A phase I randomized placebo controlled trial of the safety of 3% SPL7013 Gel (VivaGel®) in healthy young women administered twice daily for 14 days

Abstract:

To assess the safety of VivaGel® used vaginally twice daily for 14 days among healthy, sexually-abstinent women, aged 18-24 years in the USA and Kenya. Randomized placebo controlled trial. Participants were randomized 2:1, VivaGel to placebo. Safety was assessed by comparing genitourinary (GU) adverse events (AEs), colposcopy findings, vaginal lactobacilli and laboratory abnormalities by arm. Fifty-four women were enrolled; 35 in the VivaGel arm and 19 in the placebo arm. Twenty-six (74%) and 10 (53%) women reported taking all doses of VivaGel and placebo, respectively. No grade 3 or 4 AEs, or serious AEs occurred. Twenty-five (71%) participants in the VivaGel arm compared to 10 (53%) participants in the placebo arm had at least one grade 1 or 2 GU AE associated with product use (RR=1.4, 95% CI 0.8-2.2). All seven grade 2 GU AEs associated with product use occurred among four women in the VivaGel arm. Vulvar and cervical erythema, cervical lesions, symptomatic BV, urinary frequency and metrorrhagia were more common in the VivaGel arm than the placebo arm. Twenty-nine (83%) participants in the VivaGel arm had a colposcopic finding compared to 10 (53%) participants in the placebo arm (RR=1.6, 95%CI=1.0-2.5). Two women in the VivaGel arm prematurely discontinued product use themselves due to a reported GU AE. Persistence of H_2O_2-producing and non-producing lactobacilli did not differ by study arm. GU AEs and colposcopic findings consistent with mild epithelial irritation and inflammation occurred more commonly among women in the VivaGel arm.