

Poster presentation

## Lipid changes in patients receiving nevirapine (NVP) in combination with tenofovir/emtricitabine: results from the CCIAT trial

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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):P121 doi:10.1186/1758-2652-11-S1-P121

This abstract is available from: <http://www.jiasociety.org/content/11/S1/P121>

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### Background

Highly effective antiretroviral (ARV) therapy has resulted in improved patient (pt) longevity, but many ARV regimens are associated with increases in blood lipid markers, raising concern with the potential for premature atherosclerosis and coronary artery disease. Prior studies with NVP in ARV-naïve pts noted an increase in low-density lipoprotein cholesterol (LDL-C) and triglycerides (TGs), although less significant than the high-density lipoprotein cholesterol (HDL-C) increase. The contribution of the NRTI backbone to this effect was unclear.

### Methods

To address this, 39 pts were randomly chosen to participate in a lipid substudy of the Cell Cycle Independent ARV Therapy (CCIAT) trial; pts (N = 54: 67% men, 95% African-American) received NVP 200 mg twice daily in combination with once-daily tenofovir/emtricitabine (TDF/FTC) 300/200 mg in this trial which was designed to investigate the efficacy and safety of this regimen.

### Summary of results

At baseline, mean total cholesterol (TC), HDL-C, LDL-C, and TG were 168 mg/dL, 41 mg/dL, 94 mg/dL, and 165 mg/dL, respectively. Pts included in this analysis had statistically significant increases from baseline in mean HDL-C levels (+19.6 mg/dL, n = 27; p < 0.0001) and statistically significant decreases in mean triglyceride levels from baseline (-46.7, n = 27; p < 0.05) (See table in Figure 1). The

increases in mean HDL-C were statistically significant regardless of baseline level (20–30 mg/dL, p = 0.01; 31–40 mg/dL, p = 0.0007; >40 mg/dL, p = 0.004). For example, 10 pts with HDL-C >40 mg/dL who reached week 96 experienced a mean increase from 48 to 75 mg/dL. From baseline to week 96, mean TG levels decreased by 84.4 mg/dL (n = 27; p = 0.0001). There were no clinically meaningful changes in the LDL-C and TC levels observed in this study.

### Conclusion

The combination of NVP plus TDF/FTC resulted in apparent positive effects on serum lipids, with an increase in HDL-C, decrease in TGs and little change in LDL-C and TC. This regimen might improve the cardiovascular risk profile of pts taking ARV therapy.

	Change from Baseline in Lipid Levels (mg/dL)							
	Week 24		Week 48		Week 72		Week 96	
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
Cholesterol	39	8.2 (38.3)	37	2.7 (34.2)	35	7.3 (33.5)	27	10.1 (33.6)
Triglycerides	39	-46.7 (99.7)*	37	-70.6 (81.6)*	35	-82.8 (75.4)*	27	-84.4 (98.5)*
HDL-c	39	17.7 (20.8)*	37	16.1 (18.1)*	35	19.1 (21.8)*	27	19.6 (16.7)*
LDL-c	36	-2.2 (20.4)	36	1.3 (27.4)	34	4.4 (24.7)	26	7.5 (25.6)

HDL-c, high-density lipoprotein cholesterol; LDL-c, low-density lipoprotein cholesterol

\*P < 0.05

Figure 1

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