Effectiveness of a new ART formulation for children

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Background

Lopinavir/ritonavir (LPV/r) pellets are a palatable, heat-stable and easy-to administer, formulation for infants and young children who are unable to swallow tablets and whose families may not be able to afford the heat-labile syrup. However, there is a paucity of clinical data on effectiveness and safety in routine care. The LIVING study, sponsored by DnDi, aims to evaluate the effectiveness, safety, pharmacokinetics and acceptability of LPV/r pellets + ABC/3TC (or AZT/3TC) dispersible tablets, in HIV+ children unable to swallow tablets in Kenya, Uganda and Tanzania.

Methods

The study is an open-label, single-arm, prospective, multi-center, phase-3b study. Included children are ARV naıve, on LPV/r-based or failing NNRTI-based ART; with weight ≥3 and <25 kg. ART dosing is based on WHO weight bands. Children are assessed at baseline, 1 month, and then every 3-months. We evaluated viral load evolution in 4 baseline age categories.

Results

As of April 2018, 947 patients were enrolled with 100 from Epicentre in Mbarara. Baseline and week 48 viral load (VL) and CD4 were available for 354 children. The median age was 42 months, 32 (9.0%) were ART naive, 297 (83.9%) on LPV/r syrup, and 25 (7.1%) on NNRTI at baseline. There was improvement in viral load suppression across the age categories. 25 children had 34 serious AEs, 2 leading to treatment stoppage. The pellets were acceptable among caregivers and children.

Conclusions

LPV/r pellets were associated with significant HIV viral suppression, with an acceptable safety profile and good acceptability.

The LIVING study combines the four drugs needed for the treatment of paediatric HIV into an easy-to-use combination, which is heat-stable, taste-masked, solid, and does not contain alcohol or inappropriate solvents. Results to date show that LPV/r pellets-based ART in children is associated with significant HIV viral suppression and are well accepted.