | 45 | (9%) |  | | 34 | (7%) |
| 2-9% | | 6 | (1%) |  | | 8 | (2%) |
| Wild-type | | 441 | (90%) |  | | 452 | (91%) | |
| ART regimen post-randomizationd | |  |  |  | |  |  | |
| Efavirenz | | 267 | (57%) |  | | 300 | (63%) | |
| Nevirapine | | 160 | (34%) |  | | 173 | (37%) | |
| Lopinavir/ritonavir | | 39 | (9%) |  | | 0 | (0%) | |
| Data are shown by absolute numbers, “n” (%) or median (IQR). aAdults only, OLA-guided therapy (n=481) and SOC (n=470); bDoes not include 35 responses categorized as “Don’t Know” or “Refused”; cPoint mutations (K103N, Y181C, G190A, M184V) detected by OLA; dART regimen base, OLA-guided therapy (n=466) and SOC (n=473); Abbreviations: OLA, oligonucleotide ligation assay | | | | | | | | |

***Table 1:*** Enrollment characteristics of the study population by randomization arm

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Pretreatment drug resistance: categorization and**  **mutant frequency** | **OLA-guided therapy** | | **Standard of Care** | |  | |
| **N tested** | **n (%) VF** | **N tested** | **n (%) VF** | | **p-value** |
| Total | 400 | 34 (9%) | 403 | 39 (10%) | | 0·56 |
| Wild-type; <2% | 361 | 28 (8%) | 372 | 24 (7%) | | 0·49 |
| Low frequency resistance; 2-9% | 4\* | 1 (25%) | 5\* | 2 (40%) | | 0·64 |
| Resistant; ≥10% | 35^ | 5 (14%) | 26\* | 13 (50%) | | <0·01 |
| Abbreviations: OLA, oligonucleotide ligation assay; VF, virologic failure; \*prescribed NNRTI-based ART; ^only participants prescribed 2nd-line PI-based ART | | | | | | |

***Table 2:*** Virologic failure (≥400 copies/µL) by randomization arm and HIV drug-resistance mutation frequency

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Pretreatment drug resistance: categorization and**  **mutant frequency** | **Nevirapine** | | **Efavirenz** | |  |
| **N** | **n (%) VF** | **N** | **n (%) VF** | **p-value** |
| Total | 273 | 39 (14%) | 497 | 29 (6%) | <0·01 |
| Wild-type; <2% | 258 | 30 (12%) | 472 | 22 (5%) | <0·01 |
| Pretreatment drug resistance | 15 | 9 (60%) | 25 | 7 (28%) | 0·05 |
| Low frequency resistance; 2-9%\* | 3 | 2 (67%) | 6 | 1 (17%) | 0·23 |
| Resistant; ≥10% | 12 | 7 (58%) | 19 | 6 (32%) | 0·14 |
| Abbreviations: VF, virologic failure; \* Fisher’s exact test | | | | | |

***Table 3:*** Virologic failure (≥400 copies/µL) by nevirapine- versus efavirenz-based antiretroviral therapy and pretreatment drug resistance

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Adverse event grades** | **OLA-guided therapy** | | **Standard of Care** | | | **p-value** |
| Grade 1 – Mild | 5 | (5%) |  | 2 | (2%) | 0.44 |
| Grade 2 - Moderate | 27 | (26%) |  | 24 | (23%) |  |
| Grade 3 – Severe | 36 | (34%) |  | 29 | (28%) |  |
| Grade 4 – Life Threatening | 3 | (3%) |  | 5 | (5%) |  |
| Grade 5 – Death | 34 | (32%) |  | 43 | (42%) |  |
| Abbreviations: OLA, oligonucleotide ligation assay | | | | | | |

***Table 4:*** Adverse events by randomization arm