Lopinavir-RTV + NVP + 2 NRTIs in Treatment-Experienced
M97-765 Trial
Lopinavir-RTV + Nevirapine + 2 NRTIs in Treatment-Experienced M97-765: Study Design

**Study Design: M97-765**

- **Background**: Prospective, randomized, double-blind phase I/II study to evaluate the safety and efficacy of two different doses of lopinavir-ritonavir in combination with nevirapine and 2 NRTIs in treatment-experienced patients with HIV infection.

- **Inclusion Criteria (n = 70)**
  - Age ≥18
  - HIV RNA 1,000-10,000 copies/mL on 1st PI regimen
  - No past NNRTI treatment, naïve to or had received less than 8 weeks of treatment with ≥1 other NRTIs

- **Treatment Arms**
  - LPV-RTV 400/100 mg BID + NVP + 2 NRTIs (≥1 NRTI not previously received)*
  - LPV-RTV 400/200 mg BID + NVP + 2 NRTIs (≥1 NRTI not previously received)*

*Day 1-14: LPV-RTV + 2 baseline NRTIs. Day 15: NRTI regimen changed to include ≥1 new NRTI and NVP added at 200 mg QD. Day 28: NVP increased to 200 mg BID.

Lopinavir-RTV + Nevirapine + 2 NRTIs in Treatment-Experienced M97-765: Results

Week 48: Virologic Response (ITT, Missing=Failure)

Lopinavir-RTV + Nevirapine + 2 NRTIs in Treatment-Experienced M97-765: Results

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>LPV-RTV 400/100 mg BID (n = 36)</th>
<th>LPV-RTV 400/200 mg BID (n = 34)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea</td>
<td>19%</td>
<td>24%</td>
</tr>
<tr>
<td>Asthenia</td>
<td>3%</td>
<td>9%</td>
</tr>
<tr>
<td>GTT level &gt; 5x ULN</td>
<td>19%</td>
<td>33%</td>
</tr>
<tr>
<td>Total cholesterol &gt; 300 mg/dL</td>
<td>17%</td>
<td>33%</td>
</tr>
<tr>
<td>Triglycerides &gt; 750 mg/dL</td>
<td>19%</td>
<td>30%</td>
</tr>
<tr>
<td>AST/ALT level &gt; 5x ULN</td>
<td>8%</td>
<td>20%</td>
</tr>
</tbody>
</table>

**Conclusions**: “For single PI-experienced, NNRTI-naive patients, the combination of lopinavir-ritonavir, nevirapine, and NRTIs produced significant reductions in plasma HIV-1 RNA levels and increased CD4 cell counts.”

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