Darunavir/r Monotherapy versus Triple Therapy
MONOI-ANRS 136 Trial
**Study Design: MONOI-ANRS 136**

- **Background:** Randomized, open-label, phase 3 trial to evaluate noninferiority of darunavir + ritonavir (monotherapy) versus darunavir + ritonavir + 2NRTIs (triple therapy) in virologically suppressed patients.

- **Inclusion Criteria (n = 226)**
  - Age ≥18
  - HIV RNA <400 copies/mL x 18 months on 3-drug Rx
  - HIV RNA <50 copies/ml at screening
  - CD4 nadir >50 cells/mm³
  - No history of virologic failure on PI-based regimen

- **Treatment Arms**
  - Darunavir 600 mg BID + RTV 100 mg BID
  - Darunavir 600 mg BID + RTV 100 mg BID + 2NRTIs

*Both arms: 8-week run-in with DRV/r + 2 NRTIs*
Darunavir/r Monotherapy versus Triple Therapy
MONOI-ANRS 136: Result

Week 48: HIV RNA <400 copies/mL, by Baseline HIV RNA (Per Protocol Analysis)

- **Darunavir + Ritonavir**
  - All: 94%
  - <100,000 copies/mL: 100%
  - ≥100,000 copies/mL: 100%

- **Darunavir + Ritonavir + 2NRTIs**
  - All: 99%
  - <100,000 copies/mL: 97.7%
  - ≥100,000 copies/mL: 86.2%

Treatment failure = virologic failure, treatment modification/discontinuation, withdrawal

Darunavir/r Monotherapy versus Triple Therapy

MONOI-ANRS 136: Result

Week 48: HIV RNA <400 copies/mL, by Baseline HIV RNA (ITT Analysis)

Darunavir/r Monotherapy versus Triple Therapy MONOI-ANRS 136: Result

Week 48: HIV RNA <50 copies/mL, by Baseline HIV RNA (Per Protocol Analysis)

Darunavir/r Monotherapy versus Triple Therapy
MONOI-ANRS 136: Result

Week 48: HIV RNA <50 copies/mL, by Baseline HIV RNA (ITT Analysis)

- **All**: 73.2%
- **<100,000 copies/mL**: 72.7%
- **≥100,000 copies/mL**: 70.0%

**Darunavir + Ritonavir**: 80.5%

**Darunavir + Ritonavir + 2NRTIs**: 85.3%

**Conclusion**: “Darunavir/r monotherapy exhibited efficacy rate over 85% with concordant results in the magnitude of difference with darunavir/r triple drug regimen in both intent-to-treat and per protocol analyses, but discordant conclusions with respect to the noninferiority margin. Patients failing on darunavir/r monotherapy had no emergence of new darunavir resistance mutations preserving future treatment options.”
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