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Poster presentation

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A study to evaluate the efficacy, safety and tolerability of co-administered lopinavir/ritonavir (LPVr) and nevirapine (NVP) in HIV-infected adults

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Purpose of the study

The persisting concern of mitochondrial toxicity and the potential development of cardio-metabolic toxicity from nucleoside analogues has prompted clinicians to consider alternative treatment strategies. Here we investigate the efficacy, safety and tolerability of a nucleoside-sparing regimen consisting of nevirapine and boosted lopinavir in 'The NRTI-sparing Study'.

Methods

In this prospective, 48-week, two-centre study, 40 patients were recruited to receive lopinavir/ritonavir (LPV/r) soft gel capsules (SGC) (533/133 mg BID) plus nevirapine (NVP) (200 mg BID). Once HIV-RNA was <50 copies/ml, patients were allowed to switch to the new LPV/r tablet formulation (400/100 mg BID); this was not considered a switch in the analyses. Fasting lipids, CD4 count, and HIV-1 RNA were performed on days 1, 4 and 7 and weeks 2, 4, 12, 24, 36 and 48. Analyses were intention-to-treat (ITT; switch & missing = failure) and on treatment.

Summary of results

Patients were predominantly male (85%) and Caucasian (65%) with a median (range) age of 37 years (23, 69). The one non-ART-naïve patient had received NRTI monotherapy previously. At baseline the median (range) CD4 count and HIV viral load (VL) were 201 cells/mm3 (8, 614) and 5 log copies/ml (3.5, 6), respectively. At 24 and 48 weeks (ITT), 26 patients (65%; 95% CI 46–77) and 20 patients (50%; 95% CI 32–64) achieved HIV-RNA<50 copies/ml, respectively. These values rose to 26/31 (84%; CI 65–94) and 20/25 (79%) in an on treatment (OT) analysis (missing = excluded). At 48 weeks, in an OT analysis, median (range) CD4 change was +155 (-3, +534) cells/mm3 and the median (IQR) change from baseline in total cholesterol, LDL-cholesterol, HDL-cholesterol and triglycerides was +0.7 (+0.1, +1.8), +0.4 (-0.3, +0.8), +0.3 (+0.1, +0.5) and +0.6 (+0.2, +1.4), respectively. Fifteen patients switched to the LPV/r tablet formulation. Two patients developed AIDS-defining illnesses and discontinued the study drugs; two died (unrelated to study drug); two developed a rash (one Stevens-Johnson syndrome), and one developed NNRTI resistance. Overall, 15 individuals discontinued treatment. The median (range) time to discontinuation was 24 weeks (2, 43).

Conclusion

In this predominantly antiretroviral-naïve cohort, at 48 weeks 79% of the patients remaining on the NRTI-sparing regimen had HIV-RNA <50 copies/ml. These figures are comparable with previously reported figures in similar treatment strategies.