LPV/r +/- SQV in Treatment-Experienced Children

PACTG 1038
Study Design: PACTG 1038

- **Background**: Phase I/II, open-label trial to assess the safety and tolerability of high-dose lopinavir-ritonavir (LPV-RTV) with or without saquinavir (SQV) in protease inhibitor-experienced children with HIV infection.

- **Inclusion Criteria (n = 26)**
  - Children aged 2 to 18 years old
  - On PI therapy for ≥6 months
  - Failing current regimen: HIV RNA >5000 copies/mL
  - Phenotypic resistance to LPV ≥5 times wild-type
  - CD4 count ≥50 cells/mm³

- **Treatment Arms**
  - LPV-RTV 400-100 mg/m² + ≥2NRTIs
    → SQV 750 mg/m² BID added at week 4 if IQ <15
  - LPV-RTV 480-120 mg/m² BID + NNRTI + ≥2NRTIs
    → SQV 750 mg/m² BID added at week 4 if IQ <15

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**Step 1**

LPV-RTV BID + ≥2NRTIs (n=21)

**Step 2: Wk4**

- If IQ <15, add SQV BID
- If IQ <15, add SQV BID

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PACTG 1038: Results

Week 48: Virologic Response

Week 48: Immunologic Response

Median CD4 count (cells/m$^3$)

- Baseline: 262
- 24 Weeks: 341
- 48 Weeks: 572

All study subjects with evaluable viral loads

Conclusion: “In antiretroviral-experienced children and adolescents with HIV, high doses of LPV/r with or without SQV offer safe options for salvage therapy, but the modest virologic response and the challenge of adherence to a regimen with a high pill burden may limit the usefulness of this approach.”
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