

Safety of a nonoxynol-9 vaginal gel in Kenyan prostitutes. A randomized clinical trial

Martin, HL Jr.; Stevens, CE; Richardson, BA; Rugamba, D; Nyange, PM; Mandaliya, K; Ndinya-Achola, JO; Kreiss, JK

Date: 1997-05

Abstract:

OBJECTIVE: To evaluate the safety and toxicity of once-daily administration of Advantage-24 (Columbia Research Laboratories, Inc., Rockville Centre, NY), a vaginal gel containing 52.5 mg of nonoxynol-9 (N-9), including the effects of this gel on the vaginal and cervical epithelium. **STUDY DESIGN:** Randomized, placebo-controlled, double-blind crossover trial, with a 2-week product application period and a 2-week washout period. **METHODS:** Female sex workers in Mombasa, Kenya were randomized to one of two sequences, N-9 followed by placebo, or vice versa. Women were instructed to apply one applicator of N-9 or placebo gel vaginally once each day. During each of the two product periods, subjects were evaluated by questionnaire and physical examination, including colposcopy, after 7 and 14 days of product use. The primary outcome was genital epithelial disruption. **RESULTS:** Sixty subjects were randomized, of whom 52 (87%) had complete follow-up. There were four episodes of epithelial disruption, three of which occurred during the placebo period and one during the N-9 period. The estimated risk of epithelial disruption associated with N-9 use was 0.33 (95% confidence interval, 0.03-3.26). There was no increased frequency of other, nondisruptive epithelial lesions during N-9 use. **CONCLUSIONS:** No genital epithelial toxicity of N-9 vaginal gel was observed. This safety profile suggests that this N-9 product is appropriate for evaluation for human immunodeficiency virus type 1 prevention in a phase III efficacy trial