

Impact of 12 months HAART on cell-associated HIV-DNA in acute primary HIV-1 infection in the OPTIPRIM-ANRS 147 trial

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Background: Early Initiation of a potent HAART at the time of primary HIV-1 infection

(PHI) could block the virological and immunological storm and limit the establishment of HIV reservoirs. The

randomized multicenter OPTIPRIM-ANRS147 trial was designed to evaluate the impact of a 24-month

HAART initiated at the time of PHI on cell-associated HIV-DNA. **Methods:** Inclusion criteria included HIV-1

western-blot with ≤ 4 antibodies, positive HIV- RNA and $CD4 < 500/mm^3$ if PHI was asymptomatic. Patients

were randomized 1:1 to receive darunavir/r, emtricitabine/tenofovir (Arm 1) or darunavir/r,

emtricitabine/tenofovir (Arm 2). The primary endpoint was the between-arm difference in cell-associated

HIV-DNA decrease at M24. Clinical evaluation, cART tolerability, CD4 count, HIV-RNA and HIV-DNA were

collected during the trial. Hereinafter, we present the overall results of HIV-RNA and HIV-DNA decrease at

12 months. The 24 month-treatment period will be ended in July 2013.

Results: A total of 90 patients (median age: 35.5 years) were enrolled from May 2010 to July 2011, the

median time from estimated date of infection was 35 days and 43% had HIV1 Western-Blot with ≤ 1

antibody; 92% were male and 96% had symptoms. At baseline

median values for CD4, HIV-RNA and HIV-DNA were $472 \text{ cells}/mm^3$ [IQR: 368-640], 5.4 log

copies/ml [IQR: 4.9-5.8], and $3.65 \text{ log copies}/10^6 \text{ PBMC}$ [IQR: 3.35-4.02], respectively. Treatment was

well tolerated with only 2 serious adverse effects (1 lipodystrophy, 1 acute pancreatitis), both in Arm 2.

The CD4 difference at M12 was +239 cells/mm³. Plasma HIV- RNA decrease was >2 log cp/ml in 86 % subjects at M1 and HIV-RNA was < 50 cp/ml in 47%, 84%, 91% at M3, M6, and M12, respectively. Cell-associated HIV-DNA median [IQR] decrease from baseline was -0.75 [-0.94, -0.52], -1.12 [-1.33, -0.79] and -1.37 [-1.64, - 1.15] log copies/10⁶PBMC at M3 (n=73), M6 (n=63), M12 (n=39), respectively; 51.3% subjects had HIV-DNA level ≤2.3 log copies/10⁶PBMC at M12.

Conclusion: This is the first trial showing such a rapid and intense decrease in cell-associated HIV-DNA within one year. This probably results from initiation of HAART very early after HIV infection.