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3OD – Once-daily (OD) TDF-containing HAART in HIV-1-infected former IVDU-patients receiving opiate substitution: efficacy, tolerability and adherence

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Purpose of the study

There is a clinical need for antiretroviral therapy (ART) regimens that simplify dosing and make adherence easier for specific patient groups such as former intravenous drug users (IVDU) receiving opiate substitution. Availability of tenofovir DF (TDF) and other once-daily (OD) agents could offer a viable OD regimen. The 3OD study was designed to evaluate the use of OD HAART in IVDU patients.

Methods

3OD was a single-arm, multicentre, 48-weeks trial to assess efficacy, tolerability and adherence to a OD TDF-containing HAART regimen in former IVDU patients receiving opiate substitution. Of 67 patients enrolled, 27 were antiretroviral treatment naïve, 10 were virologically suppressed (<400 copies/mL), and 30 were re-starting HAART without prior virological failure. Opiate substitution was adjusted according to subject symptoms of opiate overdosing or withdrawal. Various methods were used to assess adherence: besides pill count, patients were asked to fill in a MASRI (Medication Adherence Self-Report Inventory) questionnaire and an electronic log pad diary. Calculation of adherence by pill count assumed that unreturned pills had been taken by the subjects.

Summary of results

Overall, 55% (n = 37, ITT, M = F) of patients had viral load <400 copies/mL at week 48. Using an ITT, M = E analysis, 90% (37/41) of patients reached undetectable VL (<400 copies/mL), 56% (23/41 patients) had plasma HIV-1 RNA concentrations <50 copies/mL at week 48. Only 30 patients (45%) completed the full study and the follow-up period. In 51% of patients, TDF adherence was >100% using pill count. MASRI showed adherence rates of 80–100% in 83–85% of patients; however, 15 patients never entered any data. Diary data were entered by 57 patients; diary data were entered for fewer days than patients received treatment (mean difference 113 days, calculated from treatment start and stop dates).

Conclusion

TDF in combination with other OD antiretrovirals in former IVDU patients showed comparable efficacy to that seen in the average HIV-1 infected population. However, measurement of adherence to self-administered HAART via pill count, MASRI or diary may be misleading in this population.