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Week-96 end of trial analysis of antiretroviral-naïve patients randomized to the lopinavir/ritonavir single drug arm in the MONARK trial

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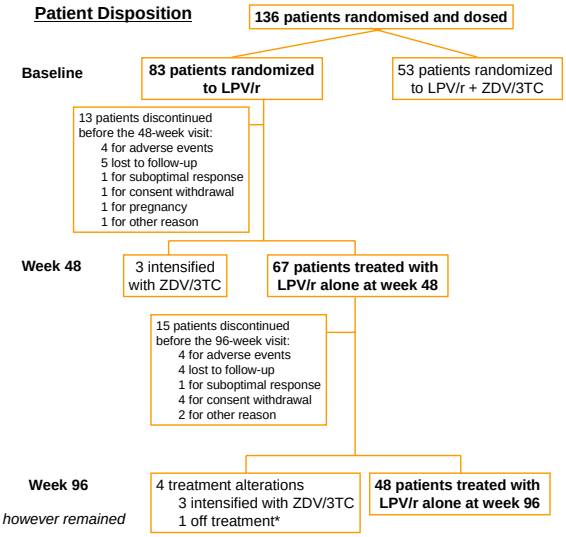
The MONARK trial enrolled 136 antiretroviral-naïve patients who were randomized and dosed with either lopinavir/ritonavir (LPV/r) monotherapy (n=83) or LPV/r + AZT/3TC (n=53).

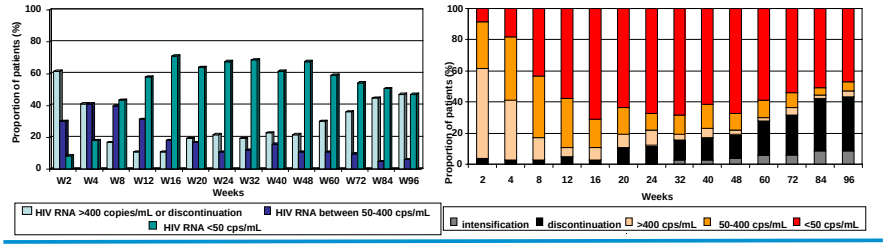
We focus here on patients in the LPV/r monotherapy arm followed through Week 96. The on-treatment (OT) analysis considers only patients who had an HIV-RNA<50 copies/mL at Week 48 (n=56). The intent-to-treat (ITT) analysis involves all patients randomized to LPV/r monotherapy (n=83).

Patient Disposition

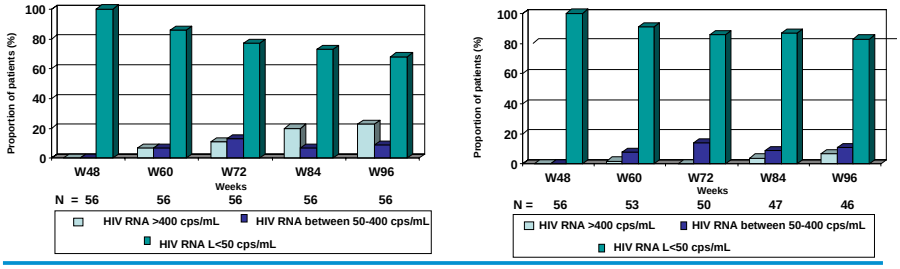


** Patient who decided to stop treatment, however remained followed in the study.*

ITT analysis (missing data = failure) from baseline through W96 for patients randomized to LPV/r monotherapy



ITT (left) and OT (right) analysis focusing on patients randomized to the LPV/r monotherapy arm, and who had reached an HIV-RNA<50 cp/mL at W48



- The follow-up of the 56 patients, virologically controlled at Week 48, indicate that 46 of them remained on LPV/r monotherapy at Week 96, with 38/46 (83%) having HIV RNA <50 copies/mL.
- Factors associated with sustained undetectable HIV-RNA through W96 were baseline HIV-RNA and an HIV-RNA<400 copies/mL at W2.
- PI-associated resistance mutations were evidenced in 5/83 patients in the monotherapy arm from baseline to W96 (46I+63P at W40, 76V at W44, 13V+46I+76V at W62, 10F+82A at W76 and 76V at W90). Among these 5 patients with selected PI resistance mutations, 3/5 intensified with NRTIs and re-suppressed to <50 copies/mL, 1/5 was switched to nevirapine + AZT/ 3TC, 1/5 continued on LPV/r monotherapy (investigator's decision).

CONCLUSIONS

- **LPV/r monotherapy was able to maintain sustained viral suppression up to W96 in patients who already achieved an HIV-RNA<50 cp/ml at W48: 83% of patients with HIV-RNA<50 cp/mL at W48 maintained an HIV-RNA<50 cp/mL at W96.**
- **The occurrence in some patients of low-level viremia (50-500 copies/mL) may increase the risk for drug resistance. Major PI-associated resistance mutations were evidenced in 5 out of 83 (6%) patients treated with LPV/r monotherapy.between baseline and W96. However, these mutations did not jeopardize future therapeutic options in any of the 5 patients.**

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