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Oral presentation

Once-a-day pediatric HAART with DDI+3TC+EFV in Burkina Faso. A phase II trial (ANRS 12103 trial)

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Background

Simplification of the administration of HAART in children should improve compliance and efficacy of these treatments. Combination of 3TC + DDI + EFV in a single daily oral administration is one option. However, pharmacokinetics, tolerance and efficacy of such once-a-day HAART have not been assessed in children. The ANRS 12103 trial is a phase II on pharmacokinetics, tolerance and compliance of a once-a-day pediatric DDI+3TC+EFV in Burkina Faso.

Material and methods

ANRS 12103 is an ongoing Open Phase II Trial with a 12 months follow up. 50 HIV-1 infected children eligible for HAART had to be included. Inclusion criteria were: weight ≥ 10 kg and aged 30 months to 15 years, naive of ARV treatment and eligible for HAART. Children received efavirenz + 3TC (8mg/kg) + DDI (240mg/m2). Clinical examination was performed weekly until M3, then monthly. Pharmacokinetics (plasma Cmin and Cmax) was done at day 15. Quaterly RNA HIV-1, CD4 counts, haematology and biochemistry are performed.

Results

Enrolment was from February to November 2006 and 98 HIV-infected children have been screened for eligibility criteria: 45 were excluded, one died before inclusion and 52 were included. Among included children there was 21 girls and 31 boys, mean age was 6.8 years, Zscore Weight for Age (W/A) and Height for Age (H/A) were respectively -1.91 and -1.99 at inclusion. Mean CD4 was 355/µl (mean CD4 percentage 9%), and median HIV-1 RNA 5.50 Log_{10} cp/ml. Among the 52 expected samples for minimum concentration of efavirenz, 50 were obtained. Thirty children were in the expected ranges (60.1%), 11 (22%) below therapeutic levels and 9 (18%) above therapeutic levels. Maximum concentrations were in the expected ranges in 23/49 children (47%), below therapeutic levels in 3/49 children (6%) and over in 23/49 children. Dosages of 3TC and DDI are ongoing.

At 9 months of follow-up, two children had died, Zscore W/A and H/A were respectively -1.37 and -1.62, and mean CD4 was 893/µl (mean CD4 percentage 20%). HIV-1 RNA was below detectable level (300 copies/ml) in 39 children (76%) and below 1000 copies/ml in two children (4%).Two HAART adverse effect occurred. One cuta-

neous eruption with a temporary stop and successful reintroduction and one increase in liver enzymes.

Conclusion

Preliminary data of this phase II trial suggest that once-a-day DDI+3TC+EFV in children provides satisfactory plasma concentration for EFV, and is associated with virological success and immune restoration. At 9-month follow up, it is effective and well tolerated.