EFV + ZDV + 3TC vs. EFV + IDV vs. IDV + ZDV + 3TC

006 Trial
EFV + ZDV + 3TC vs. EFV + IDV vs. IDV + ZDV + 3TC

006: Study Design

**Study Design: 006**

- **Background**: Open-label, randomized, phase 3 trial evaluating safety, efficacy and tolerability of efavirenz plus zidovudine plus lamivudine versus efavirenz plus indinavir versus indinavir plus zidovudine plus lamivudine

- **Inclusion Criteria (n = 450)**
  - Age ≥13 years
  - Naïve to lamivudine, NNRTIs, PIs
  - CD4 >50 cells/mm³
  - HIV RNA >10,000 copies/mL
  - No resistance to NRTIs or PIs

- **Treatment Arms**
  - EFV 600 mg QD + ZDV BID + 3TC BID
  - EFV 600 mg QD + IDV 1000 mg q8h
  - IDV 1000 mg q8h + ZDV BID + 3TC BID

Week 48: Virologic Response (Intention-to-Treat Analysis)

### Results


<table>
<thead>
<tr>
<th>Adverse Effect</th>
<th>EFV + ZDV + 3TC</th>
<th>EFV + IND</th>
<th>IDV + ZDV + 3TC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rash</td>
<td>34%</td>
<td>34%</td>
<td>18%</td>
</tr>
<tr>
<td>CNS Effects</td>
<td>58%</td>
<td>53%</td>
<td>26%</td>
</tr>
<tr>
<td>Nausea</td>
<td>15% (combined EFV groups)</td>
<td>27%</td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td>8% (combined EFV groups)</td>
<td>15%</td>
<td></td>
</tr>
<tr>
<td>Treatment Discontinuation</td>
<td>27%</td>
<td>Not reported</td>
<td>43%</td>
</tr>
</tbody>
</table>
Conclusions: “As antiretroviral therapy in HIV-1-infected adults, the combination of efavirenz, zidovudine, and lamivudine has greater antiviral activity and is better tolerated than the combination of indinavir, zidovudine, and lamivudine.”

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