

Poster presentation

The TOKEN study: safety and efficacy of Truvada or Kivexa in combination with efavirenz in treatment-naïve predominantly black African HIV patients

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Background

The safety and efficacy of tenofovir and emtricitabine co-formulated tablet Truvada has been compared with abacavir and lamivudine co-formulated tablet Kivexa in treatment-naïve HIV patients.

Methods

We collected information about HIV patients starting treatment with Truvada or Kivexa in combination with efavirenz from Jan. 2006 to Dec. 2006 with follow up through 48 weeks. Viral load (VL), CD4 count, fasting lipid profile, and estimated GFR (Cockcroft-Gault) were measured at baseline and every 12 weeks.

Summary of results

Of 139 patients, 81 were on Truvada and 58 on Kivexa. Most were black African (69%), mean age 38.1 (+/- 8.1) years and 50.3% were female. Mean baseline VL was 5.4 (+/- 5.6) log₁₀ copies/ml and CD4 count 172 (+/- 84) cells/mm³ of blood. One patient in the Truvada arm and one in the Kivexa discontinued for possible side-effects. Patients on Kivexa were HLA-B* 5701 negative. At 48 weeks, on intention-to-treat analysis, VL suppression below 400 copies/ml in Truvada and Kivexa arms were 93.5% and 96.2% (p = 0.1) and below 40 copies in 83.3% and 85.1% (p = 0.6), respectively. Mean rise in CD4 count was similar in both groups. Results were not predicted by baseline VL. Increase in serum total cholesterol (TC) was

higher in Kivexa (p = 0.04), but triglycerides (TG), HDL-cholesterol (HDL), TC/HDL and e-GFR were not different (Table 1).

Conclusion

Truvada and Kivexa in combination with efavirenz in treatment-naïve predominantly black African patients are safe and effective.

Table 1: Mean (+/- SD) serum lipids and e-GFR.

		TC mmol/l	TG mmol/l	HDL mmol/l	TC/HDL	e-GFR ml/min
Truvada	Baseline	4.0 (0.9)	1.3 (0.8)	1.2 (0.4)	3.6 (1.9)	104.7 (24.0)
	48 weeks	4.2 (0.9)	1.3 (0.9)	1.5 (0.5)	3.3 (1.1)	108.3 (36.5)
Kivexa	Baseline	4.4 (0.8)	1.5 (1.0)	1.1 (0.3)	3.8 (1.1)	104.8 (30.0)
	48 weeks	5.0 (1.0)	1.5 (1.0)	1.7 (0.8)	3.3 (1.2)	117.3 (31.7)
p-values		0.04	0.7	0.7	0.3	0.1

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