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ONE MONTH OF RIFAPENTINE/ISONIAZID TO PREVENT TB IN PEOPLE WITH HIV: BRIEF-TB/A5279

Clinical: (O) Tuberculosis and Other Opportunistic Infections

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Background: Tuberculosis (TB) is the leading killer of people with HIV infection. Preventive therapy is effective but current regimens are limited by toxicity and low completion rates. We hypothesized that an ultra-short course of isoniazid (H)/ rifapentine (P) would be non-inferior to 9 months H in people with HIV infection.
Methods: This multicenter, randomized, open-label, phase 3 trial enrolled HIV-infected individuals >13 y living in high TB-burden areas or who were TB skin test (TST)/Interferon-ϒ release assay (IGRA) positive. Antiretroviral therapy (ART) with efavirenz or nevirapine was permitted. Participants (pts) were stratified by ART status and CD4 count, randomized 1:1 to 1 month of daily H 300 mg plus P 450-600 mg (1HP) or 9 months daily H 300 mg (9H), and followed until 3 y after the last enrollment. The primary objective was to compare incidence rates (IR) of active TB, TB death, or death from an unknown cause. TB diagnoses and deaths were reviewed independently. A non-inferiority margin of 1.25/100 PY was based on an assumed IR of 2.0/100 PY in the 9H arm.
Results: 3000 pts were recruited by 45 sites in 10 countries from 5/2012-11/2014 and data are current as of 12/20/2017. 1614 (54%) were women, median age was 35 y (IQR 28-43), 1983 (66%) were Black, 730 (24%) Hispanic, and median BMI was 23.5 (IQR 20.9-27.1). Median CD4 count was 470 cells/mm3 (IQR 346-635) and 50% were on ART at entry. 634 (21%) had positive TST or IGRA. The primary endpoint occurred in 34 pts in the 1HP arm and 35 in the 9H arm, for incidence rates of 0.69/100 PY for 1HP and 0.72/100 PY for 9H (IR difference = -0.025, upper 95% CI: 0.31, Table). Rates were higher for pts not on ART at entry and those with a positive TST/IGRA, with no difference between treatments. For those with baseline CD4 counts <250 cells/mm3, incidence was higher in the 1HP arm, but the difference was not statistically significant (p=0.12). Serious adverse events occurred in 5.6% of 1HP pts and 7.1% of 9H pts (p=0.1). The incidence of targeted safety events was 3.3/100 PY with 1HP and 5.1/100 PY with 9H (P=0.03); treatment completion was higher in the 1HP arm than 9H (97% vs. 90%, P<0.01). There was 1 case of rifampin-resistant TB in each arm and 1 case of H-resistant TB in the 9H arm.
Conclusion:
Once daily 1HP was non-inferior to 9H, had fewer adverse events, and was more likely to be completed in HIV-infected adults and adolescents. This ultra-short course TB preventive therapy could be an important tool to control HIV-related TB.