



Nelfinavir (NFV): 12-Month Safety and Efficacy vs. Boosted-Indinavir (IDV/RTV), each in combination with 2 NRTIs, in Treatment Naïve Patients

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BACKGROUND : NFV and IDV are the most used PIs in day to day practice.

METHODS : A selection of all initial PI regimen containing NFV (1250mg BID)(G1) and IDV/RTV (800-100mg BID)(G2) with 2 NRTIs was done. We assessed the long term clinical, virological and immunological outcomes. Data were collected prospectively. Intent-to-treat (ITT) and on-treatment (OT) analyses were performed. The relationship between treatment group and time to switch was studied using the Cox model and adjusted on sex, age and viral load. Time to treatment switch was computed using Kaplan-Meier estimates.

RESULTS : From 01/99 to 11/00, 69 pts (G1) and 44 pts (G2) were retrieved. 57% were female, 68% Africans, 82% heterosexual, median viral load (vL) was 4.8 log and median CD4=209 cells/mm³. Both groups were comparable for all parameters. There were no statistical significant differences at M12 on proportion of pts with vL < 50 (ITT: 64% vs 70%, OT: 77% vs 87%) and on median CD4 (ITT: 404 vs 387, OT: 404 vs 223). Treatment was discontinued by 25/69 pts (36%) versus 21/44 pts (63%), p<.005. NFV-based therapy adjusted on sex, baseline vL and age was associated with a lower risk of switch (hazard ratio of switch=0.46, 95% confidence interval limits=0.26;0.84) (p<.02). Mean time to occurrence of switch was 290 (standard error (SE) 14) and 206 (SE 21) days in G1 and G2 respectively (Log-Rank test p<.002). Discontinuations due to side effects (mainly digestive) occurred in 8/25 pts (32%) vs 16/21 pts (76%). Rates of pts with at least one grade increase of cholesterol and triglycerides were: ITT, 16% vs 11%, 30% vs 41%; OT, 18% vs 19%, 39% vs 62%.

CONCLUSIONS : These two BID PI-based combinations as initial therapy were similar in terms of efficacy and impact on lipids at 12 month. However, the rate of treatment discontinuations was significantly higher in the IDV/RTV group and mainly due to side effects.

Abstracts