Journal of the International AIDS Society

Oral presentation

Open Access

O213 CD4-guided STI in patients responding to HAART

F Maggiolo*[1], M Airoldi[1], A Callegaro[1], C Martinelli[2], A Dolara[3], T Bini[4], G Gregis[1], P Quinzan[1], V Ravasio[1] and F Suter[1]

Address: [1]Ospedali Riuniti, Bergamo, Italy, [2]Ospedale Careggi, Firenze, Italy, [3]Ospedale San Gerardo, Monza, Italy and [4]Ospedale San Paolo, Milano, Italy

* Corresponding author

from Ninth International Congress on Drug Therapy in HIV Infection
Glasgow, UK. 9–13 November 2008

Published: 10 November 2008

Journal of the International AIDS Society 2008, **11**(Suppl 1):O18 doi:10.1186/1758-2652-11-S1-O18

This abstract is available from: http://www.jiasociety.org/content/11/S1/O18

Purpose of the study

To compare continuous HAART with a CD4-driven STI strategy.

Methods

LOTTI is a randomized, controlled, prospective trial. Patients with HIV-RNA <50 copies/ml and CD4 counts >700 cells/mcL were randomised to continue HAART or to stop it; 350 cells/mcL was the immunologic threshold to resume HAART. The primary end-point is clinical: development of any opportunistic disease, death from any cause, or the occurrence of diseases, other than opportunistic, requiring hospital admission. Secondary end-points are major adverse effects, virologic failures and therapeutic costs. An interim ITT analysis at 4-years follow-up is presented.

Summary of results

329 patients were randomized. The total follow-up time is 1,388 person-years. Patients in the STI group performed a total of 241 STI cycles. On average, patients in the STI group were on HAART for 34.7% (mean 515 days) of follow-up time, in the control group this value raised to 98.3% (mean 1,530 days). The primary end point of the study occurred in 12.1% of patients on STI and in 11.6% of controls (OR 1.05; 95% CI 0.5–2.1). The 95% CI for the difference between groups was far below the predefined 12% limit assumed to define equivalence. Resistance-conferring mutations were selected in 4.8% of STI patients and in 6.7% of controls (OR 0.79; 95% CI 0.3–1.8). Grade 3 or 4 adverse events were observed in 27.4% of controls and only in 20.6% of patients in the STI group. The mean daily total cost for controls was 20.29 euros and it dropped to 9.07 euros in the STI arm ($p < 0.0001$).

Conclusion

CD4-guided STIs may be a possible alternative strategic option for chronically infected individuals responding to HAART provided that CD4 decrements would be steadily maintained above a safe threshold. STIs warrant further careful prospective evaluation especially to investigate virologic and clinical outcomes in the very long period.