EFV + TDF + FTC versus EFV + ZDV-3TC
Study 934
Efavirenz + TDF + FTC + versus Efavirenz + ZDV-3TC

Study 934: Study Design

**Study Design: STUDY 934**

- **Background**: Randomized, open label phase 3 study comparing efavirenz plus either tenofovir DF and emtricitabine or fixed-dose zidovudine-lamivudine

- **Inclusion Criteria (n = 509)**
  - Antiretroviral-naïve patients
  - Age ≥ 18
  - HIV RNA ≥ 10,000 copies/ml
  - CD4 > 50 cells/mm³
  - No AIDS conditions in prior 30 days

- **Treatment Arms**
  - Efavirenz + tenofovir DF + emtricitabine
  - Efavirenz + zidovudine-lamivudine

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Efavirenz + TDF + FTC + versus Efavirenz + ZDV-3TC
Study 934: Result

Week 48: Virologic Response (< 400 copies/mL)

Efavirenz + TDF + FTC + versus Efavirenz + ZDV-3TC

Study 934: Result

Week 48: Virologic Response (<50 copies/mL)

ITT = Intention-to-Treat; NNRTI-R = Patients with baseline NNRTI mutations.

Efavirenz + TDF + FTC + versus Efavirenz + ZDV-3TC

Study 934: Result

Week 48: Immunologic Response

Efavirenz + TDF + FTC + versus Efavirenz + ZDV-3TC
Study 934: Result

Adverse Events through 48 Weeks

Efavirenz + TDF + FTC + versus Efavirenz + ZDV-3TC
Study 934: Common Adverse Events

<table>
<thead>
<tr>
<th></th>
<th>EFV + TDF + FTC (n = 257)</th>
<th>EFV + ZVD-3TC (n= 254)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dizziness</td>
<td>8%</td>
<td>7%</td>
</tr>
<tr>
<td>Nausea</td>
<td>8%</td>
<td>6%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>7%</td>
<td>4%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>7%</td>
<td>6%</td>
</tr>
<tr>
<td>Depression</td>
<td>4%</td>
<td>7%</td>
</tr>
<tr>
<td>Headache</td>
<td>5%</td>
<td>4%</td>
</tr>
<tr>
<td>Rash</td>
<td>5%</td>
<td>4%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>4%</td>
<td>5%</td>
</tr>
<tr>
<td>Anemia</td>
<td>&lt;1%</td>
<td>5%</td>
</tr>
</tbody>
</table>

**Interpretation:** “Through week 48, the combination of tenofovir DF and emtricitabine plus efavirenz fulfilled the criteria for noninferiority to a fixed dose of zidovudine and lamivudine plus efavirenz and proved superior in terms of virologic suppression, CD4 response, and adverse events resulting in discontinuation of the study drugs.”

Acknowledgment

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*The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.*