Background: Raltegravir (RAL) is a 1-in-3 integrase inhibitor (IIN) that is approved as a single drug for the treatment of HIV-1 infection, either as RAL-400 mg bid or in combination with Efavirenz (EFV) in patients failing antiretroviral therapy (ART) with triple-class resistant virus.

Methods: Phase IIa, three-arm, randomized, double-blind, placebo-controlled trial in treatment-naive patients with HIV infection (CFR-205). Patients were randomized to receive RAL 400 mg bid (n=271) or EFV 600 mg qHS (n=276) as part of the RCT 18-week trial, followed by 96-week follow-up through RCT 96 weeks in the EFV group and in the RAL group at 96 weeks in the RCT 18-week trial. 

Results: At week 96, RAL demonstrated superior antiviral activity compared to EFV, with a significant reduction in HIV-1 RNA levels in RAL group compared to EFV group (RAL: 0.192 vs. EFV: 1.092, p = 0.04). The percentage of patients with ≥Grade 2 lipoatrophy was significantly lower in the RAL group than in the EFV group (RAL: 0.192 vs. EFV: 1.092, p = 0.03).  There were no significant differences in body fat distribution between the two groups. Overall, the RAL group showed a better fat distribution compared to the EFV group. 

Conclusions: 

- Raltegravir 400 mg bid demonstrates superiority in terms of antiviral efficacy compared to Efavirenz 600 mg qHS in treatment-naive patients with HIV infection.
- The percentage of patients with ≥Grade 2 lipoatrophy was significantly lower in the RAL group than in the EFV group.
- There were no significant differences in body fat distribution between the two groups.

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