ATV + RTV versus ATV + SQV versus LPV-RTV
AI424-045 Study
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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 ritonavir-boosted atazanavir versus atazanavir plus saquinavir versus both in comparison with lopinavir-ritonavir, all given with 2NRTIs.

- **Inclusion Criteria (n = 358)**
  - Age ≥ 16
  - History of ≥ 2 failures on regimens containing ≥ 1 NRTI, a NNRTI, and a PI
  - CD4 ≥ 50 cells/mm$^3$
  - HIV RNA ≥ 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

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AI424-045: Results

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

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AI424-045: Results

Week 48: Changes in Lipid Concentrations

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.”
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