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Adherence with lopinavir/ritonavir (LPV/r) tablet and SoftGel (SGC) capsule based antiretroviral regimens and predictors of early treatment compliance

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Purpose of the Study

Simplified antiretroviral (ARV) regimens may promote adherence and improve outcomes in HIV-1 infected patients. Clinical studies have previously demonstrated greater adherence with LPV/r SGC when dosed once-daily (QD) compared to twice-daily (BID). The objectives of the current analysis are to compare adherence when LPV/r tablets and SGC are dosed QD and BID and to assess predictors of early adherence.

Methods

M05-730 is an ongoing Phase III, open-label, randomized, multicenter, multicountry study designed to evaluate the safety, tolerability, pharmacokinetics, and antiviral activity of LPV/r tablets dosed QD or BID through 48 and 96 weeks in combination with TDF and FTC (both QD) in ARV naïve HIV-1 infected subjects. In addition, the study compared safety, tolerability, and pharmacokinetics of LPV/r tablets with LPV/r SGC over the first 8 weeks of administration. Electronic monitoring (MEMS®) allowed for computation of three LPV/r compliance measures through week 12: taking (TAC; prescribed doses taken), correct dosing (COD; days with correct number of doses taken), and timing (TIC; doses taken within ± 3 hrs of prescribed interval) compliance. Using longitudinal mixed models, demographic and baseline characteristics were examined for possible associations with compliance through week 12.

Summary of Results

A total of 606 subjects were included in the analysis. Adherence was similar for subjects taking LPV/r tablets compared to SGC. Adherence to LPV/r dosed QD was statistically significantly greater than BID ($p < 0.001$). Adherence declined significantly over time ($p < 0.001$), but between-arm differences remained consistent over 12 weeks ($p = 0.353$). Week 48 clinical outcomes did not differ for subjects receiving LPV/r QD or BID. Demographic and baseline characteristics significantly associated with early compliance included sex, age, race, tobacco use, HIV/AIDS risk factors, HIV-1 RNA, and CD4 and CD8+ T-cell count ($p = 0.20$). The strongest associations were for TIC and sex (M>F), age (older>younger) and race (white>black) ($p \leq 0.003$); however, the proportion of subjects with plasma HIV-1 RNA <50 copies/mL at week 48 did not differ by sex ($p = 0.622$), race ($p = 0.724$) or age ($p = 0.610$).

Conclusion

In this large study of LPV/r, QD dosing resulted in higher levels of adherence than BID dosing. Adherence to LPV/r tablets and SGC were similar. Sex, age and race were predictors of early adherence. Differences in early adherence did not predict clinical outcomes in this study.