PHARMACOKINETICS AND SAFETY OF LOPINAVIR/РИТОНАВИР SOLUTION IN HIV-INFECTED NEWBORNS

Bekker A1, Hanan N2, Cababasa M2, Wang J3, Nakefa F4, Smith, E5, Moyo J1, Violant A2, Cotton M, Wiessner L1, Norman J4, Fournier B1, Capparelli E2, Mirochnick M2, IMPAACT P1106 team

1 Trends Clinical Research Unit, Stellenbosch University, Cape Town, South Africa
2 University of Cape Town, Cape Town, South Africa
3 University of California San Diego, California, USA
4 Center for Infectious Disease Epidemiology, Harvard T.H. Chan School of Public Health, Boston, MA, USA
5 Department of Paediatrics, University of Mzumbe, Mzumbe University, Tanzania

Objective

To describe the PK and safety of LPV/r solution in HIV-infected low birth weight (LBW) and VLBW newborns receiving LPV/r in clinical care.

Methods (continued)

- GPU safety monitoring comprised: 1) Unexpected AEs and 3) VLBW newborns.
- Infant’s LPV/r concentration and other 3, 5, 7 days 7-day window 2 and 1 week post LPV/r initiation.
- Patient’s LPV concentration for last 5-day period was normalized to total Q = 150 mg as a change from Q1. Baseline of 150 mg calculated through thoracic formula.
- On day 6-7 and week 1 post LPV/r initiation.
- Adverse events (AEs) potentially related to newborns, were classified as follows: Expected events are classified as events associated with systemic antiretroviral treatment; non-systemic events are defined as events associated with systemic antiretroviral treatment.

Results (continued)

- No differences were observed in LPV concentrations stratified by birth weight or birth weight (Figure 3).

Adverse events

- As of 26 January 2018, 34 of 35 newborns were off study (22 completed follow-up, 1 died and 1 withdrawn consent) and 1 is still on study.
- All 28 AEs of safety are evaluable newborns with serious adverse events.
- Several medications included abacavir n=22 (92%), nevirapine n=21 (88%), zidovudine n=22 (92%), lamivudine n=20 (83%), sulfamethoxazole n=20 (83%). One newborn was infected with traditional medicine and resolved.
- No cardiac complications were observed throughout the study period.

Conclusions

- In our population of HIV-infected low and normal birth weight newborns and young infants receiving LPV/r as a single daily dose, we observed no treatment related adverse events.
- We observed no treatment related adverse events.
- LPV/r was well tolerated and achieved effective plasma exposures in our newborn population, including those with an immature microbiome.

References


Acknowledgements

The poster was funded by IMPAACT. A Bekker received support from the RV147/IMPAACT team and by A. Bekker and P. Giest are employed at IMPAACT.