Introduction

Atazanavir/ritonavir (ATV/r) + abacavir/lamivudine (ABC/3TC) in antiretroviral (ART)-naive, HIV-1 infected, HLA-B*5701 negative subjects demonstrates efficacy and safety: theLine.

Methods

Abstract

Background: Results from ACTG 5202 have raised questions of a higher rate of virologic failure (VF) in subjects on ART regimen with a baseline 63% HIV-1 RNA (vRNA) ≥100,000 copies/mL. ABC/3TC was associated with a lower rate of VF but is not used commonly in clinical practice. This study compared the efficacy and safety of ABC/3TC + ATV/r with baseline vRNA ≥100,000 copies/mL. Utilizing an interim analysis of the ACTG 5202 data, patients were randomized to ABC/3TC + ATV/r arm or ABC/3TC + ATV/micronized arm. Results: 125 subjects (ITT & CSA) were included in this non-comparative, prospective analysis. median age 38; males: 83%; 62% white; 13% CDC Class C; vRNA ≥5.08 log copies/mL (median); most commonly hyperbilirubinemia (13%) and diarrhea (12%).

Table 1. Baseline Characteristics, ITT-E Population

Table 2. Subject Disposition, ITT-E Population Protocol-Defined Virologic Failure

Table 3. Proportion of Subjects with Protocol-Defined Virologic Failure

Table 4. Safety Population

Discussion

Conclusions

Acknowledgements

References