TDF/FTC + [Atazanavir/r or Darunavir/r or Raltegravir]

ACTG 5260s (Substudy of 5257)
Raltegravir vs Darunavir/r vs Atazanavir/r
ACTG 5260s (substudy of ACTG 5257): Study Design

Study Design: ACTG 5260s

• **Background**: Substudy of an open-label, randomized, phase 3 trial with objectives of comparing cardiovascular markers, changes in immune activation, and effects on body composition of 3 NNRTI-sparing antiretroviral regimens

• **Inclusion Criteria (n = 328)**
  - Substudy of ACTG 5257
  - Exclusions:
    - DM, or
    - Uncontrolled thyroid disease, or
    - Use of lipid lowering therapy

• **Treatment Arms**
  - ATV 300 mg + RTV 100 mg + TDF-FTC QD
  - RAL 400 mg BID + TDF-FTC QD
  - DRV 800 mg QD + RTV 100 mg QD + TDF-FTC QD

Week 96: Changes in Measures of Body Composition

**Graph:**

- **Limb fat**:
  - Atazanavir + Ritonavir: 11.4%
  - Raltegravir: 14.8%
  - Darunavir + Ritonavir: 14.2%

- **Trunk Fat**:
  - Atazanavir + Ritonavir: 14.0%
  - Raltegravir: 19.4%
  - Darunavir + Ritonavir: 20.8%

- **Lean Mass**:
  - Atazanavir + Ritonavir: 2.0%
  - Raltegravir: 2.0%
  - Darunavir + Ritonavir: 1.2%

Conclusions: “In treatment-naive participants initiating ART with TDF/FTC, no differences in lean mass and regional fat were found with RAL when compared with ATV/r or DRV/r over 96 weeks.”
Raltegravir vs Darunavir/r vs Atazanavir/r
ACTG 5260s (substudy of ACTG 5257): Result

Week 96: Changes in Bone Mineral Density

<table>
<thead>
<tr>
<th></th>
<th>Atazanavir + Ritonavir</th>
<th>Raltegravir</th>
<th>Darunavir + Ritonavir</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spine</td>
<td>-4.0</td>
<td>-1.6</td>
<td>-3.6</td>
</tr>
<tr>
<td>Hip</td>
<td>-3.9</td>
<td>-2.2</td>
<td>-3.4</td>
</tr>
</tbody>
</table>

Mean change in BMD from baseline (%)

Conclusions: “BMD losses 96 weeks after ART initiation were similar in magnitude among patients receiving PIs, ATV/r, or DRV/r but lowest among those receiving RAL. Inflammation and immune activation/senescence before ART initiation independently predicted subsequent BMD loss.”
Raltegravir vs Darunavir/r vs Atazanavir/r
ACTG 5260s (substudy of ACTG 5257): Result

After Week 112: Progression in Carotid Intimal Media Thickness (IMT)

Conclusion: “In ART-naive HIV-infected individuals at low cardiovascular disease risk, carotid IMT progressed more slowly in participants initiating ATV/r than those initiating DRV/r, with intermediate changes associated with RAL. This effect may be due, in part, to hyperbilirubinemia.”
Acknowledgment

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