HIV: Current Research

Extended Abstract

Feasibility and Safety of ALVAC-HIV vCP1521 Vaccine in HIV- exposed Infants in Uganda: Results from the First HIV Vaccine Trial in Infants in Africa

Dr. Kenneth Kintu

Abstract

The development of a safe and effective vaccine against human immunodeficiency virus type 1 (HIV-1) for prevention mother-to-child transmission of HIV would significantly advance the goal of eliminating HIV infection in children. Safety and feasibility results from Phase I, randomized, double blind, placebo-controlled trial of ALVAC-HIV vCP1521 in infants born to HIV-1-infected women in Uganda are reported. The Methods for HIV exposed infants were enrolled at birth and randomized (4:1) to receive vaccine or saline placebo intramuscular injections at birth, 4, 8 and 12 weeks of age. Vaccine reactogenicity was assessed at vaccination, and days 1 and 2 post-vaccination. Infants were followed until 24 months of age. HIV infection status was determined by HIV DNA PCR. The Findings From October 2006 to May 2007, 60 infants (48 vaccine, 12 placebo) were enrolled with 98% retention at 24 months. One infant was withdrawn, but there were no missed visits or vaccinations among the 59 infants retained. Immune responses elicited by Diphtherias, Polio, Hepatitis B and Hemophilic influenza type B and measles vaccination were similar in the two arms. The vaccine was well tolerated with no severe or life-threatening reactogenicity events. Adverse events were equally distributed across both study arms. Four infants were diagnosed as HIV infected [3 at birth (2 vaccine, 1 placebo) and one in vaccine arm at 2 weeks of age].The Interpretation for the ALVAC-HIV vCP1521 vaccination was feasible and safe in infants born to HIV-infected women in Uganda. The conduct of high quality infant HIV vaccine trials is achievable in Africa.

Keywords: HIV vaccine, ALVAC, infants, Africa, breast milk transmission

Dr. Kenneth Kintu
MUJHU Research Collaboration
Kampala, Uganda
E-mail: kkintu@mujhu.org