

Title: Recruitment for the first phase I HIV vaccine trial in fishing communities of Lake Victoria, Uganda

A. Nanvubya¹, F. Kibengo², J. Mpendo¹, U. Bahemuka², A. Ssetaala¹, A. Abaasa², P.Kato¹, K. Chinyenze³, A. Balyegisawa³, D. Vooijs³, C. Verlinde³, F. Priddy³, G. Mutonyi², J. Levin², N. Kiwanuka¹, A. Kamali², S.Ding⁴, E. Venneker⁴, P.Kaleebu², G. Pantaleo⁵

1. *UVRI-IAVI HIV Vaccine Program*
2. *MRC -UVRI Uganda Research Unit on AIDS*
3. *International AIDS Vaccine Initiative*
4. *Eurovacc Foundation*
5. *Division of Immunology and Allergy, Lausanne University Hospital*

Background

The EV06 trial is a collaborative trial between the European Community's FP7 IDEA program, the International AIDS Vaccine Initiative and the Uganda Virus Research Institute. It is the first phase 1 HIV vaccine trial in fishing communities, a recognized "Most at Risk Population" in Uganda. The primary objective of the trial is to investigate the impact of *Schistosoma mansoni* infection on HIV vaccine safety and immune responses.

Methods

Potential adult male and female volunteers (18-45 years) identified through community education seminars on the shores of Lake Victoria and surrounding villages were invited to the study clinics for screening. After obtaining written informed consent from each participant, detailed study information was given, HIV-infection risk was assessed, HIV counseling and testing were done and participants provided urine, blood and stool samples for testing. Eligibility was based on low HIV risk profile, helminth status, demonstration of understanding of the study, availability for the study duration of 9 months, clinical and laboratory assessments. Eligible participants were enrolled in a double blind, randomized, placebo-controlled phase I trial. Those excluded received treatment and appropriate referrals.

Results

Recruitment was completed over a period of approximately 6 months. A total of 338 (129, 38% females) were screened to enroll 72 (24, 33% females). Reasons for screen failure included; infection with helminths (103, 39%), high HIV risk behavior (37, 14%), unavailability for follow-up (26, 10%), hepatitis B or C (23, 9%), medical illness/abnormal history (22, 8%), HIV infection (6, 3%), abnormal laboratory results (6, 3%), pregnancy (4, 2%) and other non-specific reasons (56, 21%).

Conclusion

Despite a substantial proportion of screen outs due to infection with helminths, high HIV risk behavior, unavailability for follow-up and hepatitis infection, findings suggest that it is possible to recruit for HIV prevention vaccine trials in fishing communities.