Raltegravir plus OBT in Patients with Multidrug-Resistant HIV

005 Trial
Raltegravir plus OBT in Patients with Multidrug-Resistant HIV

005: Study Design

Study Design: 005

• **Background**: Randomized, double-blind, dose-ranging, placebo-controlled phase 2 trial to evaluate raltegravir compared to placebo, with optimized background therapy (OBT), in patients with multidrug-resistant HIV.

• **Inclusion Criteria (n = 179)**
  - Age ≥18 years
  - Antiretroviral-experienced with resistance to at least 1 NNRTI, 1 NRTI, and 1 PI
  - CD4 count >50 cells/mm^3
  - HIV RNA >5,000 copies/mL
  - Non-pregnant, no HCV coinfection

• **Treatment Arms (All Received OBT)**
  - Raltegravir 200 mg, 400 mg, or 600 mg BID
  - Placebo

Raltegravir plus OBT in Patients with Multidrug-Resistant HIV 005: Results

Week 24: Change from Baseline Viral Load

Raltegravir plus OBT in Patients with Multidrug-Resistant HIV 005: Results

Week 24: Virologic Response


**Interpretation**: “In patients with few remaining treatment options, raltegravir at all doses studied provided better viral suppression than placebo when added to an optimised background regimen. The safety profile of raltegravir is comparable with that of placebo at all doses studied.”

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