Raltegravir plus Ritonavir-Boosted Darunavir

ACTG 5262 Trial
Study Design: ACTG 5262

- **Background**: Open-label, single-arm, phase 2 study evaluating the efficacy of a NRTI-sparing regimen consisting of boosted darunavir plus raltegravir in persons with HIV.

- **Inclusion Criteria (n = 112)**
  - Age ≥18 years
  - Antiretroviral-naïve
  - HIV RNA ≥5000 copies/mL
  - More than one darunavir resistance-associated mutation (RAM) or known major integrase RAM

- **Treatment Arm**
  - Darunavir 800 mg QD + Ritonavir 100 mg QD + Raltegravir 400 mg BID

Raltegravir plus Ritonavir-Boosted Darunavir
ACTG 5262 Trial: Result

Week 24 and Week 48: Virologic Efficacy

HIV RNA < 50 copies/mL (%)

Week 24
- ITT Analysis: 79%
- Modified ITT Analysis: 74%

Week 48
- ITT Analysis: 71%
- Modified ITT Analysis: 61%

Virologic failure associated with baseline HIV RNA >100,000 copies/mL and lower CD4 count

Virologic Failure, by Baseline CD4 Count

Conclusion: “DRV/r + RAL was effective and well tolerated in most patients, but virological failure and integrase resistance were common, particularly in patients with baseline viral load more than 100,000 copies/ml.”

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