

Lopinavir-RTV + NVP + 2 NRTIs in Treatment-Experienced
M97-765 Trial

Lopinavir-RTV + Nevirapine + 2 NRTIs in Treatment-Experienced M97-765: Study Design

Study Design: M97-765

- **Background:** Prospective, randomized, double-blind phase I/II study to evaluate the safety and efficacy of two different doses of lopinavir-ritonavir in combination with nevirapine and 2 NRTIs in treatment-experienced patients with HIV infection
- **Inclusion Criteria (n = 70)**
 - Age ≥ 18
 - HIV RNA 1,000-10,000 copies/mL on 1st PI regimen
 - No past NNRTI treatment, naïve to or had received less than 8 weeks of treatment with ≥ 1 other NRTIs
- **Treatment Arms**
 - LPV-RTV 400/100 mg BID + NVP + 2 NRTIs (≥ 1 NRTI not previously received)*
 - LPV-RTV 400/200 mg BID + NVP + 2 NRTIs (≥ 1 NRTI not previously received)*

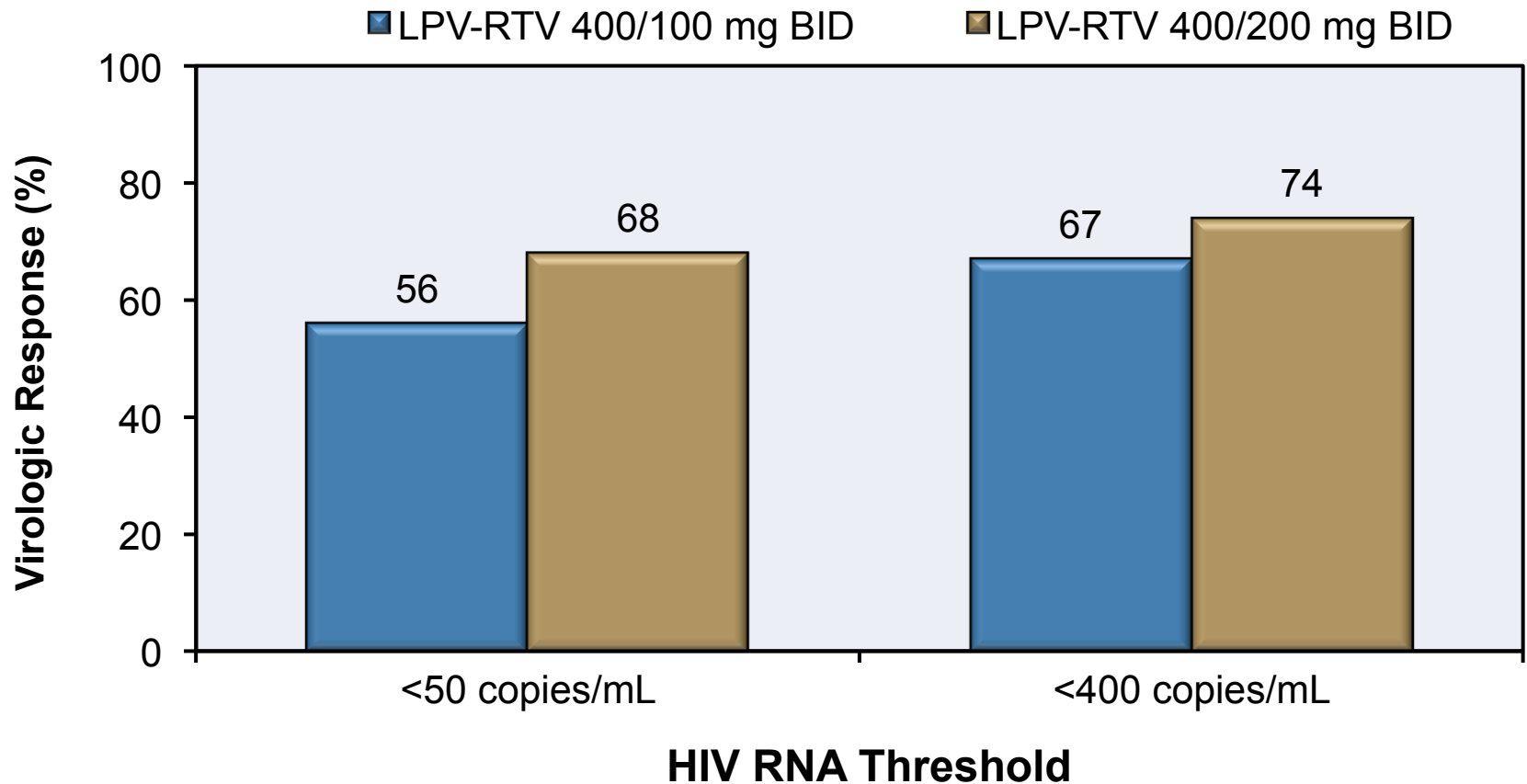
**LPV-RTV 400/100 mg BID
+ NVP + 2 NRTIs**
(n = 36)

**LPV-RTV 400/200 mg BID
+ NVP + 2 NRTIs**
(n = 34)

*Day 1-14: LPV-RTV + 2 baseline NRTIs. Day 15: NRTI regimen changed to include ≥ 1 new NRTI and NVP added at 200 mg QD. Day 28: NVP increased to 200 mg BID.

Lopinavir-RTV + Nevirapine + 2 NRTIs in Treatment-Experienced M97-765: Results

Week 48: Virologic Response (ITT, Missing=Failure)



Lopinavir-RTV + Nevirapine + 2 NRTIs in Treatment-Experienced M97-765: Results

Adverse Events and Grade 3 or 4 Laboratory Abnormalities

Adverse Event	LPV-RTV 400/100 mg BID (n = 36)	LPV-RTV 400/200 mg BID (n = 34)
Diarrhea	19%	24%
Asthenia	3%	9%
GTT level > 5x ULN	19%	33%
Total cholesterol > 300 mg/dL	17%	33%
Triglycerides > 750 mg/dL	19%	30%
AST/ALT level > 5x ULN	8%	20%

Lopinavir-RTV + Nevirapine + 2 NRTIs in Treatment-Experienced M97-765: Conclusions

Conclusions: “For single PI-experienced, NNRTI-naive patients, the combination of lopinavir-ritonavir, nevirapine, and NRTIs produced significant reductions in plasma HIV-1 RNA levels and increased CD4 cell counts.”

Acknowledgment

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