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Poster presentation

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FREE trial: induction therapy with ART (abacavir/lamivudine/lopinavir/r) followed by maintenance regimen with triple NRTI, compared to continued ART

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Purpose of the study

To assess the antiviral efficacy of a triple nucleoside reverse transcriptase inhibitor (NRTI) regimen as maintenance therapy, after successful induction with a dual NRTI and protease inhibitor (PI) combination.

Methods

Randomized, open-label, multicenter, 96-week comparative study. Main inclusion criteria: antiretroviral therapy (ART) naïve patients, CD4 ≤350 cells/μL, HIV-1 RNA concentrations (VL) > 30,000 copies/mL. Exclusion criteria included predefined abnormal values of fasting glucose, triglycerides, LDL-cholesterol or LDL/HDL ratio. Patients were randomized after they had reached VL < 50 c/mL on two consecutive occasions between 12 and 24 weeks after the start of a BID zidovudine/lamivudine and BID lopinavir/ritonavir combination. Eligible subjects switched to abacavir/lamivudine/zidovudine (TZV) bid or continued the PI-containing regimen. Primary end-point at week 96: proportion of subjects with VL < 400 c/mL. Here, we present the 48-week interim data with virological failure VL > 50 c/mL.

Summary of results

207 patients had similar baseline (BL) characteristics: mean age 41 years, 87% male, median CD4 180 cells/mm^3 (range 10–440), median VL 155,000 c/mL (900–28300000). A total of 118 subjects (57%) met randomization criteria. Of all BL data, only VL differed significantly between dropouts and randomized subjects (median 253,000 c/mL versus 118,500 c/mL, p = 0.006). After 14 weeks, 21 subjects were randomized, after 20 weeks: 40 subjects, and after 26 weeks: 57 subjects. Sixty subjects were allocated to TZV switch, and 58 subjects to continue NRTIs/PI. At 48 weeks follow-up after BL, there were no significant differences between CD4 cells in the TZV arm (median 340 cells/mm^3), and the NRTIs/PI arm (397 cells/mm^3). VL results were similar; there were two virological failures (3%) in the TZV group (1,480 person-weeks) and seven (12%) in the NRTIs/PI-group (1,475 person-weeks) after 48 weeks of therapy (Log Rank test; p = 0.13).

Conclusion

TZV as maintenance therapy after induction with NRTIs/PI in previously antiretroviral naïve patients shows an antiviral activity comparable to continuation of a PI-based

regimen at 48 weeks interim analysis. Final analysis of the data at week 96 has to be awaited to further evaluate the efficacy of TZV maintenance ART.