SQV and LPV-RTV in Treatment-Experienced Children

HIV-NAT 017
SQV and LPV-RTV in Treatment-Experienced Children
HIV-NAT 017: Study Design

**Study Design: HIV-NAT 017**

- **Background:** Single-arm, open-label, prospective phase IV study to assess the efficacy, safety, pharmacokinetics, and resistance of double boosted protease inhibitors, saquinavir (SQV) and lopinavir-ritonavir (LPV-RTV), in children with HIV infection who have failed nucleoside reverse transcription inhibitors and/or non-nucleoside reverse transcription inhibitors-based regimens.

- **Inclusion Criteria (n = 50)**
  - Children <16 years of age
  - PI naïve and failing NRTI and/or NRTI/NNRTIs

- **Treatment Arms**
  - Saquinavir 50 mg/kg BID + Lopinavir-ritonavir 230/57.5 mg/m² BID +/- lamivudine 4 mg/kg BID (only in children who previously had not taken it)

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HIV-NAT 017: Results

Week 48: Virologic Response (ITT)

Conclusions: “Double boosted SQV/LPV/r resulted in significant CD4 rise and VL decline at 48 weeks. Hyperlipidemia was common. Cmin of both PIs exceeded therapeutic concentrations. Poor adherence caused failure in 10%. No major PI mutations were found.”
SQV and LPV/r in Treatment-Experienced Children
HIV-NAT 017: Results

Week 96: Virologic Response (ITT)

Virologic Response (%)

HIV RNA Threshold

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