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Concurrent Antiretroviral/TB Treatment Decreases Mortality in HIV Patients.

Karim SSA, et al.

Background: Many TB-HIV coinfected patients delay antiretroviral therapy (ART) until TB therapy is completed due to the concerns about drug–drug interactiosn, high pill burden, overlapping drug toxicities, and immune reconstitution syndrome.

Methods: An open-label randomized trial, known as the SAPIT (Starting Antiretrovirals at three Points in Tuberculosis) trial, was conducted in Durban, South Africa to determine the optimal time to start ART in patients on TB treatment and whether integrating ART early in TB treatment differs from integrating ART late in TB treatment. TB-HIV co-infected patients assigned randomly to receive ART together with their TB treatment (integrated treatment arm: 1) early –ART starting within first 2 months of TB treatment; 2) late – ART staring after completion of the first 2-month TB treatment) were compared with 3) patients assigned to receive ART upon completion of TB treatment (sequential treatment arm). The same ART combination of once-a-day ddI, 3TC and efavirenz was used in all three trial arms.

Results: The 3-year study enrolled 645 patients with TB and HIV co-infection 18 years or older; 431 patients in the integrated treatment arm and the 214 patients in the sequentia l treatment arm. The average time from TB treatment initiation to ART initiation was 67 days in the integrated-treatment arms combined versus 261 days in the sequential-treatment arm. Twenty six patients in the sequential treatment arm died (mortality rate of 11.6 per 100 person years) while 24 patients in the integrated treatment arm died (mortality rate of 5.1 per 100 person-years). The mortality rate was 55% lower in the integrated treatment arms when compared with sequential treatment arm. This reduction in mortality in the integrated treatment arms was statistically significant both in patients with CD4 counts below 200 and patients with CD4 counts from 200 to 500. Thus, Safety Monitoring Committee recommended stopping the sequential arm while the study continues with two sub-groups within the integrated treatment arm (early TB-HIV treatment and post-intensive phase TB-HIV treatment) as per the original protocol.

Conclusions: Mortality among TB-HIV co-infected patients was reduced by a remarkable 55% if ART is initiated early during TB treatment as compared to delaying ART until TB treatment is completed.