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Poster presentation

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INDEED study: final results of an induction treatment strategy with enfuvirtide in treatment failure patients

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Purpose of the study

To evaluate the efficacy and safety of induction with enfuvirtide (ENF) + antiretroviral (ARV) optimized background (OB) and maintenance with ENF + OB vs. dropping ENF in moderate virological failure patients requiring therapeutic change.

Methods

A prospective, non-inferiority, open-label multicenter trial including patients pretreated with two or three classes of ARV, viral load (VL) = 3 to 5.5 log10 HIV-1 RNA copies/ml and possible ARV optimized background with at least two active compounds. Patients were randomized 1:1 between the groups (ENF + OB, OB) after 28 weeks of induction with ENF + OB for patients achieving VL<400 copies/ml at week 16, and VL<50 copies/ml at week 24. The primary end-point was proportion of patients with VL< 50 copies/ml at week 52.

Summary of results

84 patients included (37 centers), 80% male, 33% with AIDS. Mean duration of previous ARV treatment = 10 +/- 4 years. At inclusion, median VL = 4.3 log10 copies/ml, median CD4 = 259 cells/mm3 (<200 CD4/mm3: 32%). Number of fully active ARV in the OB (GSS) was = 2 for 74% of patients (according to genotypic resistance test performed at selection combined with all previous selected mutations). At week 4, a reduction of VL >1 log10 was observed in 92% of patients and a reduction of VL >2 log10 vas obtained in 42% (74% in patients with VL = 30,000 copies/ml at inclusion). Median reduction of VL at week 4 and week 24 were 1,9 log10 and 2,3 log10, respectively. Adequate ENF concentrations (>1,000 ng/ml) were observed in 80% of patients at week 4. At week 24, 69% of patients reached VL< 50 copies/ml regardless of GSS. Median increase from baseline in CD4 cells at week 4 and week 24 were 25/mm3 and 71/mm3, respectively. At week 52 within 45 randomized patients, 67% (16/24) in the ENF + OB arm and 57% (12/21) in the OB arm achieved VL< 50 copies/ml without failure after randomization. Median increase in CD4 from week 28 to week 52 were +18/mm3 in ENF + OB arm and -9/mm3 in OB arm. 56% of patients presented at least one injection site reaction (ISR) with no influence observed of CD4 count, VL, or lipodystrophy.

Conclusion

Addition of ENF to OB led to fast and good virological response (at least 2 log drop in VL observed in 74% of patients with initial VL >30,000 copies/ml at week 4). During maintenance phase, in this population with a smaller than planned number of patients, we cannot conclude as to the non-inferiority of OB vs. ENF + OB at week 52.