

A comparison of gel use at Soweto and Orange Farm sites participating in a Phase III randomized controlled trial of PRO 2000/5

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Background:

Various Phase III microbicide trials are underway and although these will determine safety and efficacy of the product, whether the product will actually be used and whether that use will be consistent and correct over long periods of time, must also be considerations.

Methods:

Gel use between participants enrolled at two RHRU sites at Soweto and Orange Farm (OF); in an international multi-centre, randomised, double-blind, placebo-controlled trial to evaluate the efficacy and safety of 0.5% and 2% PRO 2000/5 gels for the prevention of vaginally acquired HIV were investigated. Demographic factors including mean age of participants, education level, employment status, type of house and the number of people per household and the number of rooms used for sleeping, were compared to determine if these contributed towards differences in gel use at the sites.

Participants enrolled into the trial were given enough gel to last until their next monthly clinic visit. At follow-up visits, information regarding the number of sex acts, gel and condom use was collected. Demographic information was obtained by interview at the enrolment visit and recorded on case record forms (CRFs). Data from the first year of the trial only was used.

Results:

During this period, the Soweto clinic had enrolled 555 women and dispensed a total of 43860 gel applicators, compared to 495 women enrolled at OF and 29550 gels dispensed; indicating that OF usage was only 67.37% of that by Soweto participants. The mean number of sex acts reported in the last week (with or without gel) per participant was 5.97 and 5.17 at Soweto and OF respectively and was found to be statistically significant ($P = 0.002$). Differences in the mean age of participants (24.1 years and 30.2 years at Soweto and OF, respectively) and the type of housing (76.9% municipal and 6.4% [95% CI: 4.4% -9.1%] shacks at Soweto, whereas 32.4% [95% CI: 28.0% - 37.2%] lived in shacks at OF ~~) were observed.~~

Discussion:

The differences in the faster rate of gel use and higher mean number of sex acts at the Soweto site may be a result of a younger population who are more willing to experiment with new methods. Differences in the type of housing may allude to differences terms of privacy and freedom to experiment however such conclusions require more information. Differences in gel use may also be indicative of patterns of under or over-reporting at the sites and further investigation is required.

It is difficult to determine reasons for differences in the quantities of gel used at the sites however and demographic data alone is insufficient to identify reasons, therefore it is recommended that further investigation in the form of in depth interviews and/or focus group discussions be conducted. This information may be useful in terms of marketing and encouraging consistent gel use should a commercial product become available.