Participation in Clinical Research Could Modify Background Risk for Trial Outcome Measures

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Abstract

Data on HIV incidence and retention are needed to inform study design of efficacy trials. However, the selection criteria and interventions during an actual clinical trial could

reduce HIV incidence and thus affect the statistical power. Weinvestigated the effect of inclusion and participation in a simulated vaccine efficacy trial (SiVET) on HIV and pregnancy incidence in a fisherfolk cohort in SW Uganda. High-risk vounteers aged 18–49 years from fishing communities 30-40 km from the MRC/UVRI research centre were recruited in HIV open cohort. High risk was defined as history of multiple sex partners, unprotected sex, STI presence and absence from home for ‡ 2 days in the preceding 3 months. Consenting volunteers with at least 3 months of follow-up, no contraindications for hepatitis B vaccine and willing to use contraception were administered a licensed Hepatitis B vaccine at 0, 1 and 6 months to mimic a candidate vaccine. The cohort was followed quarterly for a year. HIV incidence, pregnancy and retention rates were compared. Results: Of 853 (55% men) individuals screened from Jan 2012-Feb 2014, 575 (60% men, mean age 28) were enrolled into the open cohort, 282 (73% men) of whom enrolled into the SiVET between July, 2012-Feb 2013. In both groups there was reduction of risky behaviours, ($p < 0.05$). A total of 13 HIV incident cases occurred in 93.0 PYO [brackets 95% CI]; incidence 13.9/100 PYO [8.1-24.1] and 10 cases in 311.6 PYO; incidence 3.2 [1.7-6.0] in the open cohort and SiVET respectively. A total of 26 pregnancies were observed in 42.7 Women Years of Observation(WYO); incidence 60.9 [41.5-89.5], and 4 pregnancies (71.4WYO); incidence 5.6 [2.1-14.8] in the open cohort and SiVET respectively.

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