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SAFETY AND EFFICACY OF DOLUTEGRAVIR-BASED ART IN TB/HIV COINFECTED ADULTS AT WEEK 24
Clinical: (O) Tuberculosis and Other Opportunistic Infections
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Background: Concurrent treatment of TB and HIV is compounded by drug interactions, overlapping toxicities, and immune reconstitution inflammatory syndrome (IRIS). The efficacy and safety of dolutegravir (DTG) in antiretroviral treatment (ART) naïve adults with HIV/TB co-infection was assessed.
Methods: INSPIRING (NCT02178592) is a Phase 3b, non-comparative, active control, randomised, open-label study in HIV-1 infected ART-naïve adults (CD4+ ≥50 cells/μL) with drug-sensitive TB. Participants on rifampin-based TB treatment for up to 8 weeks were randomised (3:2) to receive DTG (50mg twice daily during and for 2 weeks post-TB therapy, followed by 50mg once daily [OD]) or EFV (600mg OD), with 2 investigator-selected NRTIs for 52 weeks. For this Week 24 interim analysis, the proportion of subjects with plasma HIV-1-RNA <50 c/mL was derived using the FDA Snapshot algorithm in the intent to treat exposed (ITT-E) population. Safety was assessed in all subjects who received study drug. An independent committee adjudicated IRIS episodes. The study was not powered to show a difference between study arms; no formal statistical hypothesis was tested.
Results: Of 113 subjects enrolled, 69 were randomised to DTG and 44 to EFV. Median baseline HIV-1 RNA and CD4+ cell counts were 5.10 log10 c/mL and 208 cells/μL in the DTG arm and 5.24 log10 c/mL and 202 cells/μL in the EFV arm; 40% were women. The proportions of subjects with HIV-1-RNA <50 c/mL at Week 24 were 56/69 (81%) (95% CI: 72%, 90%) in the DTG arm and 39/44 (89%) (95% CI: 79%, 98%) in the EFV arm. The lower DTG response rate was driven by non-treatment related snapshot failures: five participants (7%) in DTG arm and none in EFV arm discontinued due to non-treatment-related reasons (loss to follow-up/protocol deviations). Median CD4+ cell increases at Week 24 were 146 cells/μL (IQR: 71, 214) for DTG and 93 cells/μL (IQR: 47, 178) for EFV. Two subjects discontinued study treatment due to AEs (both on EFV). TB-Associated IRIS rates (adjudicated and investigator reported) were low (DTG, n=4 [6%]; EFV, n=4 [9%]). No subjects discontinued due to IRIS or liver events.
Conclusion: Interim Week 24 results from this ongoing study show that DTG 50 mg twice daily appears to be effective and well-tolerated in HIV/TB co-infected adults receiving RIF-based TB therapy. Rates of IRIS were low. There were no new toxicity signals for DTG and no discontinuations due to liver events. These data support the use of DTG based regimen in HIV/TB co-infection.