A randomised placebo-controlled safety and acceptability trial of PRO 2000 vaginal microbicide gel in sexually active women in Uganda

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Abstract

Objectives To determine the safety of 0.5% and 2% PRO 2000 gel in terms of local and systemic adverse events (AE) and the acceptability of gel use.

Design A randomised placebo-controlled trial among healthy, sexually active African women aged 18–45 years. Between June 2003 and September 2004, 180 consenting women were randomly assigned to one of four groups: PRO 2000 gel (0.5% or 2%), placebo gel, or condom use only. Participants were screened for sexually transmitted infections, with HIV counselling and testing. Women randomly assigned to gel used this intravaginally twice a day for 28 days. Follow-up visits were fortnightly up to 6 weeks from enrolment, and comprised a physical examination including colposcopy, laboratory testing and questionnaire interviews.

Results Ten women were lost to follow-up, none due to AE. Adherence with total gel doses was 69%. Observed rates of the primary toxicity endpoints, ulceration greater than 2×1 cm and clinically relevant coagulation abnormalities were, for PRO 2000 0.5%: 1.6% (95% CI 0.04% to 8.5%) and 0% (97.5% CI 0% to 5.7%), and for PRO 2000 2%: 0% and 0% (97.5% CI 0% to 5.9%). Women randomly assigned to active gels did not show an increased rate of AE. Gel use had no significant effect on haematology and biochemistry results. Women found gel use highly acceptable.

Conclusions Both concentrations of PRO 2000 gel were found to be safe and well tolerated. These data justified testing the gels in large-scale effectiveness trials.

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