Atazanavir versus Lopinavir-ritonavir in Prior PI Failure

AI424-043 Study
Atazanavir vs. Lopinavir-ritonavir in Previous PI Failure
AI424-043: Study Design

Study Design: A1424-043

- **Background**: Randomized, open label, phase 3 trial to evaluate the efficacy and safety of atazanavir versus lopinavir-ritonavir in adults with HIV infection and a history of PI failure

- **Inclusion Criteria (n = 290)**
  - Age ≥16
  - One previous PI-based regimen failure
  - <10-fold phenotypic resistance to atazanavir and lopinavir-ritonavir
  - HIV RNA ≥5000 copies/mL
  - CD4 count ≥50 cells/mm³
  - No lipid-lowering therapy

- **Treatment Arms**
  - Atazanavir 400 mg once daily + 2 NRTIs (excluding tenofovir)
  - Lopinavir-ritonavir 400-100 mg twice daily + 2 NRTIs (excluding tenofovir)

Atazanavir vs. Lopinavir-ritonavir in Previous PI Failure
AI424-043: Results

Week 48: Magnitude of Viral Suppression (Primary Efficacy Measure)

<table>
<thead>
<tr>
<th></th>
<th>Atazanavir + 2NRTIs</th>
<th>Lopinavir-ritonavir + 2NRTIs</th>
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</thead>
<tbody>
<tr>
<td>Overall</td>
<td>-1.6</td>
<td>-2.0</td>
</tr>
<tr>
<td>PI-sensitive</td>
<td>-1.7</td>
<td>-2.0</td>
</tr>
<tr>
<td>PI-resistant</td>
<td>-1.4</td>
<td>-2.1</td>
</tr>
<tr>
<td>No NRTI mutations</td>
<td>-2.0</td>
<td>-1.9</td>
</tr>
<tr>
<td>≥ 1 NRTI mutation</td>
<td>-1.5</td>
<td>-2.1</td>
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</table>

Mean Decrease from Baseline (log_{10} copies/ml)

Atazanavir vs. Lopinavir-ritonavir in Previous PI Failure AI424-043: Results

Week 48: Virologic Response

Week 48: Virologic Response

ITT, NC=F (TLOVR)

HIV RNA <50 copies/mL (%)

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<tbody>
<tr>
<td>ITT, NC=F (TLOVR)</td>
<td>55/150</td>
<td>79/150</td>
</tr>
<tr>
<td>As Treated Analysis</td>
<td>51/111</td>
<td>80/131</td>
</tr>
</tbody>
</table>

ITT: Intent-to-treat, NC=F: noncompleter=failure, TLOVR: time-to-loss-of virologic response

Atazanavir vs. Lopinavir-ritonavir in Previous PI Failure
AI424-043: Results

Week 48: Changes in Lipid Concentrations

Conclusions: “While both treatments demonstrated good antiviral efficacy, relatively greater antiviral suppression was observed with lopinavir/ritonavir. In those patients with no NRTI mutations at baseline, both regimens demonstrated comparable virologic suppression. Atazanavir-treated patients demonstrated a superior lipid profile and required less frequent lipid-lowering treatment.”
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.*