TIME-TO-ART-INITIATION: A Risk Factor Analysis of the HPTN 052 HIV-infected Partners on Delayed Therapy


BACKGROUND

The HIV Prevention Trial Network (HPTN 052 Study) is a Phase II, two-arm, randomized, controlled clinical trial designed to determine whether early antiretroviral therapy (ART) can prevent the sexual transmission of human immunodeficiency virus type 1 (HIV-1).

A total of 1763 sero-discordant couples in which one partner was HIV-1 positive and the other was HIV-1 negative were enrolled in four continents, nine countries, and thirteen study sites.

The HIV-1 positive partner was randomly assigned to either of the two arms: immediate therapy with ART initiated upon enrollment plus HIV primary care, or delayed therapy with HIV primary care but ART initiated when the index case had two consecutive measurements of a CD4+ cell count below the line of 350 cells/mm³ or 30% CD4+. A total of 177 HIV-1 positive partners were randomized to receive delayed therapy.

RESULTS

Variable: N of baseline N of ART initiated HR 95% CI Multivariate
Gender
Female Male 441 52 REF
Age
16-25 700 101 REF
Education
No schooling primary schooling 63 16 REF
Secondary schooling Post-secondary schooling 347 88 1.47 0.96, 2.26
Sexual Status
Single/widowed/separated divorced 441 11 REF
Married living with partner 833 202 0.51 0.33, 1.13
Region
Non-Africa Africa 401 141 REF
Sexual behavior 150 52
Marital status
Single/divorced 477 72 0.50 0.46, 0.79 0.62 0.47, 0.83
Comorbid use
No Yes 51 100 0.63 0.40, 1.07
Number of sex partners
0-1 833 204 REF
>1 43 5 0.51 0.46, 1.77
Number of sexual encounters
0 225 61 REF
1-2 430 108 0.92 0.87, 1.27
>2 213 46 0.64 0.57, 1.34
CD4 (per 100/microL)
<200 1 positive partners were randomized to receive delayed therapy.

LIMITATIONS

• Additional variable that need to be considered but not collected, such as viral subtype, IL-6, IL-D and soluble CD14

• Consideration of laboratory sub-studies that require use of study samples would however be deferred until the end of the trial, to ensure that samples are available to complete all of the testing for primary and secondary study endpoints.

REFERENCES


Chen, YQ, Massa, B, Wang, L, et al. (2012) Statistical considerations for the HPTN 052 Study to evaluate the effectiveness of early versus delayed antiretroviral strategies to prevent the sexual transmission of HIV-1 in serodiscordant couples, Contemporary Clinical Trials, in press.