

LPV-RTV versus LPV-RTV + ZDV-3TC in Treatment-Naïve
MONARK Trial

LPV-RTV versus LPV-RTV + ZDV-3TC in Treatment-Naïve MONARK: Study Design

Study Design: MONARK

- **Background:** Randomized, pilot, open-label, phase 3 trial comparing the efficacy and safety of lopinavir-ritonavir monotherapy with lopinavir-ritonavir in combination with zidovudine-lamivudine in treatment-naïve patients with HIV infection
- **Inclusion Criteria (n = 136)**
 - Age ≥ 18
 - Antiretroviral-naïve
 - HIV RNA $< 100,000$ copies/mL
 - CD4 count > 100 cells/mm³
 - Exclusions for certain protease or NRTI mutations
- **Treatment Arms**
 - Lopinavir-ritonavir 400-100 mg BID
 - Lopinavir-ritonavir 400-100 mg BID + ZDV-3TC 150-300mg BID

LPV/r 400/100 mg BID
(n=83)

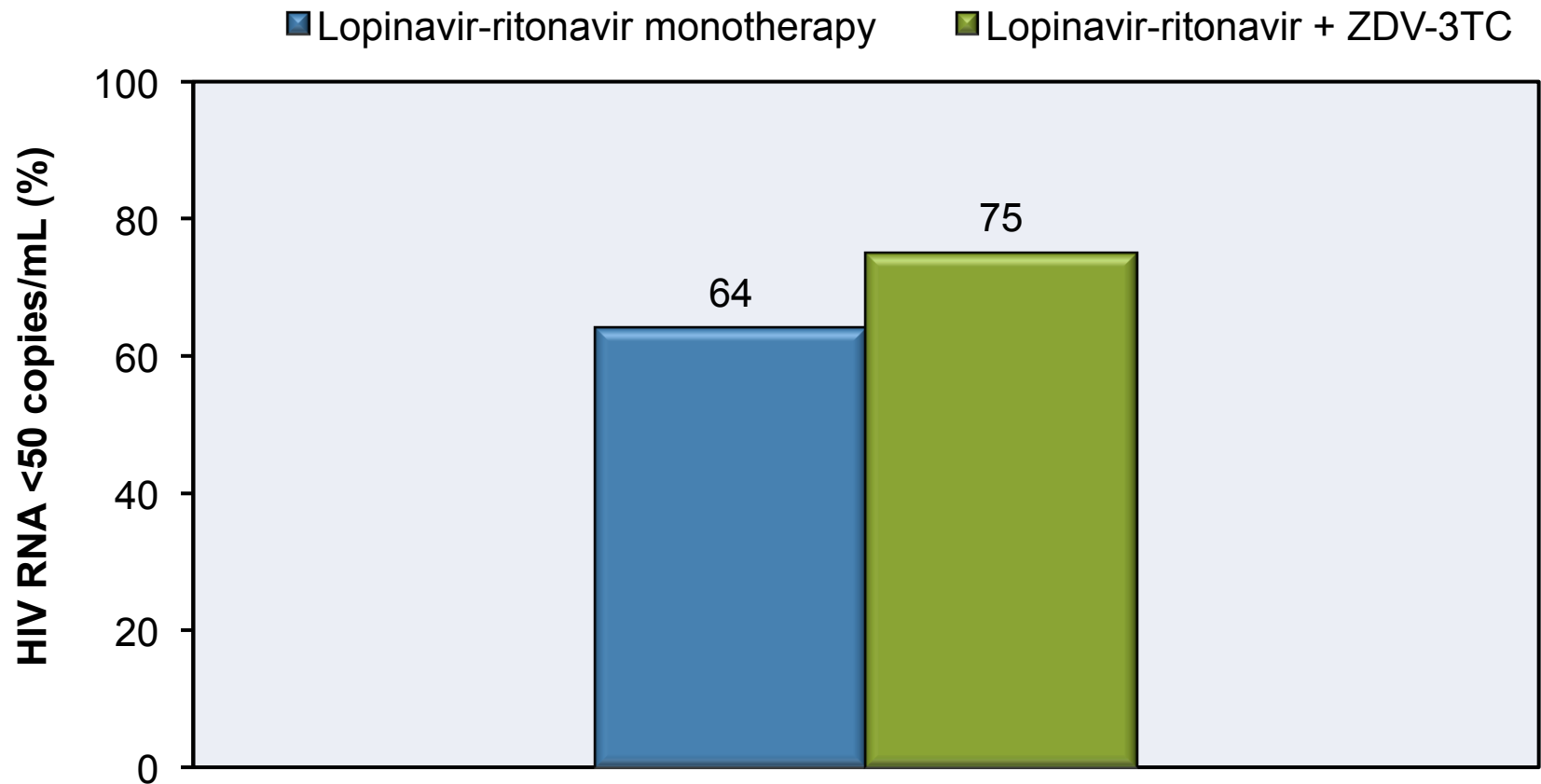
**LPV/r 400/100 mg BID +
ZDV-3TC**
(n =53)

MONARK = MONotherapy **A**nti**R**etroviral **K**aletra

Source: Delfraissy JF, et al. *AIDS*. 2008;22:385-93.

LPV-RTV versus LPV-RTV + ZDV-3TC in Treatment-Naïve MONARK: Results

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



Source: Delfraissy JF, et al. AIDS. 2008;22:385-93.

LPV-RTV versus LPV-RTV + ZDV-3TC in Treatment-Naïve MONARK: Results

Tolerance of study medications		
Adverse event or Laboratory Abnormality	LPV-RTV Monotherapy (n = 83)	LPV-RTV + ZDV-3TC (n = 53)
Diarrhea	6%	8%
AST and/or ALT elevation	12%	8%
Serious adverse event	12%	8%
Discontinuations	16%	23%

LPV-RTV versus LPV-RTV + ZDV-3TC in Treatment-Naïve MONARK: Conclusion

Conclusion: “Our results suggest that lopinavir/ritonavir monotherapy demonstrates lower rates of virological suppression when compared with lopinavir/ritonavir triple therapy and therefore should not be considered as a preferred treatment option for widespread use in antiretroviral-naïve patients.”

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