

Dhookie, J. (2008). An assessment of the acceptability of a pro 2000/5 microbicide gel in the mdp 301 trial in johannesburg Microbicides 2008. Delhi.

Background: In a Phase III trial of PRO 2000/5 vaginal gel the primary objective is to determine the efficacy and safety of this product however the success of the product is largely dependent on its acceptability amongst users. Methods: The key determinants for acceptability of a product; as determined from the pilot study include: 1. Ease of insertion of gel applicator 2. Convenience of using gel 3. Impact of gel use on sexual enjoyment Data were collected from participants enrolled in the Phase III trial in Johannesburg between October 2005 and July 2007, including 2 geographically distant sites. Information was collected on case record forms during a structured interview, at time points including 4, 24, 40 and 52 weeks of trial participation. Results were analysed using STATA. Results: 3157 responses were assessed. Participants found gel use to be very easy, 6.07% (CI 5.68- 6.49) or easy, 93.61% (93.19- 94.02). All reports of difficult with gel insertion were reported at week 4. Reasons for difficulty included pain on insertion, difficulty inserting the applicator and difficulty finding a suitable position for insertion. Gel use was also reported to be convenient 99.16% (98.99- 99.31). Gel use was found to make sex more enjoyable for 35.82% (35.01-36.63) responses, less enjoyable 1.14% (0.97-1.34) and no effect/same for 63.04%. Orange Farm participants were more likely to report gel use making sex acts more enjoyable (59.4%; 58.26-61.03), than Soweto participants (40.6%; 38.97-41.74). Conclusion: The use of the gel was generally found to be acceptable to trial participants in terms of ease of use and convenience, both improving over time, potentially attributed to familiarity with the product. A large percentage of sex acts was made more enjoyable by gel use and may be significant in marketing such a product.