

PREGNANCY OUTCOMES IN HIV +ve MOTHERS ON THE D²EFT STUDY.

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Background:

Dolutegravir (DTG) and Darunavir (DRV/r) Evaluation in adults Failing Therapy (D²EFT) was a phase IIIB/IV randomised open-label trial. People living with HIV who failed first-line ART regimen were randomly allocated to one of three arms: Standard of Care (SOC) 2 x NRTI + DRV/r or DTG+DRV/r or DTG+2NRTI. This study was conducted across 14 low and middle-income countries. Recruitment closed December 2021 with 826 participants enrolled, including 450 women.

Methods:

Pregnancy was an exclusion criterion for this study. Women of child-bearing potential had to be willing to use contraception and undergo a pregnancy test at every study visit except week 12. If pregnancy was detected during study, the protocol recommended management was:

- SOC arm - a determination regarding study drug discontinuation was made by the investigator, and continuation of study drug considered if the potential benefit justified the potential risk.
- DTG arms – D²EFT protocol recommended switching to the SOC regimen for the duration of the pregnancy, reverting to the DTG arms thereafter.

Results:

As at 31December2023, 33 pregnancies were reported on-study resulting in 25 live births including two sets of twins. The mother's mean age was 29.5 (SD: 6.8) years; 97% black. The median time on ART therapy was 3.8 (IQR: 1.9-6.8) years. The median HIV RNA level at baseline was 4.4 (IQR: 4.0-4.6) log₁₀ copies/mL. Median CD4+ count was 217.0 (IQR: 161.0-313.0) cells/μL. The median gestational age of the live births was 39.0 (IQR: 36.0-40.0) weeks with a median birth weight 2700g (IQR: 2310-3100). HIV status was negative for all but one live birth (PCR at birth and then generally at 6 weeks, and 18 months). There were 6 spontaneous abortions (including 2 ectopic pregnancies), 2 induced abortions (1 suspected, 1 confirmed), all occurring between 5- and 16-weeks' gestation. There were 2 stillbirths.

Conclusion:

This presentation further details the pregnancies and outcomes on the D²EFT study.

Disclosure of Interest Statement:

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