Rilpivirine-TDF-FTC versus Efavirenz-TDF-FTC
STaR Trial
**Study Design: STaR Study**

- **Background:** Randomized, open label, phase 3b trial comparing safety and efficacy of two single-tablet regimens, RPV-TDF-FTC and EFV-TDF-FTC, in treatment-naïve HIV-infected patients.

- **Inclusion Criteria (n = 786)**
  - Antiretroviral-naïve patients
  - Age ≥ 18
  - HIV RNA ≥ 2500 copies/mL
  - No resistance to EFV, RPV, TDF, or FTC

- **Treatment Arms**
  - Rilpivirine-tenofovir DF-emtricitabine
  - Efavirenz-tenofovir DF-emtricitabine

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**Rilpivirine-TDF-FTC QD (n = 394)**

**Efavirenz-TDF-FTC QD (n = 392)**

Rilpivirine-TDF-FTC versus Efavirenz-TDF-FTC
STaR: Result

Week 48 Virologic Response (Intent-to-Treat Analysis)

Rilpivirine-TDF-FTC versus Efavirenz-TDF-FTC
STaR: Result

48 Week Virologic Outcomes

### Treatment Emergent Adverse Events in > 5% of Subjects in Either Arm

<table>
<thead>
<tr>
<th></th>
<th>RPV-TDF-FTC (n = 392)</th>
<th>EFV-TDF-FTC (n= 394)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dizziness</td>
<td>6.6%</td>
<td>22.2%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>9.6%</td>
<td>14.0%</td>
</tr>
<tr>
<td>Somnolence</td>
<td>2.5%</td>
<td>6.9%</td>
</tr>
<tr>
<td>Headache</td>
<td>12.4%</td>
<td>13.5%</td>
</tr>
<tr>
<td>Abnormal Dreams</td>
<td>5.8%</td>
<td>24.5%</td>
</tr>
<tr>
<td>Depression</td>
<td>6.6%</td>
<td>8.9%</td>
</tr>
<tr>
<td>Anxiety</td>
<td>5.1%</td>
<td>8.4%</td>
</tr>
<tr>
<td>Folliculitis</td>
<td>5.3%</td>
<td>1.0%</td>
</tr>
<tr>
<td>Rash</td>
<td>6.1%</td>
<td>12.0%</td>
</tr>
</tbody>
</table>

Conclusion: “In treatment-naive participants, RPV/FTC/TDF demonstrated noninferior efficacy and improved tolerability compared with EFV/FTC/TDF, as well as a statistically significant difference in efficacy for participants with baseline HIV-1 RNA 100,000 copies/mL or less at week 48.”

Rilpivirine-TDF-FTC versus Efavirenz-TDF-FTC
STaR Study: Result

Development of Genotypic Resistance at Week 48

- Resistance to study drugs: RPV-TDF-FTC 4.3%, EFV-TDF-FTC 0.8%
- Any NNRTI resistance: RPV-TDF-FTC 4.1%, EFV-TDF-FTC 0.8%
- Any NRTI resistance: RPV-TDF-FTC 4.1%, EFV-TDF-FTC 0.3%

Rilpivirine-TDF-FTC versus Efavirenz-TDF-FTC
STaR Study: Result

Development of Resistance to Study Drugs at 48 weeks, by Viral Load

Conclusions: “Among subjects in the primary resistance associated populations (RAP), resistance development to RPV/FTC/TDF consisted of NNRTI and NRTI mutations and was more frequent than resistance development to EFV/FTC/TDF. In subjects with baseline viral load ≤ 100,000 copies/mL, resistance development was low (<2%) for both RPV/FTC/TDF and EFV/FTC/TDF arms and less frequent compared with subjects with baseline viral load >100,000 copies/mL, for RPV/FTC/TDF.”

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