Anaemia and nutrition among children with perinatally acquired HIV infection in South India

Funding support: ICMR 2009

Objectives of the proposal:

***Primary Objectives**:*

1. To assess the prevalence of anemia and micronutrient deficiencies (namely iron, vitamins A, B12, and folic acid) among HIV-infected children in South India.

2. To examine nutritional and non-nutritional etiological factors contributing to anemia among HIV-infected children.

***Secondary Objectives**:*

1. To compare the effect of therapeutic iron supplementation in those with nutritional anemia and anemia of inflammation, using haematological endpoints (such as hemoglobin, markers of iron status) and measurable endpoints for HIV disease progression (CD4 counts, viral load, opportunistic infections, hospital admissions, death)

2. To assess the effect of baseline anemia on growth and HIV disease progression status in children with HIV infection.

Study Summary

Anemia is common during HIV infection and is associated with increased morbidity and mortality. In India, the profile and impact of anaemia during childhood have not been adequately investigated. We propose a multi-site collaborative study to examine the prevalence of anaemia and related micronutrient deficiencies (such as iron, folic acid, vitamin B_{12}, and vitamin A) among a cohort of children with perinatally-acquired HIV infection in South India. We hypothesize that, in addition to nutritional factors, non-nutritional factors such as anemia of chronic inflammation play an important etiological role in childhood anemia in the context of HIV infection. We will also examine the effect of anaemia and subsequent iron supplementation on growth, nutrition status and HIV disease progression. Understanding the role of chronic inflammation in anemia has important implications for the clinical evaluation and treatment of HIV-infected children, as well as for designing national policies on nutritional interventions in these children.

Subject population: We plan to enroll 240 children aged 2-12 years, with perinatally acquired HIV infection aged between 2 and 12 years at three sites in South India, with equal proportions of children who are ART-naïve and on ART.

The three sites are as follows:
Site 1: St John's Hospital and associated clinics, Bangalore.
Site 2: YRG Centre for AIDS Research and Education, Chennai
Site 3: Tuberculosis Research Center, Chennai

Duration of follow-up: 2 years

Inclusion criteria:

- HIV positive status documented by reactive rapid antibody test or ELISA as per NACO guidelines.
- Perinatally acquired HIV infection (history or documentation of one or both parents being HIV-infected; in the event of lack of parental history, the absence of history of blood transfusion or contaminated needle contact that may be likely sources of HIV infection)
- ART Treatment status: "ART-naïve" (or those who have received ART for less than 2 weeks) OR "On ART" (those on ART for 6 months or longer)

Exclusion criteria:

- Acute febrile or infectious event or life-threatening event at the time of, or within 4 weeks of recruitment.
- Blood or blood component transfusion within the past 6 weeks prior to recruitment.

Study procedures:

Initial Visit: After informed consent is obtained from the caregiver, the HIV positive status will be verified. A study research assistant will obtain baseline socioeconomic and demographic data, dietary intake history, information on use of nutritional supplements and other medications, and current antiretroviral therapy and OI prophylaxis.

Dietary Intake: Trained health workers will administer the food security questionnaire and 24-hr recall to the caregivers of children enrolled in the study.

Anthropometry: Specific measurements include weight, length/height and mid-arm circumference. For younger children (aged between 2 and 4 years) recumbent length, instead of height will be measured to the nearest 0.1 cm using a length of wooden board with a sliding foot piece. Skin fold measurements will be obtained using Holtein calipers.

Laboratory evaluation: The following laboratory tests will be undertaken: hematological status (hemoglobin, reticulocytes, MCV, MCH, peripheral smear); iron status (serum iron, serum ferritin, transferrin receptors, zinc erythrocyte protoporphyrin); micronutrient concentrations (retinol, vitamin C, $B_{12,}$ folate); inflammatory markers (CRP); CD4 cell counts; albumin and lead levels; blood smear for malaria parasite; testing for occult blood; and examination of the stool for enteropathogens.

Iron Supplements: All anemic children will be given iron, folate and B_{12} supplementation (in the form of Syp. Tonoferon)– for 3 months and at end of 3rd month, investigations will be repeated, to assess the effect of iron folate and B_{12} supplementation. If iron is still low patient will be continued on supplementation and closely monitored.

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