

Ongoing project: Lopinavir-based ART for HIV-Infected children Globally (LIVING study)

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Introduction

The revised WHO treatment guidelines reemphasizes the need to treat all HIV-infected children below 5 years of age and, and initiate therapy with a Protease Inhibitor (PI)-based regimen for children less than 3 years of age regardless of prior exposure to antiretroviral in prevention of mother to child transmission (PMTCT) programme . Few antiretroviral drugs are approved for infants and toddlers and existing combination antiretroviral therapies (cARTs) which typically combine Non-Nucleoside reverse transcriptase inhibitors (NNRTI) Nevirapine (NVP) and Nucleoside reverse transcriptase (NRTI) lamivudine (3TC) plus either Abacavir (ABC) or Zidovudine (AZT). They are not optimal for newly infected infants due to their high viral loads (10 to 100 times higher than older children); in addition they are often infected with viruses already resistant to NVP, commonly used for PMTCT. For infants the only alternative to NVP is the PI, Lopinavir, boosted with ritonavir; however the available LPV/r liquid formulations for children taste very bitter, are difficult to administer, and are unstable in tropical climates. This study is evaluating the effectiveness, safety and acceptability of LPV/r pellets in addition to AZT/3TC (or ABC/3TC) paediatric fixed dose combination tablet under routine treatment

conditions in HIV infected infants and young children who cannot swallow tablets.

Methods

It is single arm, open-label, prospective, multicenter, multi-country phase IIIb study among children with a past or current documentation of a confirmed diagnosis of HIV-1 infection, eligible for treatment with LPV-based treatment, weighing ≥ 3 and < 25 kg at the time of enrolment and unable to swallow tablets. The primary endpoint is treatment effectiveness at 48 weeks based on a composite endpoint of virologic response $< 1\ 000$ copies/ml, being alive and on study drug. Patients are followed-up for 24 months.

Status of study

At the Epicentre site recruitment of participants started on 10th May 2016 and so far 68 patients have been enrolled to date.

Existing combination antiretroviral therapies for children are complex, and not optimal for newly infected infants with very high viral loads. There is need to study Lopinavir boosted with ritonavir in pellet form as the available paediatric liquid formulations have a very bitter taste and are unstable in tropical climates.