LPV-RTV versus LPV-RTV + ZDV-3TC in Treatment-Naïve

MONARK Trial
# Study Design: MONARK

**Background**: Randomized, pilot, open-label, phase 3 trial comparing the efficacy and safety of lopinavir-ritonavir monotherapy with lopinavir-ritonavir in combination with zidovudine-lamivudine in treatment-naïve patients with HIV infection.

**Inclusion Criteria** (n = 136)
- Age ≥ 18
- Antiretroviral-naïve
- HIV RNA < 100,000 copies/mL
- CD4 count > 100 cells/mm³
- Exclusions for certain protease or NRTI mutations

**Treatment Arms**
- Lopinavir-ritonavir 400-100 mg BID
- Lopinavir-ritonavir 400-100 mg BID + ZDV-3TC 150-300mg BID

**MONARK** = MONotherapy AntiRetroviral Kaletra

LPV-RTV versus LPV-RTV + ZDV-3TC in Treatment-Naïve MONARK: Results

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

## Tolerance of study medications

<table>
<thead>
<tr>
<th>Adverse event or Laboratory Abnormality</th>
<th>LPV-RTV Monotherapy (n = 83)</th>
<th>LPV-RTV + ZDV-3TC (n = 53)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea</td>
<td>6%</td>
<td>8%</td>
</tr>
<tr>
<td>AST and/or ALT elevation</td>
<td>12%</td>
<td>8%</td>
</tr>
<tr>
<td>Serious adverse event</td>
<td>12%</td>
<td>8%</td>
</tr>
<tr>
<td>Discontinuations</td>
<td>16%</td>
<td>23%</td>
</tr>
</tbody>
</table>

Conclusion: “Our results suggest that lopinavir/ritonavir monotherapy demonstrates lower rates of virological suppression when compared with lopinavir/ritonavir triple therapy and therefore should not be considered as a preferred treatment option for widespread use in antiretroviral-naive patients.”

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