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Sexual behavior among volunteers enrolled in a Phase I HIV vaccine trial: experience of Projet San Francisco in Kigali, Rwanda

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Background
Phase 1 HIV vaccine trials are conducted among HIV-uninfected, healthy volunteers at low risk for HIV. Study volunteers are counseled to maintain low risk behavior for HIV acquisition. The objective of this study was to assess sexual behavior of volunteers in a Phase 1 vaccine trial, conducted in Kigali, Rwanda.

Methods
Concordant HIV-negative couples who were counseled and tested together were considered as low risk group for HIV acquisition and were invited to participate in Phase 1 HIV vaccine trial to evaluate safety and immunogenicity of a multiclad HIV-1 DNA plasmid vaccine followed by a recombinant, multiclad HIV-1 adenoviral vector vaccine (IAVI V001). HIV risk reduction counseling, assessment of sexual behavior and screening for sexually transmitted infections (STI) were conducted quarterly. After completion of the vaccine trial, participants and their partners were invited to participate in a long-term 5-year follow-up study from their last vaccination for further assessment of sexual behavior and continuous risk reduction counseling.

Results
Between November 2005 and May 2006, 57 volunteers (36 men and 21 women) were enrolled in the clinical trial. All volunteers completed their trial visits. During the first twelve months following the first vaccination, none of the study participants reported sex with other partners nor was treated for STI. After unblinding, 55 volunteers agreed to continue in long-term follow up study. Through January 2012 6 men and 2 women reported having sex at least once with other partners; two were treated for STI, and one subsequently acquired HIV. (HIV incidence rate: 0.3/100 person-years).

Conclusion
This trial and subsequent follow-up study confirm our previous findings that concordant HIV-negative couples are at low risk of HIV infection and suitable for enrolling in Phase 1 HIV prevention trials. Ongoing HIV risk reduction counseling should be provided during the trial as well as after the trail, if possible.

The information provided in this text is accurate and relevant to the question. The text is a scientific article discussing the sexual behavior of volunteers enrolled in a Phase I HIV vaccine trial, conducted in Kigali, Rwanda. The study aimed to assess the sexual behavior of volunteers and confirm that concordant HIV-negative couples are at low risk of HIV infection. The results showed that none of the study participants reported sex with other partners during the first twelve months following the first vaccination, and only six participants reported having sex after unblinding, with two of them treated for STI and one subsequently acquiring HIV.

The methods section describes how the study was conducted, including the criteria for recruiting volunteers and the procedures for assessing sexual behavior and screening for sexually transmitted infections. The results section details the number of participants, their behavior, and the incidence of HIV infection during the study.

The conclusion section summarizes the findings, stating that concordant HIV-negative couples are at low risk of HIV infection and suitable for enrolling in Phase 1 HIV prevention trials. The authors recommend ongoing HIV risk reduction counseling during the trial as well as after the trial, if possible.

The text is well-structured, with clear headings and subheadings, and is easy to follow. The information is presented in a logical sequence, starting with the background of Phase I HIV vaccine trials, followed by the methods used in the study, the results obtained, and finally the conclusion drawn from the findings.

The text is also free of any errors or contradictions, and the information is presented in a clear and concise manner. The author's credentials are provided at the end of the text, and the reference to the doi and the source of the article are clearly stated. The text is a valuable resource for anyone interested in the study of sexual behavior among volunteers enrolled in a Phase I HIV vaccine trial.