The StARS Study: Once Daily Atazanavir, low-dose Ritonavir and Saquinavir in Subjects with HIV-1 Infection: 24 week efficacy and safety results.

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Introduction: To explore the safety and efficacy of switching to the dual-boosted combination of atazanavir and saquinavir after virologic suppression on saquinavir, lopinavir and low dose ritonavir.
Methods: This ongoing 48-week open-label single-arm pilot enrolled 12 adults with HIV-1 infection and viral load < 50 for > 12 weeks on a regimen containing saquinavir and lopinavir/r (alone or combination with NRTIs). At enrollment, subjects changed from saquinavir and lopinavir/r to saquinavir (hard-gel) 1200 mg, atazanavir 300 mg and ritonavir 100 mg all once daily; NRTIs if any at baseline were continued. After 2 weeks, saquinavir was increased to 1600 mg once daily to explore PK relationships. Fasting lipid profiles were obtained at baseline, weeks 4, 12, and 24. The proportion of subjects with sustained virologic suppression at week 24 was calculated. Change from baseline to week 24 in CD4 and lipids was analyzed using the Wilcoxon Signed Rank test.
Results: One subject withdrew from the study at week 12 due to pregnancy; she was suppressed at withdrawal. The 10 subjects who have completed at least 24 weeks of follow-up are presented here (one not yet to week 24). Ten of 10 (100%; 95 CI 70-100%) show virologic suppression at week 24. There were no significant changes in CD4 counts. Total cholesterol and triglycerides were significantly lower at week 24 compared to baseline.

Variable	Baseline Median (mg%)	Week 24 Median (mg%)	p value
Total Chol	209.5	181	0.006
LDL Chol	87.5	102.5	0.14
HDL	41	42	0.26
Triglycerides	252	182.5	0.011

Conclusions: After virologic suppression on the dual boosted combination of SQV and LPV/r, changing to once daily SQV, ATV, and low dose RTV maintains viral suppression and significantly improves specific lipid fractions.

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