

Multi-center Safety and Efficacy Trial Evaluating Three Times per Week Application of 1% and 5% Topical Imiquimod for the Treatment of Genital/Perianal Warts. L. Edwards, Carolinas Medical Center, Charlotte, NC, USA; A. Ferenczy, Jewish General Hospital, Montreal, Quebec, Canada; L. Eron, Infectious Disease Physicians, Annandale, VA, USA; D. Baker, HSC SUNY, Stony Brook, NY, USA; T. Fox, K. Gayoso, A. Hougham, M. Owens, 3M Pharmaceuticals, St. Paul, MN, USA; and the Topical Imiquimod HPV Study Group.

A multi-center, double-blind, randomized, vehicle-controlled, parallel group trial was conducted to evaluate the safety and efficacy of 1% and 5% topical imiquimod cream when compared to vehicle cream in the treatment of genital warts. Pts applied study cream overnight for 8 hrs 3X/wk for up to 16 wks or until wart clearance. Pts with wart clearance during the treatment period entered a 12-wk treatment-free follow-up period for evaluation of wart recurrence. 311 pts (180 male and 131 female) entered the trial and 109, 102, and 100 pts were randomized to 5% imiquimod, 1% imiquimod, and vehicle, respectively. 83% of pts were white with a mean (\pm SD) age of 31 (\pm 11) yrs. During the treatment period, 56% of 5% imiquimod pts, 27% of 1% imiquimod pts, and 14% of vehicle pts totally cleared their warts ($p < .0001$). Pairwise comparisons showed 5% imiquimod had a significantly higher clearance rate than 1% imiquimod ($p = .0001$) and vehicle ($p < .0001$), but 1% imiquimod was not significantly different from vehicle. Clearance rates for 5% imiquimod were 77% for females and 40% for males. Pairwise comparisons for both males and females showed that 5% imiquimod was significantly better than 1% imiquimod and vehicle, but 1% imiquimod was not significantly different from vehicle. During the follow-up period, 13% of 5% imiquimod pts, 0% of 1% imiquimod pts, and 10% of vehicle pts had a wart recurrence. Local skin reactions at the application site were more frequent with 5% imiquimod than with 1% imiquimod than with vehicle. There were no statistically significant differences among treatment groups for systemic adverse experiences. In conclusion, 5% imiquimod was significantly more effective in clearing genital/perianal warts than 1% imiquimod and vehicle, and females had higher clearance rates than males. Pts treated with 5% imiquimod also had a low recurrence rate with an acceptable safety profile.