Journal of the International AIDS Society



Poster presentation

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Efficacy and safety of tenofovir/emtricitabine compared to abacavir/lamivudine in HIV-I infected patients in clinical setting. The TEAL study

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from Ninth International Congress on Drug Therapy in HIV Infection Glasgow, UK. 9–13 November 2008

Published: 10 November 2008

Journal of the International AIDS Society 2008, 11(Suppl 1):P79 doi:10.1186/1758-2652-11-S1-P79

This abstract is available from: http://www.jiasociety.org/content/11/S1/P79

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Background

Limited direct comparative data exist between the recommended dual NRTI fixed dose combinations, tenofovir/emtricitabine (Truvada) and abacavir/lamivudine (Kivexa). A recent study (HEAT) evaluated these dual NRTI backbones with a boosted PI. However, there are no data comparing these two formulations when used with other antiretroviral drugs.

Methods

Retrospective study of HIV-1 infected patients in two Genito-Urinary Medicine clinics. Patients taking either Truvada or Kivexa were included. Data including previous treatment, resistance test, HLA B5701 status, pre-treatment CD4 count, plasma viral load, age, ethnicity, renal function, lipid profiles were gathered. Primary endpoint was the proportion of subjects with viral load <50 copies/ml at 48 weeks.

Summary of results

232 patients were included, of which 129 were on Truvada and 103 on Kivexa; 114 were treatment naive. (Tables 1 and 2.)

Conclusion

Truvada was non-inferior to Kivexa in this cohort. However, virological failure was observed in three patients when Kivexa was used with an NNRTI. Median CD4 increase was greater in Truvada arm at 48 weeks but this was not statistically significant. Further data will be presented at the meeting.

Table I:

	Truvada	Kivexa	p-value
Total number	129	103	
Male	119 (92.3%)	96 (93.2%)	0.78
Female	10	7	
Age (median, IQR)	38 (32.43)	38 (32.43)	
Ethnicity	,	, ,	
African	28 (21.7%)	39 (37.9%)	0.001
Causcasian	95 (73.6%)	55 (50.5%)	0.001
Other	6 (4.7%)	12 (11.6%)	0.001
Smoker	51 (42.5%)	31 (30.4%)	0.06
History of cardiovascular event	5 (3.9%)	4 (3.9%)	0.63
Hypertensive	9 (7.0%)	13 (12.6%)	0.14
Diabetic	3 (2.3%)	6 (5.8%)	0.14
HBV co-infected	13 (10.1%)	I (I.0%)	0.02
HCV co-infected	I (0.8%)	4 (3.9%)	0.27
AIDS diagnosis	26 (20.2%)	19 (18.5%)	0.74
ART experienced	63 (48.8%)	53 (51.5%)	0.74
Current drug			
PI	32 (24.8%)	19 (18.5%)	0.25
NNRTI	97 (75.2%)	84 (81.6%)	
Baseline laboratory markers			
CD4 (cells/mm3) median	235	228	0.49
Viral load (log copies/ml) median	4.5	3.8	0.07
Cholesterol (mmol/l) median	4.3	4.5	0.05
HDL (mmol/l) median	1.1	1.2	0.52
Triglyceride (mmol/l) median	1.4	1.3	0.59
GFR	110	107	0.14

Table 2: Week 48 results (ITT-E, Missing = excluded).

	ARV experienced	ARV experienced	ARV experienced	ARV naive	ARV naive	ARV naive
	Truvada (n = 60)	Kivexa (n = 53)	p-value	Truvada (n = 64)	Kivexa (n = 50)	p-value
Viral load <50 copies/ml	47/49 (95.9%)	35/36 (97.2%)	1.00	56/59 (94.9%)	29/33 (87.9%)	0.22
Median CD4 increase (cells/mm3)	83	62	0.36	208	170	0.59
Withdrawn due to adverse events	1	0		0	0	
Suspected ABC HSR	0	0		0	1	
Proximal renal tubular dysfunction	0	0		0	0	
Virological failure	0	1		0	2	

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