

Understanding clinical, immunological and virological outcomes in untreated and treated HIV-infected children in India: Setting up a clinical cohort

Introduction

Antiretroviral therapy has become the mainstay of HIV management, with effects ranging from improved survival and enhanced quality of life, reduced HIV transmission, and importantly, diminished stigma of infection. Pooled data from African trials indicate that without antiretroviral therapy, approximately 35% of perinatally infected children will die before 1 year of age, and over 50% of these children will not survive beyond 2 years of age. In 2005, NACO made available appropriate paediatric ART formulations and free ART access in designated ART centers throughout India. Since then, several thousands of children have been successfully initiated on ART. In order to enhance our knowledge on pathogenesis and treatment of HIV, as well as to evaluate our treatment programs, systematic collation of information and biological samples, followed by subsequent analyses are urgently required.

Objectives

The main objective of this analysis is to follow the clinical progress of children with HIV infection, record immunologic and virological outcomes, and establish a biorepository for future laboratory analysis if required.

Inclusion criteria:

- All HIV-infected children aged 0-18, regardless of the mode of transmission.
- Caregiver able to give informed consent.

Procedures: Children will be followed as per NACO guidelines for HIV care. Baseline socioeconomic and demographic data will be recorded. At each visit, weight and height will also be documented. Routine laboratory parameters such as CD4 count and hemoglobin will continue to be documented in the case report forms. Every 6 month viral load will be determined. Remaining sample will be stored for genotyping or other laboratory analysis as required.

Study Impact:

This study will help us understand viral evolution and drug resistance patterns in HIV-1 infected children over time. Detailed statistical analysis of immunological and clinical response in children newly initiated on ART may reveal potential challenges, and can direct program managers into addressing modifiable issues such as suboptimal adherence, dosing inaccuracies or drug interactions. Understanding how children respond to treatment, and how the virus changes over time, both qualitatively and quantitatively will help us review our management strategies and thus lead on to further improvement of the outcomes of HIV-infected children.

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