ATV + RTV versus ATV + SQV versus LPV-RTV AI424-045 Study



ATV + RTV versus ATV + SQV versus LPV-RTV AI424-045: Study Design

Study Design: AI424-045 Study

• **Background**: Randomized, open label trial in patients with prior treatment failure evaluating efficacy and safety of ritonavirboosted atazanavir versus atazanavir plus saquinavir versus both in comparison with lopinavir-ritonavir, all given with 2NRTIs

Inclusion Criteria (n = 358)

- Age <u>></u> 16
- History of \ge 2 failures on regimens containing \ge 1 NRTI, a NNRTI, and a PI
- CD4 \geq 50 cells/mm³
- HIV RNA <a>1,000 copies/mL

Treatment Arms

- ATV mg 300 + RTV 100 mg + 2 NRTIs*
- ATV 400 mg + SQV 1200 mg + 2NRTIs*
- LPV/r 400/100 mg BID + 2 NRTIs*





*2NRTIs = Tenofovir DF + 2nd NRTI



ATV + RTV versus ATV + SQV versus LPV-RTV AI424-045: Results

Week 48: Virologic Response (ITT), by Number of Baseline PI Mutations



Number of PI-Associated Mutations



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Week 48: Changes in Lipid Concentrations



Source: Johnson M, et al. AIDS. 2005;19:685-94.



ATV + RTV versus ATV + SQV versus LPV-RTV AI424-045: Conclusions

Conclusions: "ATV boosted with RTV is as effective and well tolerated as LPV/RTV in treatment-experienced patients, with a more favorable impact on serum lipids. Pharmacokinetically enhanced ATV provides a suitable choice for therapy of treatment-experienced HIV-infected patients."

Source: Johnson M, et al. AIDS. 2005;19:685-94.



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