LPV-RTV Monotherapy vs. LPV-RTV + 2 NRTIs

OK04 Trial
LPV-RTV vs. LPV-RTV + 2 NRTIs in Treatment-Experienced OK04: Study Design

**Study Design: OK04**

**Background**: Randomized, open-label, phase III/IV study comparing lopinavir-ritonavir monotherapy with lopinavir-ritonavir and 2 NRTIs for maintenance of viral suppression in treatment-experienced patients with HIV infection.

**Inclusion Criteria (n = 205)**
- Age ≥18
- Taking LPV/r + 2 NRTIs for ≥4 weeks
- HIV RNA <50 copies/mL for ≥6 months
- No history of virologic failure on PI regimen

**Treatment Arms**
- Lopinavir-ritonavir 400-100 mg BID
- Lopinavir-ritonavir 400-100 mg BID + 2 NRTIs (or 1 NRTI and tenofovir DF)

**Monotherapy group**
Lopinavir-ritonavir 400-100 mg BID (n = 100)

**Triple therapy group**
Lopinavir-ritonavir 400-100 mg BID + 2 NRTIs (n = 98)

LPV-RTV vs. LPV-RTV + 2 NRTIs in Treatment-Experienced OK04: Results

Week 48: Virologic Response

**Graph:**

- **HIV RNA <50 copies/mL (%)**
  - **Intention-to-treat***:
    - LPV-RTV: 84%
    - LPV-RTV + 2 NRTIs: 90%
  - **As-treated**:
    - LPV-RTV: 89%
    - LPV-RTV + 2 NRTIs: 97%

*ITT analysis: missing=failure, NRTI reintroduction=failure
**As-treated analysis: NRTI reintroduction=failure, missing or change in therapy=censored

Conclusion: “In this trial, 48 weeks of lopinavir-ritonavir monotherapy with reintroduction of nucleosides as needed was non-inferior to continuation of two nucleosides and lopinavir-ritonavir in patients with prior stable suppression. However, episodes of low level viremia were more common in patients receiving monotherapy.”
LPV-RTV vs. LPV-RTV + 2 NRTIs in Treatment-Experienced OK04: Results

Week 96: Virologic Response

![Bar chart showing virologic response at Week 96 for LPV-RTV vs. LPV-RTV + 2 NRTIs.](chart.png)

- **Intention-to-treat (ITT)**:
  - LPV-RTV: 77%
  - LPV-RTV + 2 NRTIs: 78%

- **As-treated**:
  - LPV-RTV: 86%
  - LPV-RTV + 2 NRTIs: 94%

*ITT analysis: missing=failure, NRTI reintroduction=failure
**As-treated analysis: reintroduction=failure, missing or change in therapy=censored

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