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Subgroup Analysis of Dolutegravir/Lamivudine-in ART-Naïve Adults Living with HIV with CD4 counts below 200 cells/mL: Results from the DOLCE Study.

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PURPOSE

To assess the efficacy of DT (DTG/3TC) in antiretroviral therapy (ART)-naïve adults living with HIV with low CD4 counts, considering key baseline characteristics.

METHODS

- In the DOLCE open-label trial, ART-naïve adults were randomly allocated to Dual therapy (DT) or Triple therapy (TT). The intent-to-treat exposed (ITT-E) population included participants who received ≥1 dose of study medication (n=229).
- Efficacy was defined as the proportion of participants with plasma HIV-1 RNA <50 copies/mL at week 48 (FDA Snapshot algorithm).
- Subgroup analyses were conducted by sex, age, race, country, HIV-1 subtype, baseline viral load (VL), and CD4 count. Risk differences and 95% confidence intervals (CI) were calculated.

CONCLUSIONS

The dual regimen DTG/3TC showed efficacy comparable to DTG+TDF/XTC across subgroups in the ITT-E population. These findings support its use as initial therapy for naïve adults with HIV and advanced disease across key baseline characteristics.

RESULTS

- *Randomization resulted in 152 participants in the DT group and 77 in the TT group. The overall sample was composed of 75.5% males and 24.5% females. The majority of participants (80.3%) were under the age of 50. In terms of ethnicity, 46.3% identified as Hispanic-Latino, Mixed, or Native, while 38.9% identified as White*
- *At baseline, 23.1% had VL≥500,000 c/mL, 10.0%≥1,000,000 c/mL; and 43.6% ≤100 CD4/mL; 62.0% had HIV-1 subtype B, and 25.8% subtype BF.*
- *Overall efficacy was similar in both arms: 82.2% (DT); 80.5% (TT); difference: 1.7% (95%CI: 9.0%;12.4%). Efficacy was consistent across subgroups. Participants with baseline VL ≥ 500,000 c/mL, 74.3% in DT and 66.7% in TT achieved HIV-1 RNA <50 c/mL (difference:7.6%; 95% CI: -18.5 %;33.8%).*
- *In those with CD4 ≤100 cells/mL, efficacy was 85.5% (DT) vs. 75.9% (TT) (difference: 9.6%; 95% CI: -8.0%-27.3 %). Among women, 82.9% (DT) vs. 85.7% (TT) (difference: -2.8%; 95% CI: -22.3%-16.6%); among men, 82.1% (DT) vs. 78.6% (TT) (difference: 3.5%; 95% CI: - 9.3%-16.3 %).*
- *Response rates were also similar across age groups, race, country, and HIV-1 subtypes, with no statistically significant differences (table 1)*

Proportion of participants with Plasma HIV-1 RNA < 50 copies/mL at week 48. Snapshot outcomes by subgroups - ITT-E Population efficacy.

Subgroup		TT Arm	DT Arm	Treatment Difference (95% CI)
Overall		62/77 (80.5%)	125/152 (82.2%)	1.7% (-9.0% ; 12.4%)
Sex	Female	18/21 (85.7%)	29/35 (82.9%)	-2.8% (-22.3% ; 16.6%)
	Male	44/56 (78.6%)	96/117 (82.1%)	3.5% (-9.3% ; 16.3%)
Age	< 50	48/61 (78.7%)	100/123 (81.3%)	2.6% (-9.8% ; 15.0%)
	=>50	14/16 (87.5%)	25/29 (86.2%)	-1.3% (-21.8% ; 19.2%)
Race	White	32/37 (86.5%)	46/52 (88.5%)	2.0% (-12.0% ; 16.0%)
	Black	7/9 (77.8%)	23/25 (92.0%)	14.2% (-14.9% ; 43.4%)
	Other (Native, Hispanic-Latino/Mixed)	23/31 (74.2%)	56/75 (74.7%)	0.5% (-17.8% ; 18.7%)
Country	Argentina	34/38 (89.5%)	64/77 (83.1%)	-6.3% (-19.2% ; 6.5%)
	Brazil	28/39 (71.8%)	61/75 (81.3%)	9.5% (-7.1% ; 26.2%)
Genotype sub-type	B	40/51 (78.4%)	75/91 (82.4%)	4.0% (-9.7% ; 17.7%)
	BF	15/17 (88.2%)	33/42 (78.6%)	-9.7% (-29.4% ; 10.0%)
	Other	7/9 (77.8%)	17/19 (89.5%)	11.7% (-18.8% ; 42.2%)
VL at baseline	< 500000 c/mL	50/59 (84.7%)	99/117 (84.6%)	-0.1% (-11.4% ; 11.1%)
	=>500000 c/mL	12/18 (66.7%)	26/35 (74.3%)	7.6% (-18.5% ; 33.8%)
	< 1000000 c/mL	58/70 (82.8%)	115/136 (84.6%)	1.7% (-9.0% ; 12.4%)
	=>1000000 c/mL	4/7 (57.1%)	10/16 (62.5%)	5.4% (-38.3% ; 49.0%)
CD4 count at baseline	<= 100	22/29 (75.9%)	59/69 (85.5%)	9.6% (-8.0% ; 27.3%)
	>100	38/45 (84.4%)	66/82 (80.5%)	-3.9% (-17.6% ; 9.7%)

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