Darunavir/r versus Atazanavir/r and Metabolic Parameters

METABOLIK
DRV/r versus ATV/r and Metabolic Parameters

METABOLIK: Study Design

**Study Design: METABOLIK**

- **Background:** Open-label, randomized, phase 4 exploratory study evaluating the metabolic effects of darunavir + ritonavir or atazanavir + ritonavir in treatment-naïve patients

- **Inclusion Criteria (n = 65)**
  - Age ≥18
  - Antiretroviral-naïve patients
  - HIV RNA >1000 copies/mL
  - BMI ≤30, fasting glucose ≤110 mg/dL
  - LDL ≤130 mg/dL, triglycerides ≤200 mg/dL
  - No lipid lowering medications within prior 28 days

- **Treatment Arms**
  - DRV 800 mg QD + RTV 100 mg QD + TDF-FTC
  - ATV 300 mg QD + RTV 100 mg QD + TDF-FTC

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METABOLIK: Result

Week 48: Changes in Lipids from Baseline

Week 48: Changes in Glucose, Insulin, and Insulin Sensitivity

<table>
<thead>
<tr>
<th></th>
<th>Darunavir + Ritonavir + 2 NRTIs</th>
<th>Atazanavir + Ritonavir + 2 NRTIs</th>
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</thead>
<tbody>
<tr>
<td>Glucose (mg/dL)</td>
<td>2.8</td>
<td>6.4</td>
</tr>
<tr>
<td>Insulin (μIU/mL)</td>
<td>1.0</td>
<td>-2.9</td>
</tr>
<tr>
<td>HOMA-IR</td>
<td>0.04</td>
<td>-1.24</td>
</tr>
</tbody>
</table>

HOMA-IR = Homeostasis model of assessment of insulin resistance

Conclusion: “This first pilot comparison in HIV-1-infected subjects suggests that DRV/r has a metabolic profile similar to ATV/r over 48 weeks of treatment. Further randomized studies are warranted.”
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METABOLIK Substudy: Result

Baseline, Week 12, and Week 48: Insulin Sensitivity

Insulin resistance measured by euglycemic hyperinsulinemic clamp (EHC) method

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